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Trends in in-hospital acute stroke care processes and stroke patient outcomes observed during operation of the Georgia Coverdell Acute Stroke Registry

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Trends in in-hospital acute stroke care processes and stroke patient outcomes observed during operation of the Georgia Coverdell Acute Stroke Registry

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M.D., Northwestern University Medical School, 1993

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An abstract of
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Abstract

Trends in in-hospital acute stroke care processes and stroke patient outcomes observed during operation of the Georgia Coverdell Acute Stroke Registry

By Andrea Winquist

The Georgia Coverdell Acute Stroke Registry (GCASR) seeks to monitor and improve the quality of acute stroke care in Georgia. The overall aim of this dissertation was to evaluate the impact of GCASR on stroke care processes and stroke patient outcomes in Georgia.

The first study examined trends in adherence with four stroke-care quality indicators among GCASR-participating hospitals. Conditional logistic regression models were used to estimate the average monthly within-hospital change in adherence, and to assess hospital characteristics associated with the rate of improvement.

The second study evaluated the impact of one registry intervention, monthly educational conference calls, and sought to separate call effects from the effects of other registry interventions. Conditional logistic regression models were used to examine within-hospital changes in adherence with three quality indicators in temporal association with calls focusing on those indicators, considering various models for change over time.

The third study evaluated the association between stroke patient outcomes and the operation of the GCASR pilot registry using state-wide hospital discharge data for ischemic stroke admissions linked with death certificate data. The outcomes considered were death within 1 year of an index stroke admission, and readmission within 1 year of discharge. Intent-to-treat proportional hazards models were used to compare the hazards of these outcomes for patients admitted to hospitals randomly selected for registry participation and patients admitted to non-selected hospitals.

The studies showed that GCASR operation has been associated with improvements in care processes among participating hospitals, with hospitals with lower stroke volumes showing the greatest rate of improvement. Registry-wide monthly conference calls do not appear to change care processes shortly after the call, but may have more global effects in improving quality indicator adherence. A reduction in the hazard of readmission for recurrent stroke among patients admitted to hospitals randomly selected for registry participation was seen in association with operation of the GCASR pilot registry. These studies suggest some future directions for registry recruitment and quality improvement activities. For ongoing registry evaluation, it will be important to repeat the analysis of changes in stroke patient outcomes for the current implementation phase registry.

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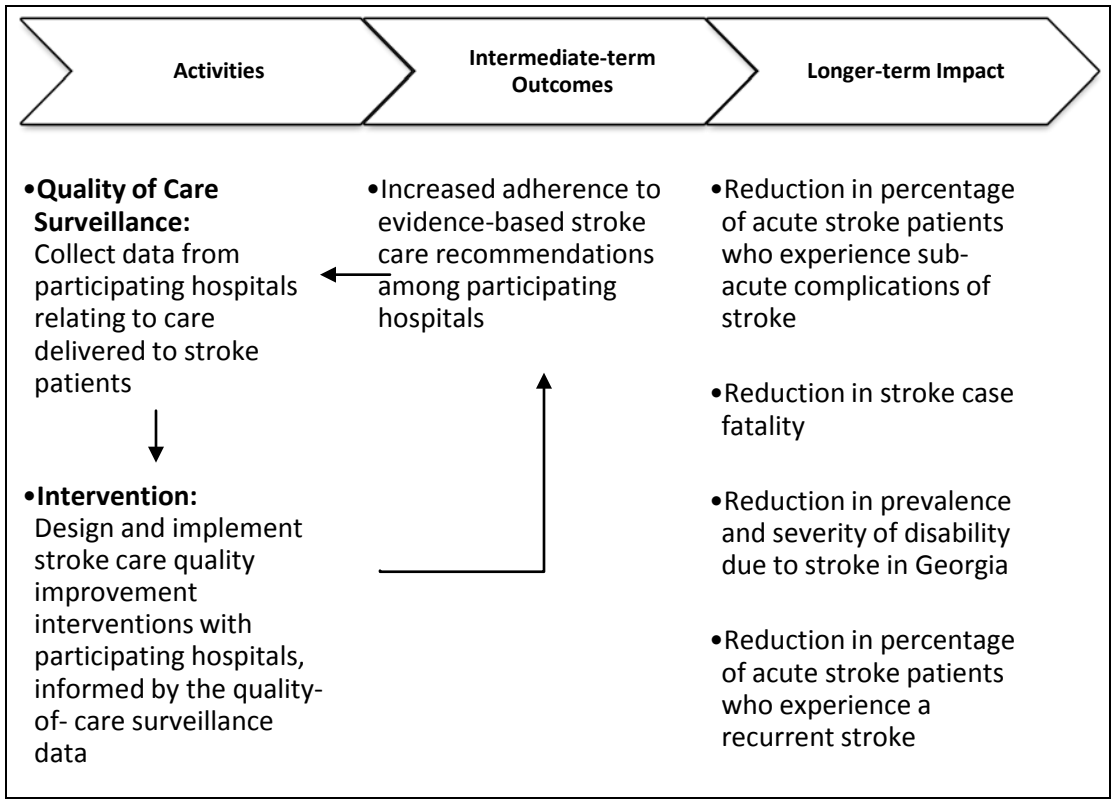
Chapter 1: Rationale and Aims of Dissertation

Stroke causes more than 140,000 deaths each year, and is the third leading cause of death in the United States. Each year, approximately 795,000 people in the United States experience a stroke, with approximately 185,000 of those strokes being recurrent strokes.[1] Stroke disproportionately affects residents of Georgia, which in 2006 had a stroke mortality rate 16% higher than the national average.[2] Among those who survive a stroke, approximately 15-30% are permanently disabled.[1] Preventable medical complications of stroke such as deep vein thrombosis[3] and pulmonary complications resulting from dysphagia[4] can lead to poorer clinical outcomes in stroke patients. Several measures have been shown to improve outcomes in acute stroke patients,[5] but evidence–based recommendations for stroke care are not always followed in clinical practice.[6]

The Georgia Coverdell Acute Stroke Registry (GCASR) is a quality-of-care surveillance and intervention program administered by the Georgia Division of Public Health. GCASR is funded by the Centers for Disease Control and Prevention (CDC) as part of the Paul Coverdell National Acute Stroke Registry.[7] The goals of GCASR are to conduct public health surveillance for the quality of in-hospital acute stroke care in Georgia in a representative way, use the collected data to guide stroke care quality improvement interventions, and design and implement interventions to improve the quality of in-hospital acute stroke care. The anticipated outcomes of these activities are increased adherence to evidence-based clinical recommendations for stroke care, and ultimately, reduction of the impact of stroke in Georgia including complications of acute stroke, stroke case fatality, the prevalence and severity of disability due to stroke, and recurrent strokes. A logic model for the registry operation is shown in Figure 1A.

Figure 1A. Georgia Coverdell Acute Stroke Registry Logic Model



GCASR started in 2001 as a pilot project, administered through Emory University, involving 46 hospitals in Georgia. Full implementation, after incorporation into the Georgia Division of Public Health, began in November 2005. Now that GCASR has been in operation for several years, a key question is, "Has GCASR been successful in achieving these desired impacts?" It is important to answer this question to evaluate the effectiveness of GCASR, which is the primary intent of these dissertation studies. The answer to this question can also contribute to general knowledge about the effectiveness of this novel type of type of public health surveillance and intervention program.

The overall goal of the dissertation is to examine the association between registry participation by hospitals and changes in patterns of adherence to stroke care guidelines and outcomes of acute stroke care during the time period of GCASR operation. This goal will be addressed through three specific aims of the dissertation, which are to:

1) Examine observed changes in care processes among participating hospitals, and hospital factors associated with those changes
2) Examine the effectiveness of one specific registry intervention, monthly conference calls with hospitals, in improving care processes, and
3) Assess the impact of registry participation by hospitals on longer term stroke outcomes in Georgia.

In support of these studies, analyses relating to data quality will also be performed.

The Emory University institutional review board (IRB) determined this study to not require IRB review because it was determined not to meet the definition of research under 45 CFR Section 46.102(d), and the Georgia Department of Human Resources IRB approved this study through its "Approval Without Detailed Review" process, which has criteria similar to criteria for IRB exemption under federal regulations.

Chapter 2: Literature Review

The Public Health Burden of Stroke

Stroke is brain tissue death due to interruption of blood supply to the brain. There are two general types of stroke, ischemic stroke and hemorrhagic stroke. Ischemic stroke accounts for approximately 80% of strokes and is due to blockage of an artery supplying blood to the brain. Hemorrhagic stroke accounts for approximately 20% of strokes and is due to rupture of an artery in or around the brain.[8]

During 2005, stroke caused more than 143,000 deaths in the United States, making stroke the third leading cause of death. In the United States overall, stroke death rates have been declining since the 1970's.[9] In 2004, the Healthy People 2010 target of 50 stroke deaths per 100,000 (age adjusted) was achieved on a national level, with the rate falling further to 44 per 100,000 by 2006.[10] However, stroke disproportionately affects residents of Georgia. Georgia is part of a region in the southeastern United States, called the "Stroke Belt," which has had higher stroke mortality rates than the rest of the United States for more than 60 years.[11] Several Georgia counties, particularly in the area of the coastal plain, which has been called the "buckle" of the stroke belt, have substantially higher stroke death rates than the rest of the state. The causes of the higher stroke mortality rates in Georgia and other states in the stroke belt are not entirely understood, but the contribution of higher stroke incidence rates appears to be larger than the contribution of higher stroke case fatality.[11,12] During 2006, stroke caused 3,826 deaths in Georgia, accounting for 6% of all deaths. Twenty-three percent of those deaths occurred in persons aged <65 years. Stroke mortality rates have been decreasing in Georgia, as in the United States overall, and the gap between stroke mortality rates in the United States overall and in Georgia has decreased.[13] However, in 2006 Georgia had an age adjusted stroke mortality rate of 51 per 100,000 (16% higher than the national average),[2] and had not yet met the Healthy People2010 target for stroke mortality.[10]

In addition to causing significant mortality, stroke also causes significant morbidity and medical care costs. Each year in the United States, approximately 795,000 people in the United States experience a stroke.[1] In Georgia during 2006, there were approximately 23,000 hospitalizations due to stroke, with an average length of hospital stay of 6 days and an average hospital charge of $26,900. Total hospital charges for stroke in Georgia during 2006 were $618 million.[2]

For affected patients, stroke has serious sequelae. Estimates of the percentage of ischemic stroke patients dying within 30 days have varied between studies, with estimates of 8-12% for those aged 45-64 years and 8% for those aged 65 years and older in the Atherosclerosis Risk in Communities Study,[1] 8.1% overall in the Cardiovascular Health Study,[14] and 12.6% overall in a study of ischemic stroke patients during 2003-2005 in the Registry of the Canadian Stroke Network.[15] Case fatality with-in 1 year is even higher. A study of Medicare beneficiaries in Connecticut during 1995 found 26.1% mortality within 1 year,[16] and a study of first ischemic stroke patients in Scotland during 2004-2005 found 1 year mortality of 27.2%,[17] while a study of patents enrolled in the Registry of the Canadian Stroke Network during 2003-2005 found a 1-year mortality rate of 23.6%.[15]

Among those who survive an initial stroke, the risk of recurrent stroke is substantial. The Northern Manhattan Study, which followed patients after a first ischemic stroke occurring during 1993-1996, found that approximately 1.5% of patients experienced a recurrent stroke within 30 days and 7.7% experienced recurrent stroke within 1 year.[18] Similarly, a study of Connecticut Medicare beneficiaries during 1995 found readmission for recurrent stroke within 1 year in 6.1% of patients admitted for stroke during 1995.[16] More recent studies of readmission for recurrent stroke have had similar findings. A study of first ischemic stroke patients in Scotland during 2004-2008 found that 10.8% were re-hospitalized for stroke within 1 year,[17] and a study of patients with a first ischemic stroke during 2000-20004 in the Brain Attack Surveillance in Corpus Christi project in Texas found that 7.5% experienced recurrent stroke within 1 year.[19]

Stroke can also cause significant long-term disability, including paralysis, loss of speech capability, and cognitive deficits as well as medical complications. Stroke can cause loss of a person's independence. Approximately 50% -70% regain functional independence, but 15% - 30% are permanently disabled, and 20% require institutional care at 3 months.[1] Stroke also is associated with the risk for several medical complications, such as deep vein thrombosis (DVT), pulmonary embolism, and difficulties swallowing (dysphagia). Approximately 50% of hemiplegic acute stroke patients have evidence of DVT within 2 weeks, in the absence of preventive measures.[3] DVT leads to a risk for pulmonary embolism (PE), which can be fatal. Although only approximately 1% of stroke patients experience PE, PE accounts for approximately 10% of deaths after stroke.[5] Dysphagia is found in 37% to 78% of stroke patients, depending on the stroke type and the methods used to detect swallowing difficulties.[4] Dysphagia increases a patient's risk for pneumonia due to aspiration of materials taken by mouth. A pooled analysis of 7 studies in stroke patients found that the relative risk for pneumonia was 3.17 (95% Confidence Interval (CI) 2.07-4.87) among patients with dysphagia compared with patients without dysphagia.[4]

Public Health Approach to Stroke including Quality of Care

Given the magnitude of the public health burden of stroke, careful attention has been given to the most effective means of addressing stroke as a public health problem. The 2003 publication entitled, "A Public Health Action Plan to Prevent Heart Disease and Stroke"[20] from the Centers for Disease Control and Prevention listed six intervention approaches to addressing heart disease and stroke, including policy and environmental change, behavioral change, detecting and controlling risk factors, emergency care and acute case management, rehabilitation, and end of life care. These approaches can be considered in two groups: measures aimed at preventing the stroke event (policy and environmental change, encouraging behavioral change, and detecting and controlling risk factors for stroke), and measures intended to influence

outcomes after an initial stroke has occurred (emergency care and acute case management, rehabilitation, and end of life care). Examples of measures to prevent an initial stroke event include no-smoking policies (policy and environmental change); encouraging increased physical activity (behavioral change), and detection and treatment of hypertension and high blood cholesterol levels (detecting and controlling risk factors). These are all activities that are generally associated with public health. However, once a stroke occurs, there is still a significant opportunity to influence the long-term outcome, including the resulting disability, complications, and the risk for recurrent stroke. Therefore, a comprehensive public health approach to stroke includes attention to ensuring high quality emergency care and acute case management, rehabilitation after a stroke, and end-of-life care. The Coverdell Stroke registry focuses on the quality of medical care for treatment of acute strokes. This is a relatively new area of focus for public health.

The impact that medical care can have on the public heath burden of coronary heart disease (CHD), which has many of the same risk factors as stroke, was estimated in a study by Ford et al[21] that used the IMPACT model to estimate the relative contributions of changes in risk factors and changes in the use and effectiveness of cardiac treatments to the decline in U. S. deaths due to CHD during 1980-2000. The IMPACT model estimated the number of CHD deaths that would have been expected in 2000 if age-specific CHD mortality rates observed in 1980 had continued. Next, the number of deaths postponed or prevented was calculated as the expected number of 2000 CHD deaths minus the observed number. The model then separately calculated the number of CHD deaths that would have been expected to have been prevented or postponed due to medical treatments (using data on the number of CHD cases by specific diagnosis in 2000, the 1-year case fatality rate by diagnosis, the proportion of patients receiving each medical treatment, and the estimated risk reduction due to each treatment), and due to reductions in risk factors (using data on change in the mean level or prevalence of each risk factor in the population between 1980 and 2000, the expected change in mortality per unit change in the mean or

prevalence of each risk factor, and the number of 1980 CHD deaths). The estimated number of deaths prevented or postponed due to medical treatments and changes in risk factors together accounted for 90% of the total observed decline in CHD mortality, with changes in medical treatments accounting for approximately 47% of the decline and changes in risk factors accounting for approximately 44% of the decline.

The WHO MONICA (Multinational Monitoring of Determinants and Trends in Cardiovascular Disease) Project[22] provided some evidence that medical treatments may also have a large impact on stroke mortality rates. The stroke portion of the MONICA project was a prospective study monitoring stroke rates and 28-day case fatality rates over time in 14 populations in 9 countries during 1982-1995. The analysis compared stroke event rates and case fatality rates in various countries. Declining stroke mortality rates were observed in 8 of the 14 populations in men and in 10 of the 14 populations in women. Many of the remaining populations, with increasing stroke mortality rates, were in Eastern Europe. In populations with decreasing stroke mortality, approximately two thirds of the decrease was attributable to decreased case fatality, while in populations with increasing stroke mortality, the increase was largely explained by increased case fatality. The authors concluded that the findings could be due to changes in case management or disease severity. However, the fact that many of the countries with increasing stroke mortality rates (and case fatality rates) were in former USSR countries, that were experiencing great changes in healthcare organization during that time period, was interpreted to suggest that that deteriorating quality of medical care could have been part of the explanation for the increase in stroke case fatality rates.[23]

Public Health Surveillance for Stroke Including Quality of Stroke Care

If the quality of medical care for stroke is a public health issue, and a potential target for public health intervention, then it must also be the subject of public health surveillance. Surveillance is defined as "the ongoing systematic collection, analysis, and interpretation of outcome-specific data for use in the planning, implementation, and evaluation of public health practice."[24] Historically, surveillance for chronic diseases initially focused on mortality data, and began incorporating data from cancer registries in the 1970's, and data on behavioral risk factors in the 1980's and 1990's.[25] In 1999, the Council of State and Territorial Epidemiologists published a set of 73 standard chronic disease surveillance indicator definitions to help standardize methods for chronic disease surveillance across states.[26] In 2004, the Centers for Disease Control and Prevention published a revised set of indicators for chronic disease surveillance,[25] which included 92 standard chronic disease surveillance indicator definitions. The revised and expanded set of indicators included indicators relating to physical activity and nutrition, tobacco and alcohol use, cancer, cardiovascular disease, diabetes, end stage renal disease, chronic obstructive pulmonary disease, asthma, osteoporosis, vaccinations, dental care and overarching conditions such as poverty, high school completion, life expectancy, and others.[25] Data sources for the 92 indicators include vital statistics, the Behavioral Risk Factor Surveillance System (BRFSS), the Youth Risk Behavior Surveillance System (YRBSS), cancer registries, hospital discharge data, tobacco data sources (such as the Youth Tobacco Survey (YTS) and state revenue data sources), the United States Renal Data System (USRDS), and the Current Population Survey (CPS).[25,27] A limitation to implementation of the chronic disease indicators is that not all of the data sources are available in all states. In 2005, only 22 states and the District of Columbia had access to the data sources for all of the indicators, and many states had limited chronic disease epidemiology capacity.[27] Indicators specifically relating to stroke include prevalence of stroke risk factors, stroke mortality rates, and stroke hospitalization rates.

Although the current set of chronic disease indicators includes several preventive services such as cancer screening procedures, vaccinations, cholesterol screening, preventive care for diabetes, and preventive dental care, measures of the quality of care for acute diseases such as stroke or myocardial infarction are not included.[25,27] In general, surveillance possibilities are limited by the availability and ease of obtaining the required information, and this is an issue for surveillance for the quality of medical care. Information about medical care delivery can be limited by the comprehensiveness of information in health records, the format of the data (electronic or paper), the quality of data including electronic data recorded through coding schemes, the proportion of patients for whom information is available, and legal and administrative barriers.[28]

Information related to the quality of medical care can be difficult to collect, requiring labor-intensive medical record reviews. Surveillance for the quality of medical care beyond preventive services has largely developed in conjunction with the development of managed care. Murray reviewed these developments[29] and the factors that led to the need for health care quality surveillance, including new types of health care payment systems that changed incentives for providers and had the potential to reward providers for providing less care. Quality of care surveillance systems were established by managed care organizations to monitor the quality of care provided by medical care providers in their systems, as a means of establishing accountability to counteract the potentially negative impact of these changing incentives on quality of care.

Quality of care surveillance systems have been conducted by private organizations as well as by federal agencies overseeing Medicare and Medicaid reimbursement. Due to resource limitations, information relating to medical care quality often has relied on data sources that were originally designed for billing purposes. These data sources can have data quality limitations, can lack generalizability to populations outside the specific health plan under consideration, and also have limited clinical detail. Nevertheless, they can be a useful source of readily available data for

addressing selected quality of care questions, such as delivery of vaccinations, screening procedures, and rates of follow up visits for specific conditions.[29] However, the clinical detail available in claims data is not sufficient to address many quality-of-care questions that involve detailed definition of eligible populations and details of the care delivered.

In designing systems to measure quality of care, a definition of quality is needed, just as a careful definition of the health outcome of interest is essential for any successful surveillance system. Donabedian articulated the elements that compose quality of health care, including structure, process and outcomes.[30] In Donabedian's framework, good structure leads to good processes, which are expected to lead to good outcomes. Quality assessment must rely on known relationships between these elements. Specific criteria for evaluating structure, process and outcomes are ideally based on strong scientific knowledge.

As with all surveillance systems, consideration must also be given to the use of the data that is collected. Uses of quality-of-care data have varied with the different interests of different users of the information, ranging from use by employers in selection and management of health plans that they offer to their employees, and use by consumers in choosing a plan, to use by managed care organizations to help guide and assess quality improvement programs.[29] For the purpose of public health surveillance, information is collected for such uses as assessing public health status, defining public health priorities, evaluating problems, defining public health priorities, guiding prevention and programmatic activities, evaluating the effectiveness of these activities, and guiding research activities.[24] In the context of quality of care, the data collected can also serve as part of the intervention itself, because data feedback to institutions can be one component of a stroke quality improvement intervention.

Georgia Coverdell Acute Stroke Registry- Surveillance and Intervention

The mission of the Georgia Coverdell Acute Stroke registry is to both monitor and improve the quality of in-hospital medical care delivered to acute stroke patients at participating hospitals in Georgia. The first aspect of this mission, monitoring the quality of care, is a surveillance function. Data relating to care delivered to acute stroke patients is collected from medical record reviews conducted by participating hospitals, and is then used to guide interventions at the registry level to improve the quality of acute stroke care, and to evaluate the effectiveness of those registry interventions. In addition to being a surveillance system for the quality of care, the Georgia Coverdell Acute Stroke Registry is also a public health intervention program, which is part of the overall Georgia Cardiovascular Health Initiative. Data plays a role in the intervention component of the registry, as the data are provided back to hospitals, with benchmarking against the performance of other hospitals. This allows use of the data for guiding and evaluating quality improvement initiatives at the hospital level. In addition to data feedback with benchmarking, the registry also provides other registry-level quality improvement interventions, including educational interventions, engagement of local stroke opinion leaders, and others. All of these registry activities, relating to both measurement of quality of care and quality-of-care interventions, are based on evidence from the medical literature.

Evidence-based Stroke Treatments

The foundation of any program to monitor and improve the quality of acute stroke care is knowledge of the elements of structure and process that lead to good stroke patient outcomes. Clinical trials have shown several types of medical interventions to be effective in improving outcomes in stroke patients. Based on the findings of these trials, evidence-based stroke care recommendations have been developed. Evidence-based clinical recommendations cover many aspects of stroke care including acute treatment and general management of stroke patients in the

acute phase,[5] secondary prevention,[31,32] stroke care organization in the hospital setting,[33,34] organization of stroke systems of care in communities,[35] and recommendations for rehabilitation care after stroke,[36] among others.

A few specific recommendations are worthy of elaboration, as they have been some of the areas of particular focus of GCASR stroke quality-of-care measures and are the particular focus of some studies in this dissertation. One of these is acute ischemic stroke treatment using tissue plasminogen activator (t-PA). T-PA is a treatment that, when given in the very acute phase of an ischemic stroke (optimally within 3 hours, with evidence of effectiveness as long as 4.5 hours after a stroke), can improve functional outcomes in acute ischemic stroke patients.[5,37] The National Institute of Neurological Disorders and Stroke (NINDS) trial[38] was one of the major randomized, placebo controlled clinical trials of tPA as a treatment for acute ischemic stroke. This trial compared outcomes among patients treated with tPA within 180 minutes of stroke onset and patients treated with placebo. A favorable outcome was defined as complete or nearly complete neurological recovery at 3 months as measured by 4 scales. The odds ratio for a favorable outcome at 3 months was 1.7 (95% CI 1.2-2.6) for the t-PA group compared with the placebo group. Some other individual clinical trials did not find a significant benefit of t-PA,[39,40,41] but the various trials differed in the time allowed between stroke onset and treatment, and in the overall stroke severity in the populations studied.[5,37] A significant benefit of t-PA was confirmed in a pooled analysis of multiple large clinical trials, with the odds of a favorable outcome at 3 months (defined similar to the NINDS trial but using only 3 of the 4 scales), decreasing as the time from stroke onset to treatment increased (0-90 minutes OR=2.8, 95% CI 1.8-4.5; 91-180 minutes OR=1.6, 95% CI 1.1-2.2; 181-270 minutes OR=1.4, 95% CI 1.1-1.9; 271-360 minutes OR=1.2, 95% CI 0.9-1.5).[42] Initial recommendations for use of t-PA have been for treatment only within 3 hours of onset, although the ECASS-3 trial has recently found that treatment with t-PA is safe and effective when administered between 3 and 4.5 hours after stroke onset.[43,44] Although t-PA is effective in improving functional outcomes of ischemic stroke

patients, use of t-PA is also associated with an increased risk of intracerebral hemorrhage.[5,37] A review of thrombolytic therapy studies found an increase the odds of death among treated groups within the first 10 days after stroke which persisted to the 3-6 month follow-up point, although this was not statistically significant for studies specifically studying recombinant t-PA (OR for death within 10 days =1.21, 95% CI 0.86-1.70, OR for death at the end of follow up at 3-6 months =1.16, 95% CI=0.88-1.54)[37]. Despite the established risks, systematic reviews and consensus groups of experts in the field have determined that treatment with t-PA has a net benefit.[37,5]

Another important specific area of stroke treatment includes interventions to prevent development of DVT in acute stroke patients. Prevention of DVT involves measures such as early mobilization when possible, administration of subcutaneous heparin for immobilized patients, and use of intermittent compression devices for immobilized patients who cannot receive heparin.[5,45] A review of 10 controlled trials of use of heparin in acute ischemic stroke found an 81% reduction in DVT with heparin use ($p<0.0001$) and a 58% reduction in PE which was not statistically significant but was based on few events.[46] The International Stroke Trial also found a reduction in pulmonary embolism among patients with acute ischemic stroke randomized to heparin (heparin 0.5%, no heparin 0.8%, $p<0.05$).[47] Intermittent compression devices are also effective in preventing DVT, although they have been less studied than heparin.[48] However, intermittent compression devices may be less effective than heparin, and have not been shown to reduce the risk of pulmonary embolism, so they are recommended as an option for patients at high risk of bleeding for whom heparin cannot be used.[48]

Screening a patient for dysphagia is another measure relevant to all stroke patients that can allow appropriate management of oral intake to prevent aspiration.[49] Institution of a clinical analysis program that focused on stroke patients in one hospital led to identification of aspiration pneumonia as the leading cause of morbidity and mortality among patients at that facility.[50] After initiation of automatic assessment of stroke patients by an interdisciplinary stroke team and

implementation of measures specifically targeted to decrease inadvertent administration of fluids to new stroke patients, that hospital observed a decrease in aspiration pneumonia from 6.4% in 1995 to 2.7% in 1997 ($p<0.05$),[51] and 0% in 1999.[50]

Several measures have also been found to be effective in preventing recurrent stroke among stroke patients.[31,32] Measures for prevention of recurrent stroke include control of risk factors for stroke such as hypertension, diabetes, hyperlipidemia, smoking, obesity, and physical inactivity; interventional measures to address specific causes of stroke in specific groups of stroke patients; anticoagulation for stroke patients with atrial fibrillation and other cardiac conditions that can lead to cardioembolic stroke; antithrombotic therapy for patients with non-cardioembolic ischemic stroke; and other treatments for specific sub-groups of stroke patients.[31] Antithrombotic medications appear to be most effective in reducing the risk of recurrent stroke when they are initiated within 48 hours.[52] Even for less time-sensitive secondary prevention measures, several studies have found that initiation of secondary prevention treatment and relevant counseling within the hospital, rather than waiting until after discharge, is associated with higher patient compliance and better outcomes for patients with cardiovascular disease. [53]

The secondary stroke prevention measure selected as the particular focus for studies in this dissertation was smoking cessation counseling or treatment. Smoking increases the risk of stroke. A meta-analysis of studies of the association between cigarette smoking and stroke found that smoking increases the risk of stroke overall by 50%, and when examined by stroke type, almost doubles the risk of ischemic stroke.[54] The increased risk of stroke starts to decrease shortly after a person quits smoking, and is essentially eliminated after approximately 5-15 years, with specific durations before risk elimination varying between studies.[55,56,57,58] Counseling, nicotine products and oral smoking cessation medications have all been found to be effective in helping smokers quit, with the combination of medication and counseling being more effective than either counseling or medication alone. [59]

The benefits of smoking cessation include benefits in reducing risks for multiple other diseases in addition to stroke.[58] The benefit of a smoking cessation program in improving patient outcomes was demonstrated in a randomized clinical trial that assigned patients to either 1) a smoking cessation program involving a physician recommendation, group sessions and nicotine gum; 2) the smoking cessation program plus ipatropium medication; or 3) usual care. That trial found higher smoking cessation rates after 5 years in the intervention groups combined compared with the usual care group, and a hazard ratio for all-cause mortality of 1.18 (95% CI 1.02-1.37) for the usual care group compared with the intervention groups after up to 14.5 years of follow up.[60]

Evidence of Suboptimal Adherence to Stroke Care Guidelines

Despite the evidence for the effectiveness of therapies and other clinical interventions in acute stroke patients, and the publication of multiple clinical recommendations for stroke care, several studies have shown that adherence to these evidence-based recommendations is incomplete and variable both in the United States overall, and specifically in Georgia. An early study by Kahn et al[61] examined the quality of care delivered to Medicare patients hospitalized for several conditions, including stroke, during 1981-1986, using several care process measures.[62] They found deficiencies in assessment of the clinical condition of stroke patients (determination of history of previous stroke in 48-53% of patients and assessment of gag reflex in 35-38% of patients), but better implementation of blood pressure monitoring, electrocardiogram assessment and measurement of serum potassium.

The Community Quality Index (CQI) Study[63], conducted by RAND during October 1998-August 2000, assessed all medical care received in the previous 2 years by people in a random sample of households in 12 metropolitan areas. The study included telephone interviews as well as medical record abstractions. Quality of care was assessed using 439 quality indicators, based on national guidelines and medical literature, that were developed by RAND in

collaboration with expert panels. The measures related to all phases of medical care (screening, diagnosis, treatment and follow-up), and included both in-patient and out-patient care for a wide variety of medical conditions. The quality indicators included 10 indicators related to stroke care which were assessed among 101 eligible patients. Overall stroke patients received 59.1% of recommended care for these indicators.

Studies of the quality of care delivered to Medicare beneficiaries provide another source of information about the care delivered to stroke patients. A study of Medicare patients hospitalized during 1997-1999[64] analyzed data from chart abstraction for a sample of admissions for each state. That study assessed quality of care using quality indicators related to acute myocardial infarction, heart failure, stroke, pneumonia, breast cancer and diabetes that were based on widely accepted practice guidelines and developed as part of other national quality-of-care efforts or surveillance systems, or in consultation with expert and professional groups. Data analysis was conducted by state. Results were reported for three measures related to stroke care, including warfarin prescribed for patients with atrial fibrillation, for which adherence to recommended care was 55% in the median state and 50% in Georgia; prescription of an antithrombotic medication at discharge for patients with acute stroke or TIA, for which adherence was 83% in the median state and 79% in Georgia; and avoidance of sublingual nifedipine for patients with acute stroke, for which adherence was 95% in the median state and 91% in Georgia.

A later study examined the change in the quality of care received by Medicare beneficiaries hospitalized during 1998-1999 to 2000-2001,[65] using methods similar to the earlier report but with recalculation of adherence for the 1998-1999 period using revised analytic methods. This study examined absolute and relative improvement in adherence with the various quality indicators between 1998-1999 and 2000-2001 by state. The performance in the median state improved for 20 of 22 indicators. Adherence for the median indicator in the median state, increased from 69.5% to 73.4% over this time period.

However, each state's ranking in terms of performance on the quality indicators relative to other states remained stable over time. Georgia's overall rank was 48th (out of 52 including states, Puerto Rico and DC) during 1998-1999 and 47th during 2000-2001. Georgia was also in the lowest quartile among states for median relative improvement. Looking at the three specific indicators relating to stroke care during 2000-2001, adherence with warfarin prescription for patients with atrial fibrillation was 57% (increase of 3 percentage points relative to recalculated percentages for 1998-1999) in the median state and 51% (increase of 1 percentage point) in Georgia; adherence with antithrombotic prescription at discharge for patients with acute stroke or TIA was 84% in the median state (increase of 2 percentage points) and 80% in Georgia (increase of 1 percentage point); and adherence with avoidance of sublingual nifedipine for patients with acute stroke was 99% in the median state (increase of 4 percentage points) and 100% in Georgia (increase of 9 percentage points).

A more detailed source of information about the quality of care delivered to stroke patients is the Paul Coverdell National Acute Stroke Registry Prototypes. During October 2001 through November 2002, the CDC funded eight prototype registry projects, led by academic and medical institutions across the country, to test models for measuring the quality of care delivered to stroke patients.[7] "Wave I" projects, funded in 2001, were located in Georgia, Massachusetts, Michigan, and Ohio. These prototype projects gathered data concerning each step of emergency and hospital care for stroke patients. All states used a common set of data elements. Analysis was weighted to account for the hospital sampling scheme in each state.[6] Three of the quality indicators used to measure adherence with recommended care included, 1) delivery of tissue plasminogen activator (t-PA) for ischemic stroke patients, 2) dysphagia screening for all stroke patients, and 3) delivery of smoking cessation counseling or treatment for smokers. The percentage of patients receiving care meeting each of the quality indicators varied between indicators. It was lowest for use of t-PA, with the percentage of patients receiving t-PA among all ischemic stroke patients (without regard to eligibility) ranging from 3.0% in Georgia to 8.5%

in Massachusetts. Adherence was higher, but still below 50%, for dysphagia screening (ranging from 38.5% in Georgia to 50.7% in Massachusetts) and smoking cessation (ranging from 16.5% in Ohio to 34.1% in Michigan). For all of these indicators, the percentage adherence for Georgia was lower than most or all of the other states.[6]

Another study, published in February 2008, examined stroke care at 99 hospitals participating in the American Heart Association's "Get with the Guidelines" stroke quality of care improvement program during April 2003-March 2004.[66] In that study, the percentage adherence was higher than in the Coverdell prototypes, with adherence at baseline being 23.5% for delivery of rt-PA to eligible patients, 75.4% for DVT prophylaxis, and 38.8% for smoking cessation. The percentage adherence with the quality indicators varied widely between hospitals.

Broader Context of Health Care Quality

The discrepancy between evidence-based recommendations and care delivered to patients, as well as the variability in care, that has been found for stroke care has been found for many other medical conditions as well. Quality of medical care is complex. Donabedian[30] described several important considerations relating to the quality of medical care including both technical and interpersonal aspects of care, contributions from many levels of the health care system, and the need to assess how various outcomes of care are valued. However, on a practical level, assessment of the quality of care has often focused on only the technical components of quality.

The quality of medical care in the United States was the subject of a review commissioned by the National Coalition on Health Care and the Institute of Medicine's Technical Advisory Panel on the State of Quality.[67] The review commissioned by the Institute of Medicine's Technical Advisory Panel on the State of Quality highlighted two common approaches to measuring quality of care, including assessing the appropriateness of care, and assessing adherence to professional standards, which often involves creating a list of quality

indicators based on standards of care from statements of professional medical organizations or panels of experts. This review cited many studies in the literature documenting inappropriate care, ranging from inappropriate antibiotic use to inappropriate surgeries. It also cited many examples of studies documenting lack of delivery of care meeting professional standards for preventive care and for conditions such as asthma, diabetes, myocardial infarction and many others. The authors concluded that while excellent care is available, the quality of care varied between hospitals, cities and states.

The RAND CQI Study conducted during October 1998-August 2000,[63] described above, looked at a care for a wide variety of medical conditions, with the analysis including 6712 participants who were determined to be eligible for at least one care process. Overall, patients received an estimated 54.9% of recommended care, with this percentage being similar for preventive care (54.9%), acute care (53.5%), and care for chronic conditions (56.12%). There was variation in the percentage of recommended care received between specific conditions, ranging from 10.5% for alcohol dependence to 78.9% for senile cataracts. Adherence was best for processes requiring an encounter or other intervention (73.4%) and worst for processes requiring counseling or education (18.3%).

The study of care delivered to Medicare patients hospitalized during 1997-1999[64] found a wide range in the percentage adherence for the median state between measures, ranging from 11% for patients with pneumonia being screened for pneumococcal immunization status before discharge to 95% for avoidance of sublingual nifedipine in stroke patients. States in southeast consistently ranked low in quality; Georgia's overall rank was 47 out of 52 (including states, Puerto Rico and DC).

Associations between hospital characteristics and quality of care

Given the variability in the quality of medical care, institutional characteristics associated with high quality care have been of interest. As an extension of the study by Kahn, et.al,.[61]

summarized above, Keeler et al[68] examined associations between quality of care and hospital characteristics through an analysis of data for a sample of hospital admissions for congestive heart failure, myocardial infarction, pneumonia, stroke, and hip fracture during 1981-1982 and 1985-1986 in five states. The data included data relating to care processes and adjusted data on mortality within 30 days of admission. They found that quality varied between states, and that quality of care was higher, in general, at teaching hospitals, larger hospitals, privately owned hospitals, and urban hospitals than at non-teaching hospitals, smaller hospitals, publically owned hospitals, and rural hospitals.

A more recent study of data reported by hospitals to the Centers for Medicare and Medicaid Services (CMS) through the Hospital Quality Alliance for hospital admissions during 2004 also addressed the question of associations between hospital characteristics and quality of care.[69] The data reported to CMS included data on quality of care for myocardial infarction (MI), congestive heart failure (CHF) and pneumonia. The study examined associations between care for these three conditions and hospital characteristics including profit status, academic status, number of beds, and region of the country. After adjustment for potential confounders, academic hospitals had higher summary quality scores than non-academic hospitals for acute MI and CHF, but lower scores for pneumonia. Not-for profit hospitals had higher scores for all three conditions than for-profit hospitals. Hospitals in the Midwest and Northeast regions of the United States had higher scores for all three conditions than hospitals in the West and South. The number of beds was significantly associated only with quality scores for pneumonia, with smaller hospitals having higher scores.

In addition to different baseline levels of quality of care, changes in quality may also relate to hospital characteristics. A study by Bradley et al[70] of data collected through the National Registry of Myocardial Infarction examined associations between hospital characteristics and hospital-level rates of change in beta blocker use during 1996-1999. Overall during 1996-1999, beta blocker use increased steadily from 46% of patients in April 1996 to >68% of patients in

September 1999. The degree of improvement in beta-blocker use varied widely between hospitals, with some hospitals showing increased use and others showing decreased use. After adjusting for patient-level characteristics, higher rates of improvement were associated with higher hospital volume of acute myocardial infarction (AMI) patients (among non-teaching hospitals), teaching status (among hospitals with lower AMI volume), location in the New England region, and lower baseline beta blocker use rates. Schwamm et al[71] in a study of the effect of a stroke care quality improvement program reported greatest improvement in stroke care processes among academic hospitals, hospitals with the highest number of beds, and hospitals with the highest number of annual stroke admissions.

Evidence for Medical Care Quality Improvement Strategies

Given the evidence of sub-optimal adherence to recommendations and variations in adherence between hospitals and regions, extensive research has been done to identify interventions that are effective in improving the quality of medical care. Gross et al,[72] in their review of strategies for guideline implementation, point out that, "just as practice guidelines are evidence-based, so too should implementation methods be evidence-based." The review by Gross et al considered the results of multiple Cochrane reviews of specific strategies used to promote implementation of clinical guidelines, and classified these strategies as generally ineffective, variably effective, or generally effective. Strategies considered generally ineffective included passive educational approaches, including simple dissemination of guidelines and publication of research findings, and purely didactic educational interventions. Strategies considered variably effective included audit and feedback, local opinion leaders and consensus conferences, and consumer education. Strategies considered generally effective included reminders to healthcare providers, one-on-one education of providers (academic detailing), interactive educational interventions, barrier oriented interventions which are tailored to specific identified barriers to implementation, and multifaceted interventions which make use of several

of these strategies in combination. Some interventions were considered most effective in specific contexts, such as audit and feedback for prescribing and test ordering, and academic detailing for promoting learning about a new drug.

A second review of the effectiveness of strategies for improving guideline implementation, by Grimshaw et al,[73] was done through the UK Health Technology Assessment program. It included 235 studies reporting 309 comparisons of interventions. Examples of interventions that were examined by the included studies included reminders, dissemination of educational materials, audit and feedback, multifaceted interventions, and interventions involving educational outreach. Overall, the review found that most intervention studies observed "modest to moderate" improvements in care. Dissemination of educational materials was evaluated in 18 of the reviewed studies and was found to have modest effects, which may be short lived. Educational meetings were evaluated in only a 3 studies and were found to have small effects, if any. Audit and feedback was evaluated in 10 studies, and all studies found improvement, with modest effects. Patient-directed interventions were evaluated in 7 studies, all of which found improvement with moderate to large effects. Reminders (evaluated in 38 studies), were found to have moderate effects. The review also considered 178 studies of multifaceted interventions that evaluated various combinations of interventions. The authors found it difficult to draw generalizable conclusions due to the large number of different combinations of interventions, but they found that effects did not seem to increase as number of components increased.

Davis et al[74] conducted a review of 14 studies of the effectiveness of formal continuing medical education activities in changing physician behavior and health outcomes. The included studies examined 24 separate interventions, of which 17 met the author's criteria for formal continuing medical education. The review found that 9 of the 17 interventions had a positive impact on physician performance and 3 (of 4 for which this was examined) had a positive effect on health care outcomes. Educational interventions that included an interactive component were found to be more effective than purely didactic interventions.

Forsetlund et al[75] conducted a more recent review with very similar findings. The review by Forsetlund et al included 81 studies of the effectiveness of professional education meetings and found that educational meetings can improve adherence to desired practices, particularly if they have higher attendance and include an interactive component. However, the additional benefit of educational interventions in the context of other interventions was less clear. The effect of educational interventions was not found to be substantially different from the effect of other types of interventions, such as educational outreach visits; and multifaceted interventions that included educational meetings were not found to have an effect substantially different from educational meetings alone.

The Georgia Coverdell Acute Stroke registry has directly used several of the types of interventions that were covered in these reviews, including audit and feedback, educational interventions, and local stroke opinion leaders. It also encourages use of other types of interventions, such as reminders through standing orders, by hospitals. One type of intervention used by the registry that requires a particular amount of staff effort is educational interventions. Therefore, the registry's educational interventions are the subject of particular study in this dissertation.

Evidence for Multi-hospital Stroke Quality Improvement Programs Impacting Care Processes

Beyond the level of specific quality improvement interventions is the level of multi-hospital quality improvement programs such as GCASR. Several studies have found improvements in stroke care processes associated with hospital participation in stroke registries or other types of multi-hospital stroke quality-of-care improvement programs. These programs have varied in many ways including the specific types of quality improvement interventions used, their duration of operation, and the extent of hospital involvement in directly monitoring the

quality of care. Studies of time-limited interventions will be described first, followed by studies of ongoing, continuous quality improvement interventions.

Time-limited Interventions

Jacobs et al conducted a study of Medicare beneficiaries in Michigan[76] which compared hospital performance on 7 quality indicators during a baseline period (July 1998-June 1999) and during a follow up period (January-June 2001) after an intensive quality improvement initiative among Michigan hospitals conducted by the Michigan Peer Review Organization. Adherence with the selected indicators was assessed through centralized abstraction of a sample of medical charts for admissions during the baseline and follow up periods. The intervention included data feedback, provision of stroke care quality improvement tool kit, site visits, regional meetings and telephone consultations. The study found significant improvement in 4 of the 7 quality indicators after the intervention.

The stroke PROTECT program[53] aims to facilitate early initiation and long-term maintenance of secondary prevention measures for stroke, including initiation of specific medications and behavioral interventions before discharge for patients with stroke or TIA. The stroke PROTECT program initially started at the University of California, Los Angeles (UCLA), and PROTECT -based programs have subsequently been implemented at several other hospitals. A detailed evaluation was conducted of the initial project at UCLA.[77] The intervention consisted of pocket cards for physicians, pre-printed order sheets, medication algorithms, physician and patient information materials, in-service sessions for nursing staff, and a tracking sheet. The impact of the program was evaluated through medical chart abstractions conducted for consecutive stroke patients for the first 12-months of the program (April 2002-March 2003), and for a historical cohort of consecutive stroke patients admitted during the previous year (April 2001-March 2002). The study found a statistically significant increase in the use at discharge of statins and specific medications used for controlling hypertension during the first 12 months of implementation compared with the previous year.

Gropen et al[78] evaluated the impact of the New York State Stroke Center Designation Project. The project sought to determine whether an integrated system involving transport of stroke patients to designated stroke centers would improve the quality of stroke care. In July 2002, all hospitals in the Brooklyn and Queens neighborhoods of New York City were invited to participate. Hospitals completed a survey to determine whether hospitals met the requirements for pilot stroke center designation. Hospitals that did not initially meet the requirements were given 30 days to meet the requirements. Adherence was encouraged through educational meetings, distribution of stroke quality improvement tools, and an interactive community server. On-site visits were conducted to verify adherence with requirements. In May 2003, EMS started to triage acute stroke patients to designated stroke centers. The impact of the project on acute stroke care was evaluated through centralized abstraction of medical charts for all stroke cases from 32 hospitals serving two New York counties during March –May 2002 (before the start of the stroke center designation program) and August-October 2003 (after designation of pilot stroke centers). Overall, there was an increase in the percentage of acute stroke patients that were admitted to hospitals that eventually were designated as stroke centers, as well as improvements overall (among all stroke patients in the area) in process-of-care measures including time to physician evaluation and time to CT, tPA administration, and admission to a stroke unit. There was also evidence of better performance at stroke centers than non-stroke centers on these measures.

The California Acute Stroke Pilot Registry (CASPR),[79, 80] was one of the prototype registries funded by CDC through the Paul Coverdell National Acute Stroke Registry program. CASPR implemented interventions with 7 hospitals that participated in the registry, including development and encouragement of use of a set of standard stroke orders, data collection and feedback, and meetings about stroke care quality improvement. The impact of the program was assessed through comparison of data from chart abstractions for stroke admissions at participating hospitals during year 1 (November2002-January 2003), before development and encouragement

of use of standing orders, and during year 2 (November 2003-January 2004) after use of standing orders was encouraged. Among the hospitals that implemented standing orders, the study found significant overall improvement between year 1 and year 2 in optimal treatment (defined by the total number of quality indicators met), with significant improvement in the use of 4 of the 6 evidence-based measures. No improvement was observed at the hospital that did not implement standing orders.

The Oregon Stroke Centers Prototype Registry (OScPRey) [81] was a Wave-II Paul Coverdell prototype registry starting during 2002. OScPRey included 16 hospitals. At the start of the registry, hospitals completed a questionnaire about characteristics of their stroke programs. Staff at participating hospitals entered data for stroke patients admitted during December 2002-November 2003 into a software application and transmitted data to the registry. The registry provided monthly reports comparing the performance of all participating hospitals (by ID number) on various indicators. At the end of the registry, hospitals were asked whether they had used the monthly reports for quality improvement. Four hospitals had never used the quality reports for quality improvement. Hospitals that used the reports had subjectively-identified sustained positive changes in 1 to 4 of 7 indicators over the last 3 months of the study, while report non-users had either no sustained positive changes or a change in only 1 indicator.

The Care and Prevention, Treatment Utilization Registry for Stroke (CAPTURE Stroke) was the Illinois Paul Coverdell prototype registry.[82] The CAPTURE Stroke registry included 12 selected hospitals that participated in phase 1 (June 2002-May 2003) and 7 additional volunteers that participated in phase 2 (June 2003-May 2004). Three phase 1 hospitals discontinued participation in phase 2. Chart abstraction and entry of data into an online tool was done by trained staff at participating hospitals. Phase I hospitals prospectively abstracted data for admissions during November 2002-March 2003 (baseline) and February 15-May 14, 2004 (follow-up). At end of phase 1, investigators presented hospital-specific and state-wide reports to staff at Phase 1 hospitals. Presentations were followed by discussions of plans for quality

improvement in phase 2. Hospitals that started in phase 2 did prospective abstractions for admissions during February 15-May 14, 2004 (follow up period) and retrospective abstraction of charts for admissions during part of the baseline period (January-March 2003). No interim feedback was given to hospitals that started in phase 2. In adjusted models, there was improvement in the mean change for 5 of 7 quality indicators in the feedback group compared with 1 of 7 in the non-feedback group. The difference in the mean change between the two groups was significant only for lipid screening.

Stoeckle-Roberts et al [83] reported on the experience of a collaborative quality improvement project (QIP) that started in 2004, after the end of the Michigan Paul Coverdell prototype project. The quality improvement project invited the 15 hospitals that had participated in the prototype registry to participate. Eight of the original prototype-participating hospitals participated in the QIP, as well as 5 other hospitals that were participating in American Stroke Association's (AHA's) Operation Stroke program. The QIP defined 16 performance measures, and collected data through ASA's "Get with the Guidelines-Stroke" patient management tool. The QIP conducted three learning sessions and monthly conference calls with participating hospitals relating to stroke care quality improvement. Adherence at baseline, defined as the 30 most recent stroke cases discharged before January 1, 2004 (the start of interventions), was compared with adherence for the last 30 records entered for discharges starting July 2004 (the end of 6-month intervention period). Statistically significant improvements were observed for 5 of the 16 measures using chi-squared tests.

Cadhilac et al[84] reported on the experience of a project in New South Wales, Australia which evaluated the impact of a health system redesign program to improve access to evidence-based stroke care. The program included establishment of a coordinating committee and nine stroke area networks with 19 stroke care units, development of minimum standards of care, educational forums, employment of new staff, purchasing of new equipment and refurbishing wards, and establishment of ongoing funding. The evaluation used data from medical record

audits for up to 50 consecutive stroke patients admitted during the pre-intervention (2001-2002) and post-intervention (2003-2005) periods at 15 stroke units that had received funding. The primary end point was the level of impairment after stroke based on the modified Rankin scale at discharge or 7-10 days after the stroke. The study also looked at changes in 18 process-of-care indicators. The evaluation found improvement in modified Rankin scores which was not statistically significant after adjustment for case mix and clustering. There was a statistically significant improvement in 17 of the 18 process-of-care measures.

Ongoing Continuous Quality Improvement Interventions

Three previous studies have reported on registries that had a longer duration and hospital-based data collection, allowing implementation of continuous quality improvement interventions and examination of trends in the quality of care over time. One study, by Hills and Johnston[85] reported the improvement that they observed over the course of operation of a web-based acute stroke registry with continuous hospital-based data collection. The registry had 86 participating hospitals during 1999-2003, and used data collection and feedback with benchmarking as the principal quality improvement intervention. The study evaluated duration of hospital participation in the registry as a predictor of hospital performance on three quality indicators including administration of antithrombotics within 48 hours, deep vein thrombosis (DVT) prophylaxis, and prescription of antithrombotics at discharge. They found that longer duration of registry participation was significantly associated with increased adherence with each of the three indicators. The association between increased adherence and duration of participation persisted after controlling for calendar year for antithrombotics within 48 hours and antithrombotics at discharge, providing some indication that the improvements were not just reflective of temporal trends. However, hospitals participated for varying lengths of time, and hospitals that participated the longest may have been the most motivated to implement changes.

Two studies have assessed the impact of the American Heart Association's "Get With the Guidelines-Stroke" program. Quality improvement interventions in the "Get With the

Guidelines-Stroke" program include organizational stakeholder and opinion leader meetings, collaborative workshops, hospital tool-kits, local opinion leaders, and hospital recognition, as well as data collection with continuous, real-time data feedback. Data are abstracted and entered into an on-line tool on an ongoing basis by staff at participating hospitals. Data for stroke admissions during a baseline period (prior to the hospital starting participation in the quality improvement intervention) are also collected by each hospital. LaBresh et al examined changes in stroke care at 99 volunteer hospitals participating in the American Heart Association's "Get with the Guidelines" program during April 2003-March 2004.[66] Significant improvements between baseline and the fourth quarter of participation were seen for 11 of 13 process-of-care measures. Schwamm et al[71] subsequently reported on the experience of a volunteer sample of 790 hospitals participating in the program during 2003-2007. Time of hospital participation in the program was associated with a clinically meaningful and statistically significant improvement in seven pre-specified stroke quality-of-care performance measures between baseline and year 5. Multivariate analysis found a 1.18-fold yearly increase in the odds of receiving each performance indicator (with each opportunity for care considered as a separate event) that was independent of secular trends, with the greatest rates of improvement seen at larger hospitals, hospitals with the highest number of annual stroke admissions, and teaching hospitals.

Importance of measuring outcomes as well as processes

Although several studies have demonstrated improvements in processes of care associated with stroke care quality improvement programs, this is only part of the larger picture. Process-of-care measures are important for demonstrating increased adherence to recommended practices, but they do not measure the ultimate goal of these programs, which is improvement in patient outcomes. Hammermeister et al[86] emphasized the importance of including all three of the components of quality described by Donnabedian,[30] structure, process, and outcomes, in assessment of improvements in the quality of care. They reviewed studies examining the

relationship between care processes and outcomes, and found that many studies related to various conditions have shown a relationship between care-processes and outcomes, but some have not. In addition, they found that while relationships between care processes and outcomes have been demonstrated for several conditions at the patient level, most studies examining the relationship between care processes and outcomes at the hospital level had been inconclusive. Krumholz et al,[87] in an article reporting on hospital performance on 30-day mortality and readmission rates for myocardial infarction and heart failure, outlined some of the limitations of focusing only on process measures. Process measures usually relate to only a portion of the total care that a patient would receive, and often include only a minority of patients with a condition due to inclusion criteria.

Studies of the Impact of Quality-of-care Improvement Programs on Patient Outcomes

Despite the importance of consideration of outcomes in addition to care processes, fewer studies of changes in the quality of care have considered patient outcomes than have considered care processes. There have been more studies considering changes in outcomes for other cardiovascular diseases than for stroke.

Other cardiovascular diseases

Peterson et al,[88] reported a study of data from the National Registry of Myocardial Infarction which collected data on care provided to patients with myocardial infarction and used data feedback with benchmarking to promote continuous quality improvement. The study examined changes in use of various guideline-recommended therapies for patients with myocardial infarction and changes in in-hospital mortality for patients admitted to participating hospitals between July 1990 and December 2006. They found an increase in use of guideline-based acute and discharge therapies for patients with both ST-segment elevation myocardial infarction and non-ST-segment elevation myocardial infarction, and also found a decline in in-hospital mortality rates for both conditions. Fonarow et al[89] studied hospitalizations with

discharge during 2002-2004 to hospitals participating in the ADHERE registry, which collects data on quality of care and in-hospital outcomes for patients with heart failure and uses data feedback with benchmarking to facilitate quality improvement. The study found significant improvement in 3 of the 4 Joint Commission heart failure quality-of-care indicators over time, as well as statistically significant improvements in need for mechanical ventilation, length of stay, and in-hospital mortality.

However, improvements in outcomes have not uniformly been observed along with improvements in care processes. Two studies[90,91] reported analyses of data for patients enrolled in the Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients With Heart Failure (OPTIMIZE-HF), a program involving 259 hospitals that used data collection and feedback with benchmarking as well as provision of process-of-care improvement tools, an educational workshop, and educational web-based seminars, to promote quality- of-care improvement for patients with heart failure. In addition to collecting data on care processes, OPTIIMIZE-HF also captured 60 and 90 day post-discharge outcomes for a pre-specified cohort of patients. In one study, Fonnarow et al[90] analyzed data for discharges of patients with heart failure during March 2003-December 2004 and saw significant improvement over time in 3 of 4 Joint Commission performance measures for heart failure and for 5 of 6 additional measures, as well as a significant reduction in length of stay. In-hospital mortality improved slightly but the change was not statistically significant. In the cohort with post-discharge follow-up, adjusted post-discharge mortality and the combined outcome of post-discharge mortality or readmission showed a trend toward improvement but the changes were not statistically significant. In a second study focusing on the subset of patients for whom 30 and 90 day outcome information was collected,[91] none of 5 performance measures developed by the American College of Cardiology and the American Heart Association was significantly associated with reduced mortality risk, and only one was associated with improvement in the combined outcome of mortality or re-hospitalization, while one measure not included in the recommended measure set

(use of beta blockers) was significantly associated with reduced risk of mortality and mortality or re-hospitalization during follow-up. In a brief review of studies of related to the Centers for Medicare and Medicaid (CMS) performance measures for heart failure, Fonarrow and Peterson[92] noted that although there has been marked improvement during 2002-2007 in adherence with the 4 CMS heart failure performance measures, the improvement in adherence was not accompanied by improvement in 30-day or 1 year mortality rates, which remained stable whether adjusted or unadjusted.

Stroke

Few studies have examined the impact of quality improvement programs for stroke care on patient outcomes. Evidence for a link between stroke care processes and patient outcomes was provided by a study by Ingeman et al,[93] using data from the Danish National Indicator Project. That study demonstrated a relationship at the patient-level between adherence with acute stroke care process measures and lower 30 and 90 day mortality rates. This association remained significant for only early admission to a stroke unit and early assessment of nutritional risk after adjustment for modified Rankin score and Charlson co-morbidity index when the analysis was restricted to a subgroup (n=3554) for which this information on was available. However, evidence of improvement in stroke patient outcomes in relation to stroke care quality improvement programs has been found in only a few studies. The study in New South Wales, Australia,[84] summarized above, which evaluated the impact of health system redesign program to improve access to evidence-based stroke care, found improvement in modified Rankin scores after the intervention, but this was not statistically significant after adjustment for case mix and clustering. A second study[94] considered the impact of the PROTECT-Stroke program at UCLA, also described above, on patient outcomes. That study compared 3-month follow-up outcome data for patients admitted during September 2003-February 2004 at the intervention hospital with outcomes for patients admitted during that period at a similar hospital without a stroke quality-of-care intervention. The study found a lower rate of vascular events (stroke, TIA or myocardial

infarction) during the 3 months after stroke admission among patients admitted to the intervention hospital compared with patients at the non-intervention hospital (adjusted percentages with outcome 8.4% vs. 22%, p=0.036). However, the authors noted that this was a non-randomized and non-blinded study, and further studies are needed to confirm a beneficial impact of stroke quality improvement programs on clinical outcomes after stroke hospitalization.

The Broader Context of Stroke Care Quality Improvement Interventions

Several organizations have established systems intended to improve the quality of care for stroke and other conditions. Although a complete review of the history of medical care quality improvement programs is beyond the scope here, it is important to note that many organizations are part of the effort to monitor and improve the quality of medical care.[95,96] The Joint Commission on Accreditation of Health Care Organizations (Joint Commission),[97] accredits hospitals, long term care facilities, and other types health care organizations. The Joint Commission has established the ORYX®[98] system through which accredited hospitals report on a set of "Core Measures" that monitor care processes related to a selected set of clinical conditions. For the first time starting in May 2009, hospitals can select a set of stroke measures for core measure reporting.

The Joint Commission has also established special disease-specific certification programs, including the Primary Stroke Center Certification Program, for hospitals that want to achieve special recognition in specific areas.[99] In several states, there have been recent efforts to require ambulance personnel to preferentially transport stroke patients to either Joint Commission certified Primary Stroke Centers, or to hospitals that have been designated as stroke centers through some other mechanism.[100,101]

The National Quality Forum (NQF) was established in 1999, as a result of recommendations from a report issued in 1998 by the President's Advisory Commission on

Consumer Protection and Quality in the Health Care Industry.[102] NQF has become the central organization for review and endorsement of performance measures, and the Joint Commission's performance measures are reviewed by NQF.

The Centers for Medicare and Medicaid Services (CMS, formerly called the Health Care Financing Administration), in the Department of Health and Human Services has been involved with the quality of medical care through various quality improvement programs throughout its history, with the current program being called the Quality Improvement Organization (QIO) program.[103] The Quality Improvement Organizations are private organizations with contracts with CMS for improving the quality of care delivered to Medicare beneficiaries and for ensuring that services for which Medicare pays are reasonable and necessary. CMS has also instituted public reporting of quality measures and pilot projects to evaluate pay-for-performance programs.[104]

The National Committee for Quality Assurance (NCQA)[105] is a not-for-profit organization that evaluates and publically reports on the quality of care provided by a variety of organizations. NCQA programs include accreditation programs for health plans and other types of organizations, certification programs for groups like physician organizations, and physician recognition programs, including a Heart/Stroke physician recognition program. Accredited health plans are required to report on as set of quality measures defined in the Healthcare Effectiveness Data and Information Set (HEDIS). HEDIS measures are used by commercial health plans as well as Medicare and Medicaid. Hospitals and other health care providers are faced with meeting the reporting requirements of all of these organizations.

In addition to these broad quality-of-care programs, there are also several large programs that specifically address the quality of stroke care. As noted above, the Joint Commission has a program for certification of Primary Stroke Centers which focuses on stroke quality of care. The American Heart Association/American Stroke Association has the "Get with the Guidelines-Stroke" program which works with hospitals on stroke care quality improvement and provides

recognition to hospitals that achieve a specific level of adherence with a set of stroke care quality indicators.[106] In this context, the CDC has also established the Paul Coverdell National Acute Stroke Registry[107] which seeks to measure, track, and improve the quality of care for acute stroke patients through funding state health department-based stroke registries.

This section has provided only a sample of the various types of programs that are seeking to address the issue of the quality of medical care in general, and the quality of stroke care specifically. This larger context is important to consider when evaluating the effectiveness of the Georgia Coverdell Acute Stroke Registry (GCASR) for several reasons. First, any improvements in care processes or outcomes that are observed must be interpreted with recognition of the many other programs that could have contributed to improvements. It is also important to recognize that the extent to which a hospital is able to devote resources to a program like GCASR can be limited by the resources that they need to devote to other types of quality improvement programs, some of which influence payment and market share. Finally, the overall contribution of GCASR must be evaluated with consideration of the overall context in which it is operating.

Questions to be addressed by this dissertation

This review of the literature has demonstrated that there is an extensive evidence base for the stroke quality-of-care measures, and the stroke care quality improvement methods used by GCASR. There is also a significant evidence-base for the concept that multifaceted, multi-hospital quality-of-care improvement programs like GCASR can improve care processes. However, there are several important areas in which information gained from this registry evaluation can make important contributions.

Although several previous stroke care quality improvement programs have shown improvement in care processes, it is of interest from a program evaluation standpoint to determine whether similar improvement has occurred among GCASR hospitals. This question can also be of significance beyond program evaluation for GCASR, because GCASR is different from the

previously evaluated programs in some important ways. Compared with the previous studies of long term stroke registries that have supported ongoing continuous quality improvement,[71,85] GCASR is unique in that the two previous registries with ongoing data collection did not seek to recruit a representative sample of hospitals. In addition, both previous studies required a fee for hospital participation, while GCASR paid the costs of the data collection tool for hospitals that were selected for the registry to encourage participation by a broad range of hospitals. The focus of GCASR, as a program based in the Georgia Division of Public Health, is on stroke quality-of-care surveillance and stroke care quality improvement interventions as part of the Division's larger Cardiovascular Health Initiative. It is of interest to determine whether GCASR, as a public health-based program, shows improvements similar to those seen in the previous studies. It is also of interest to further define the types of hospitals that have benefited most from the registry. This is an issue that has been examined in only one previous stroke registry study,[71] which included a population of hospitals that may be different in important ways from the population of hospitals participating in GCASR. Study 1 will address these issues by addressing the following specific aims:

Study 1a: Among GCASR participating hospitals, describe observed changes over time in four selected stroke care processes; and

Study 1b: Describe how within-hospital changes over time in the four selected process outcomes have differed between hospitals with different characteristics

Another area in which the findings of the registry evaluation can be of broader significance is clarification of the relative contribution of specific quality improvement intervention components within a multifaceted quality improvement program. Although some small studies of multi-hospital stroke care quality improvement programs have focused on the impact of a specific intervention, such as implementation of standing orders, most large studies of stroke care quality improvement programs have evaluated the programs overall without sorting out the relative contributions of the various components of the interventions. For GCASR, the

registry's conference calls with hospitals have been a particular focus, and it is of interest to determine whether these have been effective in promoting improvements in care processes. While several reviews of previous studies of the effectiveness of educational interventions, when considered as a sole intervention, have found that educational interventions can be effective in improving clinical practice, and that educational interventions that involve an interactive component are generally more effective than purely didactic educational interventions,[72,74,75] less is known in general about the contribution of educational meetings within the context of a larger multifaceted intervention. Study 2 will address this issue by addressing the following specific aim:

> ***Study 2: Among participating hospitals, determine whether there has been a temporal association between registry conference calls intended to impact three of the selected quality indicators and changes in adherence with those quality indicators***

Finally, a very important issue that is of critical importance to evaluation of the impact of the registry, but that also has not been sufficiently addressed in previous studies, is whether a stroke quality-of-care program like GCASR can have an impact on longer-term patient outcomes. While there is a suggestion that some previous stroke quality-of-care interventions have improved patient outcomes, evidence from these studies has been weak. Study 3 will address this issue by addressing the following specific aim:

> ***Study 3: Among all hospitals in Georgia, assess the impact of the GCASR pilot registry on longer-term adverse ischemic stroke patient outcomes including mortality and readmission for stroke within 1 year of admission***

Chapter 3: Background on the Georgia Coverdell Acute Stroke Registry

The Georgia Coverdell Acute Stroke Registry is funded by CDC as part of the Paul Coverdell National Acute Stroke Registry, which was named after Paul Coverdell who was a senator from Georgia who died of a massive stroke while in Congress. GCASR seeks to reduce stroke case-fatality, disability due to stroke, and the incidence of recurrent stroke in Georgia by monitoring and improving the quality of acute stroke care in the hospital setting. The registry addresses all phases of hospital care for stroke, including rapid diagnosis of stroke, treatment of stroke, prophylaxis measures to prevent additional medical complications in stroke patients, discharge planning, and prevention of recurrent stroke.[108]

The registry has gone through two major phases. GCASR was first established in 2001 as a prototype project ("pilot registry"), administered through Emory University, involving 46 hospitals in Georgia. Full implementation and incorporation into Georgia's Division of Public Health began in 2005. The registry has involved strong collaboration with Emory University, the American Heart Association/American Stroke Association (AHA), the Georgia Medical Care Foundation, and the Georgia Hospital Association. Since its inception, GCASR has sought to work with a representative sample of hospitals throughout the state, in order to facilitate delivery of high quality stroke care in all types of hospitals in the state.

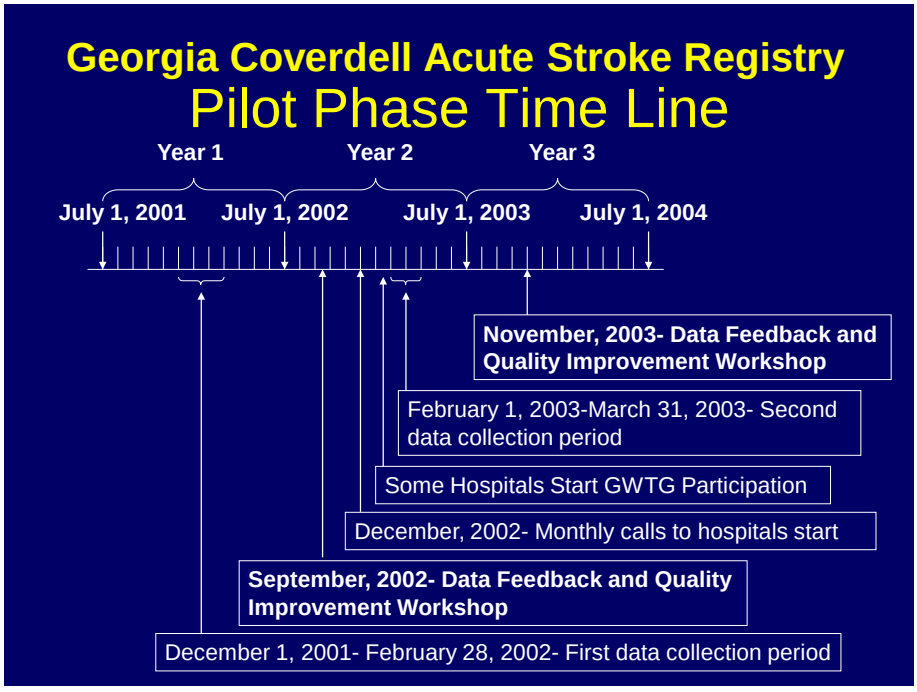
Pilot Registry

The GCASR pilot registry operated during 2001-2004 (see Figure 3A). Hospitals were selected for recruitment for the pilot registry though a random sample of hospitals in the state. Of the 151 hospitals in Georgia with at least one admission for acute stroke during 2000, the sample included the eight hospitals with the most cases of acute stroke each year in the largest county plus a random sample (n=52) of the remaining 143 hospitals for a total of 60 sample hospitals.

Hospitals that were not selected but who desired to work on stroke quality improvement were welcomed to participate in registry activities, although they were not actively recruited.

During the pilot phase, hospitals participating in the pilot registry were asked to submit medical charts to the Georgia Medical Care Foundation for centralized data abstraction related to acute stroke care for acute stroke patients discharged during December 2001-February 2002 and February 2003-March 2003. Hospitals received feedback from the chart abstractions and participated in in-person stroke quality improvement workshops during September 2002 and November 2003. Other registry quality improvement activities included monthly calls with hospitals starting in December 2002, and availability of registry staff to provide stroke care quality improvement resources and facilitate networking between hospitals. In early 2003, some hospitals also started participation in the American Heart Association/American Stroke Association's "Get With The Guidelines- Stroke" program.

Figure 3A. Georgia Coverdell Acute Stroke Registry Pilot Phase Time Line



Implementation Phase Registry

Hospital selection and recruitment

After the prototype registries, CDC chose to fund state health departments for the implementation phase of the national registry starting in 2004. The registry is now administered by the Georgia Division of Public Health but it still involves very strong partnerships with Emory University, and other organizations. During the implementation phase, hospitals were recruited based on the same sample of hospitals used during the pilot registry, and volunteer hospitals were again welcomed to participate. At the time of hospital recruitment for the implementation phase, three sample hospitals had gone out of business or merged with other hospitals, leaving 57 sample hospitals.

Recruitment during the implementation phase was done in 2 phases. During the fall of 2005, passive invitations were sent to the 57 sample hospitals that were still in operation. Further, hospitals not in the representative sample but who had volunteered to participate in the pilot registry were also included, for a total of 69 invited hospitals. Twenty-six hospitals responded and were enrolled starting in November 2005. Of these, 19 were in the representative sample and 7 were volunteer hospitals. During the fall of 2006, hospitals in the representative sample that had not already enrolled were again invited to participate, and were actively encouraged to participate through phone calls with hospital quality improvement staff. Starting in October 2006, 25 additional hospitals were enrolled in the registry (20 selected and 5 volunteer). Two additional volunteer hospitals joined the registry during December 2006 and March 2007. Hospitals that joined the registry in November 2005 are considered cohort 1, and those joining in October 2006 or later are considered cohort 2. During April 2007 through December 2007, 11 selected hospitals discontinued participation. The trend in the number of participating hospitals over time is shown in figure 3B. As the registry expanded, it included greater geographic representation of hospitals in the state. A comparison of locations of hospitals that participated

during the first year of the registry and locations of participating hospitals as of October 2006 is shown in Figure 3C.

Based on hospital discharge data from 2005, the 53 total participating hospitals represented approximately 57% of stroke admissions in the state (ICD-9 codes 430-438). Of the 53 hospitals that participated in the registry, 45 entered patient data into the registry for discharges during the time period examined in the analyses for this dissertation (November 1, 2005 through October 31, 2007).

Figure 3B. Trends in the number of hospitals participating in the Georgia Coverdell Acute Stroke Registry, November 2005-July 2008.

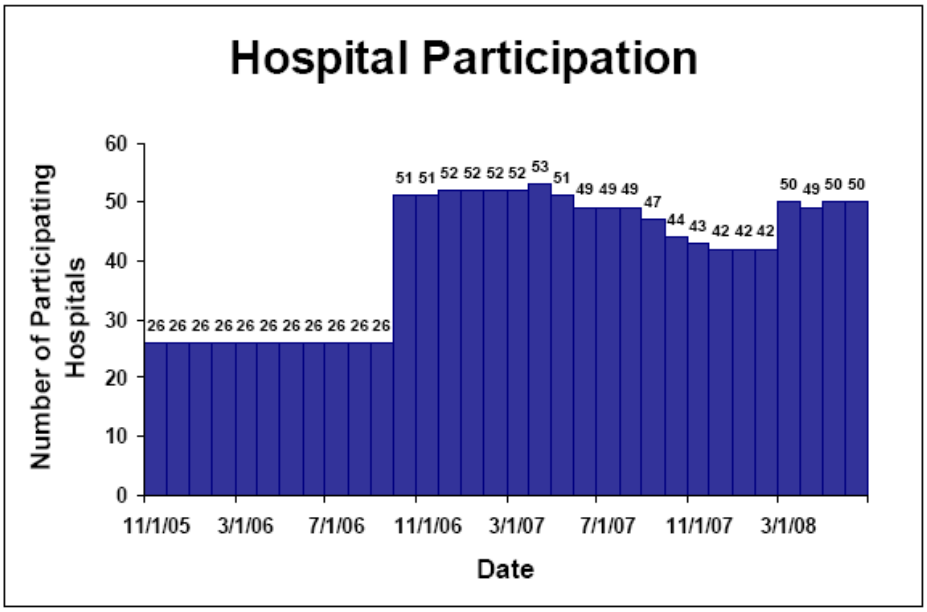
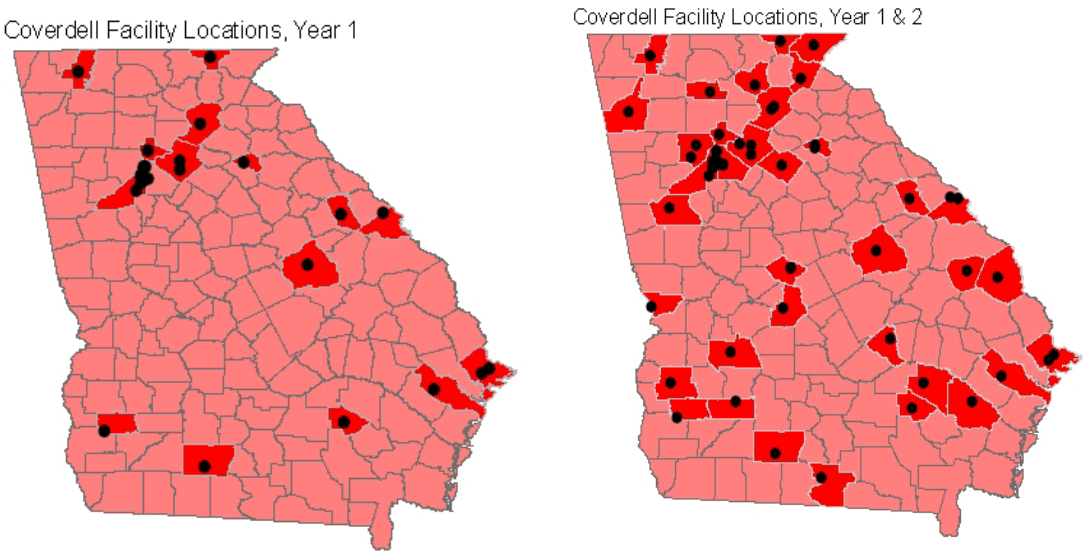


Figure 3C. Locations of hospitals participating in the Georgia Coverdell Acute Stroke Registry, starting in November 2005 (Year 1) and starting in October 2006 (Year 2)



Data collection

During the implementation phase, hospitals have been asked to abstract their own data for all admitted patients with a clinical diagnosis of stroke or transient ischemic attack (TIA) into an on-line, secure data entry system (Outcome, Inc., Cambridge, MA). The data collection system is the same tool used by the AHA's "Get With the Guidelines-Stroke" Program[66] with modifications to meet the specifications of the Paul Coverdell National Acute Stroke Registry. The data collected include patient demographic and clinical characteristics; diagnostic procedures, treatments and counseling received while in the hospital and at discharge; and in-hospital outcomes. The registry asks hospitals to identify patients for the registry based on a clinical diagnosis of stroke, rather than based on ICD codes, and to identify such patients when they arrive at the hospital or shortly afterwards, if possible, to allow monitoring of the quality of care concurrent with the delivery of care. Data abstraction is done by hospital staff members who are trained in data abstraction for the registry at kick off workshops and through individual telephone

training sessions. To protect patient confidentiality, the registry data does not include patient names, medical record numbers, or other direct identifiers. Data for separate admissions for the same patient cannot be linked.

Quality Improvement Activities

The current registry has expanded upon the quality improvement interventions that were used during the pilot phase. GCASR quality improvement interventions with individual hospitals during the implementation phase included collection of patient-level data from hospitals relating to stroke care processes, feedback of summary data to hospitals with benchmarking against other hospitals, individualized quality improvement consultations, monthly individualized telephone calls, site visits, and general availability of registry staff (including a registry neurologist and hospital coordinator) to help answer stroke quality improvement questions or connect hospitals with resources available through other registry hospitals. Additional registry-wide interventions included monthly conference calls and newsletters, annual workshops in collaboration with American Heart Association's "Get With the Guidelines" program, and encouragement for hospitals to share stroke care quality improvement resources with each other.

The registry-wide monthly conference calls were designed to facilitate interaction among registry hospitals regarding stroke care quality improvement. Each month, a topic related to stroke care was selected based on interests expressed by hospitals and needs identified through analysis of registry data. Some calls focused on specific stroke care quality indicators, while others focused on broader topics related to stroke care quality improvement. During most months, a speaker proficient in the topic was asked to prepare a presentation to start the teleconference. Active interaction among hospitals related to the topic was encouraged after the presentation. Calls had varying levels of interaction. For some calls, a more explicitly interactive format was followed, with the selected presenter conducting a guided discussion rather than starting with a didactic presentation. Each call lasted 1 hour. Presenters were often from one of the GCASR participating hospitals that had experienced success with a particular area of stroke

care. The types of hospital personnel who participated in the calls varied with the call topic, but most often included nurses involved with stroke care quality improvement at their institutions. A few days before each call, copies of the slides used in the presentations were distributed to all registry hospitals, regardless of the hospital's call attendance, and highlights of the calls were briefly summarized in the registry's newsletters. Call topics were usually announced a few weeks to 1 month before each call. For each call, a record was kept of the hospitals that had at least one staff member attend the call, but the specific attendees from each hospital and the number of attendees at each hospital were not recorded.

Quality of Care Measures

During the implementation phase, the registry initially used 10 quality indicators, developed by CDC, to measure the quality of stroke care. The 10 indicators used during the first two years of the implementation phase included:

- Tissue plasminogen activator (t-PA) administration
- Dysphagia screening
- Antithrombotic administration within 48 hours
- DVT Prophylaxis
- Lipid Profile Measurement
- Stroke education
- Smoking cessation advice/counseling
- Assessment of the need for rehabilitation
- Discharge with antithrombotic therapy
- Anticoagulation for Atrial Fibrillation

Each indicator identified a treatment or other intervention that had been previously shown to be effective in improving outcomes among stroke patients with relevant characteristics ("eligible patients"). The adherence percentage for each indicator was calculated among eligible patients. Patients eligible for each intervention were identified based on the data elements

entered into the registry database by hospital staff, forming the denominator for percentages calculated. Patients with contraindications for a measure that were documented in the medical record, or for whom eligibility could not be determined, were considered ineligible and were removed from the denominator for each measure. Patients for whom receipt of the intervention was documented in the medical record were considered to have received care meeting the quality indicator and were included in the numerator of the percentages. Hospitals had continuous on-line access to information about the percentage adherence for each indicator among the patients for whom they had entered data.

Chapter 4: Methods

Data Sources

Data Sources for the dissertation analyses include patient-level registry data entered by hospitals for stroke discharges during November 1, 2005 through October 31, 2007, registry participation records for hospitals during December 2005 through April 2008, data on hospital characteristics, hospital discharge data for discharges during 2001-2005 with a longitudinal identifier, and Georgia death certificate data for deaths during 2001-2005

Hospital Characteristics

Data on the number of beds for each hospital and the type of hospital ownership were obtained from the Georgia Hospital Association's 2007 hospital directory. The type of ownership was categorized as private ownership versus not-for-profit or hospital association ownership. The number of stroke admissions during 2006 for each hospital was calculated using hospital discharge data from the Georgia Hospital Association, based on ICD-9 CM codes 430-438. The teaching status and census tract for each hospital was obtained from a Georgia hospital database maintained by the Georgia Division of Public Health, Office of Health Information and Policy. Categorization of each hospital as metropolitan or non-metropolitan was based on the 2000 Rural-Urban Commuting Areas (RUCA) Code[109] for the census tract in which the hospital was located, with RUCA Codes <4 categorized as metropolitan and RUCA codes ≥4 categorized as non-metropolitan. The area of the coastal plain in Georgia is the area of the state with the highest stroke mortality rates.[110] A hospital was classified as serving the coastal plain of Georgia if the county in which the hospital is located is primarily in the Sea Island or East Gulf Coastal Plain physiographic sections, based on a physiographic map of Georgia.[111]

Database Linkage

Linkage methods for Studies 1 and 2

Registry data entered by hospitals into the on-line data collection tool were linked with hospital participation records and data on hospital characteristics through a registry hospital identifier.

Linkage methods for Study 3

Study 3 linked patient-level data for patients discharged from hospitals in Georgia ("hospital discharge data") with Georgia death certificate data for the years 2000-2006. The hospital discharge data included a unique longitudinal patient identifier, based on the patient's name, date of birth and sex. Stroke admissions (principal ICD-9 diagnosis codes 430-438) were selected from the hospital discharge data. For each patient, the first stroke admission during 2000-2006 was the index admission. The primary analysis considered the hospital of first presentation to be the index hospital. A secondary analysis considered the index hospital to be the hospital at which the patient was finally admitted after a series of early transfers (on the same day or the day following the previous admission). Both analyses included only index admissions during 2001-2005 with a primary diagnosis of ischemic stroke (primary ICD-9 code 433.01, 433.11, 433.21, 433.31, 433.81, 433.91, 434.01, 434.11, 434.91, or 436). Admissions through 2006 for all stroke types were included in identification of stroke readmissions.

An identifier matching the longitudinal identifier in the hospital discharge data was created in the death certificate data set using decedent identifying information, after which identifiers were removed. De-duplicated, de-identified mortality records were linked with hospital discharge records using a deterministic linkage based on the longitudinal identifier. The accuracy of the linkage was assessed by examining the percentage of patients dying before discharge or discharged to hospice who had linked death data, the percentage of linked cases for which the race was the same in both data sets, and the percentage of linked cases for which the final stroke admission was after the date of death from the linked death certificate. Hospital

discharge data were linked with a hospital's registry selection and participation status through an OHIP hospital identifier.

Quality Indicator Calculations

The quality indicator calculations used for this dissertation were a modification of the initial quality indicator calculations developed by CDC for the Paul Coverdell National Acute Stroke Registry (see the link on the CDC Paul Coverdell National Acute Stroke Registry web site[7] for the current measures used, an earlier version of these measures was used as the starting point for these calculations). In-hospital strokes were excluded from the data set. In all cases, the instructions for abstractors at hospitals stated that receipt of the measure must be documented in the medical record to be recorded in the registry.

This dissertation focuses on four of the ten indicators used during the first two years of the GCASR implementation phase registry, including receipt of tissue plasminogen activator (tPA), dysphagia screening, DVT prophylaxis, and smoking cessation counseling. These four indicators were chosen for the dissertation because:

- They represent various stages of stroke patient care. T-PA administration represents the most acute phase because t-PA must be given within 3 hours of stroke onset. Dysphagia screening is a measure that is a little less acute, and can span the transition of a patient from the emergency department to the hospital floor. Dysphagia screening must be completed before a patient has any oral intake and requires coordination of care. DVT prophylaxis is an in-hospital measure that is implemented within 48 hours of admission, and smoking cessation counseling is a measure that happens in preparation for discharge.
- These measures were ones that did not have a very high level of adherence at baseline, and thus had room for improvement.

- They include measures that were the previous focus (DVT) of the registry (DVT prophylaxis was the focus until July 2008) and the new focus for the registry (dysphagia screening was the focus starting in July 2008).
- These measures were relatively well defined.

The original CDC quality indicator definitions for dysphagia screening and smoking cessation were used without modification. The quality indicator definition for DVT prophylaxis was based on older CDC calculation dated July 5, 2006. That definition differed from later versions of the measure, which included patients admitted for 2 days or less in the denominator if they got DVT prophylaxis but not if they did not. The older definition was used to ensure that the definition of the denominator was not dependent on whether or not the patient received DVT prophylaxis.

The definition for the t-PA administration indicator was modified from CDC calculations dated July 5, 2006, which differed slightly from later versions. The modification from the original CDC definition for the t-PA administration indicator consisted of a refinement in the use of the "other" field for reasons for non-treatment. No exclusions were based solely on the hospital simply checking "other" as a reason for non-treatment. All written "other" reasons for non-treatment were individually reviewed for patients that were not excluded from the tPA measure by other factors. If a written reason for non-treatment was based on the patient's clinical condition, it was considered a valid reason for non-treatment and the patient was excluded from the denominator for the measure. However, if a written reason for non-treatment was clearly related only to hospital processes, it was not considered a valid reason for non-treatment and the patient was not excluded from the denominator for the measure.

In all analyses, adherence with a quality indicator was defined at the patient level as delivery of care meeting the indicator, considered among indicator- eligible patients only. Detailed descriptions of the definitions used to determine adherence for each of these four quality indicators are listed in Table 4A. All analyses were conducted for each indicator separately.

Table 4A. Quality Indicator Definitions

Indicator	Indicator-eligible patients (Denominator)	Patients receiving care meeting the indicator (Numerator)
Dysphagia Screening	-Any stroke type except TIA (includes ischemic stroke of uncertain type, ischemic stroke, subarachnoid hemorrhage, intracerebral hemorrhage, hemorrhagic stroke not otherwise specified, or stroke not otherwise specified). AND -Not NPO for entire hospital stay.	-Received dysphagia screening prior to any oral intake.
Smoking Cessation	-Any stroke type (as defined for dysphagia screening plus TIA). AND -Discharge destination **not**: transferred to another short term general hospital for inpatient care, left against medical advice or discontinued care, expired, expired in medical facility (such as hospital, SNF, ICF or freestanding hospice), hospice-home, hospice- medical facility, or missing. AND -Medical history of smoking, defined as smoking at least one cigarette in past year.	-Received counseling to stop smoking, smoking cessation advice, or smoking cessation therapy.
DVT Prophylaxis	-Any stroke type (as defined for smoking cessation). AND -Admitted for more than 2 days. AND -Not documented to be ambulating within 48 hours (documented not to be ambulating within 48 hours, ambulation status recorded as “not documented”, or ambulation question blank).	-DVT prophylaxis started within 48 hours after arrival. Acceptable prophylaxis included heparin (including low dose, subcutaneous heparin), low molecular weight heparin, a trial-based antithrombin agent, warfarin (or other agent with similar action), and pneumatic compression stockings. TED hose alone did not meet the criteria.

Table 4A. (continued)

Indicator	Indicator -eligible patients (Denominator)	Patients receiving care meeting the indicator (Numerator)
tPA	-Ischemic stroke of uncertain type or ischemic stroke and **NOT** a diagnosis of subarachnoid hemorrhage, intracerebral hemorrhage, or hemorrhagic stroke not otherwise specified. AND -Time from onset to hospital arrival is not missing, and is > 0 and ≤2 hrs. AND -The patient did not receive tPA at a transferring hospital, was not on a thrombolytic investigational protocol, and did not receive another type of intervention within 3 hours after onset. Other interventions include intra-arterial clot removal, intra-arterial thrombolytic, or a thrombolytic for which the type was not specified. AND -No documented valid contraindication checked. (NONE of the following: uncontrolled hypertension; rapid improvement; CT findings contraindicating tPA; severity too mild or too severe; seizure at onset; recent surgery/trauma; recent IC surgery (3 mo.), head trauma, or stroke; patient or family refused; consent not obtainable; history of intracranial hemorrhage, brain aneurysm, vascular malformation, or brain tumor; age; active internal bleeding (<22 days); platelet count <100,000, abnormal PT or aPTT; glucose <50 mg/dl or >400 mg/dl; no IV access; life expectancy less than 1 year or severe co morbid illness; investigative therapy for acute ischemic stroke). AND -No other written-in contraindication related to the patients clinical condition. (Reasons for not giving tPA related only to hospital processes were not considered valid contraindications.)	-Patient received IV tPA within 3 hours of onset.

Statistical Analysis

Study 1

Data entered into the GCASR database by participating hospitals for stroke discharges during November 1, 2005 through October 31, 2007 were included in the analysis. Cases entered by hospitals with discharge dates prior to a hospital's GCASR start date, in-hospital stroke cases, entries for patients aged <19 years, cases with no clinical diagnosis related to stroke, and duplicate entries were excluded from the analysis.

To assess the degree to which hospitals that submitted data were representative of all hospitals in Georgia, characteristics of hospitals that submitted data were compared with characteristics of hospitals in Georgia that did not submit data but were eligible for the registry (defined as non-federal, acute care or critical access hospitals providing adult hospital care during 2007). Differences between groups were assessed using the chi-squared test for categorical variables and the Wilcoxon Rank sum test for continuous variables.

To assess the impact of GCASR's quality improvement activities on stroke care processes, a three-stage analytic strategy was used. The first stage of the analysis consisted of descriptive analyses of the overall adherence percentage for each indicator. In the second stage of the analysis, logistic regression models were used to identify hospital characteristics that were associated with adherence among admissions that occurred during the first 6 months of a hospital's registry participation (baseline models). In the third stage of the analysis, conditional logistic regression models were used to quantify within-hospital trends over time in adherence by cohort, and to identify hospital characteristics that were associated with differing rates of change in adherence over time (trend models).

In the descriptive analyses, the overall adherence percentage for each indicator was calculated for each registry cohort by month and for the first and last six months of any hospital participation for each cohort. This descriptive analysis included all indicator eligible-patients

without regard to the number of eligible patients per hospital, and aggregated patients across hospitals within cohorts.

Baseline models first assessed associations between adherence and each hospital characteristic alone among admissions that occurred during the first 6 months of a hospital's registry participation (Models 1a). These models were followed by multivariate models that included all of the considered hospital characteristics (Models 1b). Hospital characteristics considered included the hospital's registry cohort, registry selection status (selected or volunteer), number of beds (<median of 250 vs. ≥250), type of ownership (private versus not for profit or hospital association ownership), location in metropolitan or non-metropolitan area, teaching status, number of stroke admissions during 2006 (<median of 258 vs. ≥258), and location in or outside the coastal plain area. Because in these analyses patients are nested within hospitals, the baseline models accounted for clustering of patients within hospitals through inclusion of a random intercept for hospital in the models. Baseline models included only hospitals with at least 10 admissions entered for the relevant quality indicator over the time period under consideration in the analyses (November 1, 2005 through October 31, 2007).

The forms of the baseline models were as follows:

Models 1a

$$\text{logit}(P(Y_{ij} \mid b_i)) = \beta_0 + \beta_1(characteristic) + b_i$$

Where:

$P(Y_{ij})$=probability of patient j at hospital i receiving care meeting the quality indicator among eligible patients

b_i=random effect for hospital, assumed to be normally distributed with a mean of 0 and a variance σ^2

Characteristic: Characteristics and the variable value associated with each category are listed in the table below:

Hospital Characteristic	Category	Variable Value
Cohort	Cohort 2	1
	Cohort 1	0
Registry selection status	Volunteer	1
	Selected	0
Number of beds	<250 beds	1
	≥250 beds	0
Type of ownership	Private	1
	Not for profit or hospital association	0
Location in Non-metropolitan area	Location in micropolitan area, small town, or rural area	1
	Location in metropolitan area	0
Teaching status	Teaching	1
	Non-teaching	0
Number of stroke admissions during 2006	Below median (<258)	1
	At or above median (≥258)	0
Location in Coastal Plain	In coastal plain	1
	Not in Coastal Plain	0

Models 1b

$$\text{logit}(P(Y_{ij} \mid b_i)) = \beta_0 + \beta_1(cohort) + \beta_2(selection\_status) + \beta_3(number\_of\_beds) + \beta_4(type\_of\_ownerhips) + \beta_5(Non-metropolitan) + \beta_6(teaching) + \beta_7(stroke\_admissions) + \beta_8(coastal\_plain) + b_i$$

Where:

$P(Y_{ij})$=probability of patient j at hospital i receiving care meeting the quality indicator among eligible patients

b_i=random effect for hospital, assumed to be normally distributed with a mean of 0 and a variance σ^2

Variable values for the hospital characteristics are as defined above.

In trend models, conditional logistic regression, conditioning on hospital, was used to assess the average within-hospital monthly change in adherence. The conditional logistic regression analysis accounts for clustering of patients by hospital, and controls for unmeasured hospital characteristics.[112] In these models, the primary interest was in the association between the patient's month of discharge and the odds of adherence. The month of discharge was considered as a continuous variable (1-24) to determine the average monthly change in the odds of adherence. Terms for interactions between month and hospital characteristics were used to estimate average monthly changes in adherence for separate groups by hospital characteristics, and to determine the statistical significance of differences in trends between groups. The initial trend models included a term for the interaction between discharge month and hospital cohort only, to assess overall trends in adherence for each cohort (Models 1c with the characteristic being the hospital cohort). Subsequent models considered interactions between discharge month

and each of the hospital characteristics separately (characteristics defined as in the baseline models), to identify hospital characteristics that were individually associated with different rates of change in adherence (Models 1c). A multivariate model was then fit that included terms for all two-way interactions between hospital characteristics and discharge month (Model 1d). Finally, models were fit that included terms for the interaction between a hospital's baseline adherence level (in quartiles) and discharge month to determine whether, overall, hospitals with different baseline adherence levels had different rates of change in adherence (same form as Models 1c but with the baseline adherence quartile as the hospital characteristic). All trend models, like the baseline models, included only hospitals with at least 10 admissions entered for the relevant quality indicator over the time period under consideration in the analyses (November 1, 2005 through October 31, 2007).

The forms of the trend models were as follows:

Models 1c

$$\text{logit}(P(Y_{ij} \mid y_{i1} \ldots y_{in_i})) = \beta_0 + \beta_1(month) + \beta_2(month)(characteristic)$$

Where:

$P(Y_{ij})$=probability of patient j at hospital i receiving care meeting the quality indicator among eligible patients.

n_i =total number of patients for hospital i in the analysis.

Month=continuous variable for month starting with month=1 for November 2005 and ending with month=24 for October 2007

Characteristic= 1 if hospital characteristic was present and 0 if hospital characteristic was absent. Characteristics and the variable value associated with each category are as described above. Note that although the main effects for hospital characteristics are not in the model, these effects are implicitly included through conditioning on the hospital.

Model 1d

$$\text{logit}(P(Y_{ij} \mid y_{i1}...y_{in_i})) = \beta_0 + \beta_1(month)$$
$$+ \beta_2(month)(cohort) + \beta_3(month)(selection\_status)$$
$$+ \beta_4(month)(number\_of\_beds) + \beta_5(month)(type\_of\_ownership)$$
$$+ \beta_6(month)(non-metropolitan) + \beta_7(month)(teaching)$$
$$+ \beta_8(month)(stroke\_admissions) + \beta_9(month)(coastal\_plain)$$

Where:

$P(Y_{ij})$=probability of patient j at hospital i receiving care meeting the quality indicator among eligible patients.

n_i =total number of patients for hospital i in the analysis.

Month=continuous variable for month starting with month=1 for November 2005 and ending with month=24 for October 2007

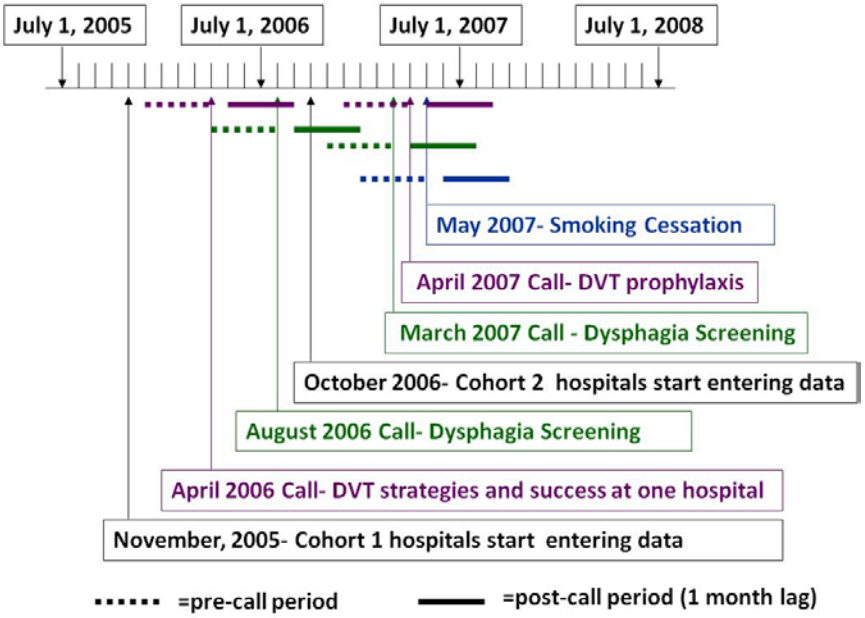
Characteristic= 1 if hospital characteristic was present and 0 if hospital characteristic was absent. Characteristics and the variable value associated with each category are as described above. Note that although the main effects for hospital characteristics are not in the model, these effects are implicitly included through conditioning on the hospital.

All p-values are two sided. P-values less than 0.05 were considered statistically significant. All analyses were performed using SAS software version 9.2 (SAS Institute, Cary, NC).

Study 2

Statistical analyses were conducted to examine within-hospital changes in adherence with three of the 10 registry quality indicators in temporal relation to the registry-wide conference calls that focused on those indicators, using an interrupted time series design. The calls included in this evaluation were selected a priori, before the analyses were conducted, and included all calls related to dysphagia screening, DVT prophylaxis, and smoking cessation counseling conducted during November 1, 2005 through October 31, 2007. Calls relating to these three indicators were chosen for detailed evaluation because these indicators had been the particular focus of registry quality improvement efforts and of analyses for previous registry evaluation studies. Conference calls related to these quality indicators were held in April 2006 (DVT prophylaxis), August 2006 (dysphagia screening), March 2007 (dysphagia screening), April 2007 (DVT prophylaxis), and May 2007 (smoking cessation counseling) (Figure 4A).

Figure 4A. Timing of evaluated GCASR Registry-wide educational conference calls and topics covered



*Only the post-call periods after a one month lag are shown. The post-call periods after a three month lag are not shown.

The specific quality indicator calculations used in this evaluation were a modification of the initial quality indicator calculations developed by CDC for the Paul Coverdell National Acute Stroke Registry that were in use during the time period considered, as described above. All analyses were conducted separately for each indicator and call.

Descriptive Analyses

For each of the calls in the analysis, hospital characteristics were compared for hospitals that attended the call and hospitals that did not attend among fully participating hospitals that were participating in the registry on the call date ("eligible for the call"). Fully participating hospitals were hospitals that had entered at least some patient data into the registry for discharges during November 2005-October 2007. Among hospitals that were eligible for each call, hospital characteristics were also compared for hospitals that did and did not have adequate data for the evaluation, defined as having entered data for at least 5 admissions for indicator-eligible patients with discharge dates during the baseline period and both follow up periods for the respective call. Finally, hospital characteristics were examined in relation to the percentage of all registry conference calls which the hospital attended among calls for which the hospital was eligible. The statistical significance of differences between groups for continuous variables was assessed using the Wilcoxon Rank Sum test. The statistical significance of differences between groups for categorical variables was assessed using the Fisher's Exact Test.

Models for Changes in Quality Indicator Adherence

To examine within-hospital changes in quality indicator adherence in temporal relation to the calls, conditional logistic regression models were used, conditioning on hospital. In all models, adherence with the relevant quality indicator during the 4 months preceding the call (pre-call period), was compared with adherence during the 4 months after two lag periods (follow-up periods). The lag periods lasted 1 month and 3 months after the call to account for the time needed for hospitals to implement changes based on learning during the call before any effect on quality indicator adherence would be expected. For the May 2007 call, the follow-up period after

the 3 month lag was only 3 months in duration due to the end of the available data at the end of October 2007.

Two types of models for change over time were used. Initial models ("pre-post average models") simply compared a hospital's average level of adherence during the two follow-up periods with that hospital's adherence during the pre-call period. Observations during the lag periods were excluded from these analyses. Initial pre-post average models did not consider a hospital's call attendance status, as "intent to treat" models. Models were then considered that included terms for the interaction between the time period and the hospital's call attendance status (Models 2a).

The second type of models for change over time ("trend models") evaluated a hospital's average monthly rate of change in adherence during the two follow up periods compared with the average monthly rate of change in adherence during the pre-call and lag periods. The odds ratios obtained from these models compare the odds of quality indicator adherence in a given month with the odds of adherence during the previous month, on average, within each period. The trend models were considered the primary analysis. The trend models assumed that after a lag period, there would be acceleration in the rate of improvement in quality indicator adherence if the calls had the desired impact. These models included a continuous variable for the month of discharge, and a spline, with one knot at the end of the lag period, allowing for an increase or decrease in the average monthly change in the odds of adherence starting at the end of the lag period. The average monthly change in the odds of adherence during each follow up period was compared with the average monthly change in the odds of adherence during the pre-call period and lag period combined. Trend models were first fit that did not consider a hospital's call attendance status, as "intent to treat" models (Models 2b without term for participation). Models were also fit that included interactions between the terms for baseline and follow-up monthly change in adherence and the hospital's call attendance status (Models 2b).

For both types of models, separate models were constructed for each call. The analysis included only hospitals that were eligible for each call and that had adequate data for the evaluation, to allow stable estimates of average adherence and the rate of change in adherence during each period.

The forms of the models used were as follows:

Models 2a (Conditional Logistic Regression Pre-Post Average Models)

$$Logit\left(P\left(Y_{ij}\middle|Y_{i1}\ldots Y_{in_i}\right)\right)=\beta_0+\beta_1(Period)+\beta_2(Participation)(Period))$$

Where:
$P(Y_{ij})$=probability of patient j at hospital i receiving care meeting the quality indicator among eligible patients.

n_i =total number of patients for hospital i in the analysis.

Participation=1 if hospital participated in the call and 0 if the hospital did not participate in the call. Note that although a main effect for participation status is not in the model, this hospital characteristic is implicitly in the model though conditioning on hospital.

Period=0 if during 4 months before call, 1 if in 4 months after lag period

Models 2b (Conditional Logistic Regression Trend models)

$$Logit\left(P\left(Y_{ij}\middle|Y_{i1}\ldots Y_{in_i}\right)\right)=\beta_0+\beta_1(X_1)+\beta_2(X_2)+\beta_3(X_1)(Participation)+$$
$$\beta_4(X_2)(Participation)$$

Where:

$P(Y_{ij})$=probability of patient j at hospital i receiving care meeting the quality indicator among eligible patients.

n_i =total number of patients for hospital i in the analysis.

Participation=1 if hospital participated in the call and 0 if the hospital did not participate in the call. Note that although a main effect for participation status is not in the model, this hospital characteristic is implicitly in the model though conditioning on hospital.

X1=Month from start of 4 month pre-call period, with the first month of that period having a value of 1

X2=X1-5 if X1>5, 0 otherwise

Consideration of global effect of calls

The possibility that the calls may have had an impact that cannot be detected in temporal relation to specific calls was considered. To examine the more global association between call participation and quality indicator adherence, we examined the overall within-hospital monthly rate of change in quality indicator adherence in relation to the overall percentage of registry-wide calls which each hospital attended, among calls for which the hospital would have been eligible. This analysis was conducted using conditional logistic regression models for adherence with each of the three selected quality indicators that included a term for the month of discharge and terms for the interaction between discharge month and categories of hospital call attendance percentage. For this analysis, hospitals were divided into 4 groups by the percentage of calls that they attended among calls for which they were eligible. The four groups were selected to achieve balance between groups in relation to both the number of hospitals and the number of admissions in the analysis. The models controlled for two-way interactions between month and other hospital characteristics, including the hospital's registry cohort, the annual number of stroke admissions (at or above the median versus below the median), metropolitan location, and teaching status (Models 2c).

The form of the models for global call participation was as follows:

Models 2c (Conditional Logistic Regression Global Call Participation Models)

$$Logit\left(P\left(Y_{ij}\middle|Y_{i1}\ldots Y_{in_i}\right)\right)$$

$$= \beta_0 + \beta_1(month) + \sum_{k=2}^{4} \beta_k\,(month)(call\ group\ k)$$

$$+ \beta_5(month)(cohort2) + \beta_6(month)(stroke\_admissions)$$

$$+ \beta_7(month)(non-metropolitan)$$

$$+ \beta_8(month)(teaching)$$

Where:

$P(Y_{ij})$=probability of patient j at hospital i receiving care meeting the quality indicator among eligible patients.

n_i =total number of patients for hospital i in the analysis.

Month= continuous variable for month starting with month=1 for November 2005 and ending with month=24 for October 2007

Call group=groups by the percentage of calls that the hospital attended among calls for which they were eligible. The four groups were selected to achieve balance between groups in relation to both the number of hospitals and the number of admissions in the analysis.

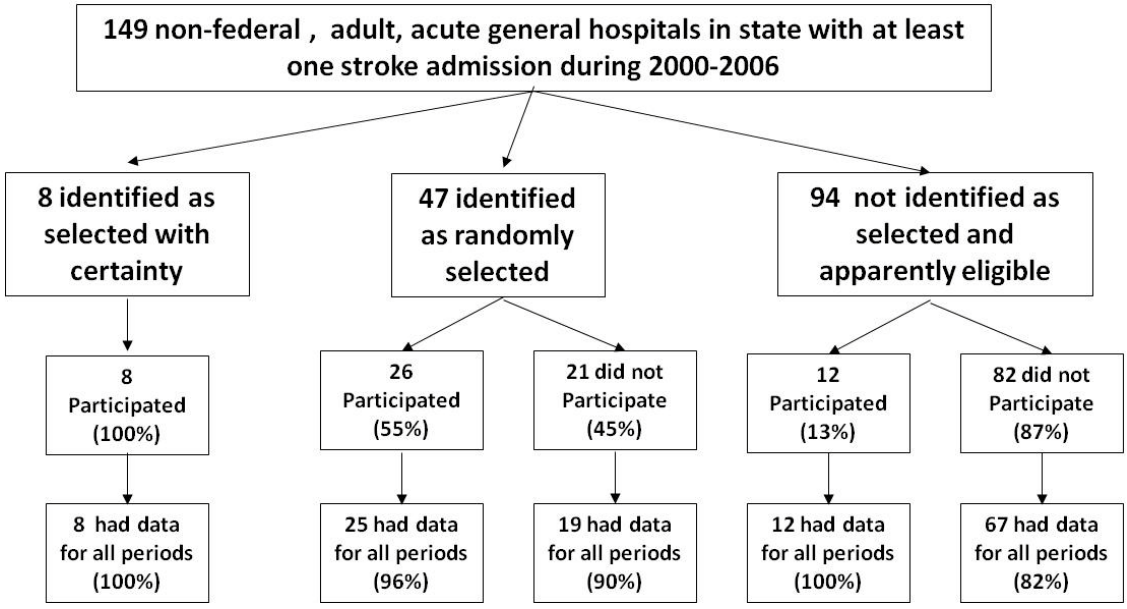
Note that although a main effect for call participation is not in the model, this hospital characteristic is implicitly in the model though conditioning on hospital.

Study 3

Study 3 considered all non-federal, adult acute care general hospitals in Georgia. Facilities that were not primarily general acute care hospitals or that had no stroke admissions during 2001-2006 were excluded from the evaluation, leaving 149 eligible hospitals (Figure 4B). Of the 149 eligible hospitals, 47 had been randomly selected for participation in the pilot registry, of which 26 (55%) participated in the registry. An additional 5 hospitals had also been randomly selected but were not included in the evaluation because they had closed before the end of the

pilot period (2 hospitals), or they were considered ineligible for the evaluation (1 pediatric facility, 2 long term care facilities). Eight hospitals had been selected with certainty for participation in the pilot registry because they had the highest annual number of acute stroke admissions in the largest county. All eight hospitals selected with certainty met the evaluation criteria and participated in the registry. Ninety-four non-selected hospitals met the evaluation criteria, of which 12 (13%) participated in the pilot registry.

Figure 4B. Hospital Selection and Participation, Georgia Coverdell Acutre Stroke Pilot Registry, 2001-2004



Outcome variables

The primary outcomes of interest were death within 1 year of the index admission date, and readmission within 1 year of the index admission discharge date. A patient was considered to have died if either the last stroke admission indicated in-hospital death or there was a death date from a linked death certificate. If dates of death from the hospital discharge data and the death certificate data were not the same, the date of death from the hospital discharge data was used. Time to readmission was calculated as the time from the index admission discharge date to the

admission date for the next admission that was not part of an initial chain of transfers for the index event.

Regression Models

To determine whether changes in these outcomes were seen in association with operation of the GCASR pilot registry, two types of models were used. The primary models were intent-to-treat Cox proportional hazards models, that compared the hazard of the outcomes for patients admitted to selected and non-selected hospitals during each of three time periods separately, accounting for correlation between patients admitted to the same hospital through robust variance estimation (Model 3a). The three time periods were the 6 months prior to the start of the pilot registry (January-June 2000), the last 6 months of the pilot registry (January-June 2004), and the 6-month period 1 year after the last 6 months of the pilot registry but before hospital participation in the implementation phase registry started (January-June 2005). Admissions to hospitals selected with certainty were excluded from the intent-to-treat analyses.

As secondary analyses, Cox proportional hazards models were considered that compared outcomes of patients admitted during Jan-June 2001 with outcomes of patients admitted to the same hospitals during Jan -June 2004 or Jan-June 2005. These models were stratified by hospital to create within-hospital comparisons that account for clustering of patients within hospitals and control for all hospital characteristics. These models included a term for the time period and a term for the interaction between time period and hospital selection status (for intent-to treat analyses) or combined selection and participation status (for complier's analyses) (Models 3b).

All models considering the outcome of death within 1 year of admission censored patients 1 year after the index admission date. Models considering the outcome of readmission within 1 year of discharge censored patients at the time of death or 1 year after the index admission discharge date. All models controlled for patient-level characteristics including age (in 7categories: 18-39, 40-49, 50-59, 60-69, 70-79, 80-89, and 90+ years), race (white, black and other) and gender. To ensure a consistent set of hospitals in all analyses, all models excluded

admissions to hospitals that did not have at least 1 index admission during each time period under consideration. This led to exclusion of admissions to 18 hospitals (1 randomly selected participating, 2 randomly selected non-participating, and 15 non-selected non-participating) (see Figure 4B). All analyses excluded admissions for patients aged <18 years.

The forms of the models were as follows:

Models 3a (Intent to treat models)

$$h(t) = h_0(t)e^{\beta_1(ss)+\sum_{i=1}^{6}\beta_{2i}(age\ category\ i)+\beta_3(sex)+\sum_{j=1}^{2}\beta_{3j(race\ category\ j)}}$$

Where ss=selection status
Models fit for admissions during each of three time periods separately

Models 3b (Conditional logistic models with interaction between time period and either selection status or combined selection and participation status)

$$h(t|hospital) = h_{0g}(t)e^{\beta_1(time\ period)+\beta_2(time\ period)(status)+\sum_{i=1}^{6}\beta_{2i}(age\ category\ i)+\beta_3(sex)+\sum_{j=1}^{2}\beta_{3j(race\ category\ j)}}$$

Where:
ss=selection status and g denotes a separate stratum and separate baseline hazard for each hospital.

Time period =0 if admission is during January-June 2001and =1 if admission is during January-June 2005

Status for models by selection status=1 if selected, 0 if not selected
Status for models by combined selection and participation status was a set of dummy variables for categories by combined selection and participation status with the non-selected, non-participating group as the reference group.

Several sensitivity analyses were done. All analyses were repeated considering the index hospital to be the hospital at which the patient was admitted after early transfers rather than the hospital at which the patient first presented. The proportional hazards assumption was assessed graphically for each variable in the models through examination of log –log survival curves, and through examination of correlations between Schoenfeld residuals and failure time rankings.

Based on these assessments, the proportional hazards assumption was considered reasonable for the patient-level covariates (age category, sex and race). However, to assess the sensitivity of the results to this decision, all proportional hazards models were repeated, stratifying on these patient characteristics. In addition, to further assess the proportional hazards assumption for the main exposures of interest (hospital selection and participation status), all survival analyses were repeated examining the outcomes within 30 and 90 days of admission or discharge.

All analyses were performed using SAS software version 9.2 (SAS Institute, Cary, NC). Cox proportional hazards models used SAS PROC PHREG. All p-values are two sided. P-values less than 0.05 were considered statistically significant.

Chapter 5: Manuscript for Study 1

(References, tables, and figures not continuous with larger document.)

Trends in stroke quality-of-care indicator adherence among hospitals participating during the first two years of the Georgia Coverdell Acute Stroke Registry

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ABSTRACT

Background: The Georgia Coverdell Acute Stroke Registry (GCASR) seeks to monitor and improve the quality of acute stroke care in Georgia. This study examined trends in quality indicator adherence among GCASR-participating hospitals, and hospital characteristics associated with improvement in adherence.

Methods: Registry data were analyzed for patients discharged during 11/1/2005 through 10/31/2007, representing patients admitted to 45 hospitals (31% of registry-eligible hospitals in Georgia). Conditional logistic regression was used to estimate the average monthly within-hospital change in the odds of eligible patients receiving care meeting four quality indicators (tPA administration, dysphagia screening, DVT prophylaxis and smoking cessation counseling). Models with interaction terms were used to assess differences in trends by hospital characteristics.

Results: There was overall improvement in adherence with all four quality indicators during the time period examined, with odds ratios for the monthly within-hospital change in adherence of 1.01-1.08. The improvement was statistically significant for dysphagia screening, DVT prophylaxis, and smoking cessation among hospitals that joined the registry on 11/1/2005; and for dysphagia screening among hospitals that joined on 10/1/2006 or later. In multivariate models, particularly rapid improvement was identified for specific types of hospitals for some indicators. Of note was a high rate of improvement for dysphagia screening and DVT prophylaxis among hospitals with a number of stroke admissions below the median. This group of hospitals also had lower baseline adherence for these indicators.

Conclusions: These results show improvement in the four quality indicators temporally associated with registry participation; however, the observed improvement cannot be definitively attributed to a registry impact apart from secular trends. The results suggest that hospitals with

fewer stroke admissions may particularly benefit from the registry, and recruitment efforts among these hospitals should be continued.

Key Words: stroke, quality of health care**,** registries

INTRODUCTION

Stroke causes more than 140,000 deaths each year, and is the third leading cause of death in the United States. Each year, approximately 795,000 people in the United States experience a stroke, with approximately 185,000 of those strokes being recurrent strokes.[1] Stroke disproportionately affects residents of Georgia, which in 2006 had a stroke mortality rate 16% higher than the national average.[2] Among those who survive a stroke, approximately 15-30% are permanently disabled.[1] Preventable medical complications of stroke such as deep vein thrombosis[3] and pulmonary complications resulting from dysphagia[4] can lead to poorer clinical outcomes in stroke patients. Several measures have been shown to improve outcomes in acute stroke patients,[5] but evidence-based recommendations for stroke care are not always followed in clinical practice.[6]

The Georgia Coverdell Acute Stroke Registry (GCASR) is funded by the Centers for Disease Control and Prevention (CDC) as part of the Paul Coverdell National Acute Stroke Registry.[7] GCASR seeks to reduce stroke case- fatality, disability due to stroke, and the incidence of recurrent stroke in Georgia by monitoring and improving the quality of acute stroke care in the hospital setting. GCASR was first established in 2001 as a prototype project ("pilot phase"), administered through Emory University, involving 46 hospitals in Georgia. Full implementation and incorporation into the Georgia Department of Human Resources, Division of Public Health began in 2005. A characteristic that distinguishes GCASR from some of the other large stroke care registries that have been previously reported in the literature,[8,9] is that it has actively sought to work with a representative sample of hospitals throughout the state, in order to facilitate delivery of high quality stroke care in all types of hospitals. This report reviews the trends in adherence with selected evidence-based stroke quality-of-care indicators among hospitals participating in GCASR during its first two years of full implementation, and examines the extent to which trends in adherence have differed in hospitals with different characteristics.

METHODS

Hospital selection and recruitment

Recruitment during the implementation phase was done in 2 stages. During the fall of 2005, invitations were sent to a representative sample (n=57) of hospitals that had been previously selected, from the 151 hospitals in Georgia with at least one admission for acute stroke during 2000, to participate in the earlier pilot phase.[6] Hospitals that had been in the sample for the pilot phase included 8 hospitals selected with certainty as the hospitals with the highest number of stroke admissions in the largest county, and 49 randomly selected among the remaining eligible hospitals. Further, hospitals not in the representative sample but that had volunteered to participate in the pilot registry were also included, for a total of 69 invited hospitals. Twenty-six hospitals responded and were enrolled starting in November 2005. Of these 19 were in the representative sample and 7 were volunteer hospitals. During the fall of 2006, hospitals in the representative sample that had not already enrolled were again invited to participate, and were actively encouraged to participate through phone calls with hospital quality improvement staff. Starting in October 2006, 25 additional hospitals were enrolled in the registry (20 selected and 5 volunteer). Two additional volunteer hospitals joined the registry during December 2006 and March 2007. Hospitals that joined the registry in November 2005 are considered cohort 1, and those joining in October 2006 or later are considered cohort 2. Of the 53 hospitals that participated in the registry, 45 entered patient data into the registry for discharges during the time period examined in the analysis (November 1, 2005 through October 31, 2007).

Data collection

Hospitals that participated in the registry were asked to enter data for all admitted patients with a clinical diagnosis of stroke or transient ischemic attack (TIA) into an on-line, secure data entry system (Outcome, Inc., Cambridge, MA). The data collection system is the same tool used by the American Heart Association/American Stroke Association's (AHA's) "Get With the Guidelines-Stroke" Program[10] with modifications to meet the specifications of the Paul Coverdell

National Acute Stroke Registry. The data collected included patient demographic and clinical characteristics; diagnostic procedures, treatments and counseling received while in the hospital and at discharge; and in-hospital outcomes. Data abstraction was done by hospital staff members who were trained in data abstraction for the registry at kick off workshops and through individual telephone training sessions. To protect patient confidentiality, the registry data did not include patient identifiers. The Emory University institutional review board (IRB) determined this study to be exempt from IRB review as a non-research activity, and Georgia Department of Human Resources IRB approved this study through its "Approval Without Detailed Review" process, which has criteria similar to criteria for IRB exemption under federal regulations.

Quality Improvement Activities

GCASR quality improvement interventions with individual hospitals during the implementation phase included data feedback to hospitals with benchmarking, individualized quality improvement consultations, monthly individualized telephone calls, site visits, and general availability of registry staff to help answer stroke quality improvement questions. Additional registry-wide interventions included monthly conference calls and newsletters, annual workshops in collaboration with AHA's "Get With the Guidelines" program, and general encouragement for hospitals to share stroke care quality improvement resources with each other.

Quality of Care Measures

During the implementation phase, the registry used 10 quality indicators, developed by CDC, to measure the quality of stroke care. The 10 indicators used during the first two years of the implementation phase included tissue plasminogen activator (t-PA) administration, dysphagia screening, antithrombotic administration within 48 hours, deep vein thrombosis (DVT) prophylaxis, lipid profile measurement, stroke education, smoking cessation advice and counseling, assessment of the need for rehabilitation, discharge with antithrombotic therapy, and anticoagulation for atrial fibrillation. Each indicator identified an intervention that had been previously shown to be effective in improving outcomes among stroke patients with relevant

characteristics ("eligible patients"). The adherence percentage for each indicator was calculated among eligible patients. Patients eligible for each intervention were identified based on the data elements entered into the registry database by hospital staff, forming the denominator for percentages calculated. Patients with contraindications for a measure that were documented in the medical record, or for whom eligibility could not be determined, were considered ineligible and were removed from the denominator for each measure. Patients for whom receipt of the intervention was documented in the medical record were considered to have received care meeting the quality indicator and were included in the numerator of the percentages. Hospitals had continuous on-line access to information about the adherence percentage for each indicator among the patients for whom they had entered data.

Hospital Characteristics

Data on the number of beds for each hospital and the type of hospital ownership were obtained from the Georgia Hospital Association's 2007 hospital directory. The type of ownership was categorized as private ownership versus not-for-profit or hospital association ownership. The number of stroke admissions during 2006 for each hospital was calculated using hospital discharge data from the Georgia Hospital Association, based on ICD-9 CM codes 430-438. The teaching status and census tract for each hospital was obtained from a Georgia hospital database maintained by the Georgia Division of Public Health, Office of Health Information and Policy. Categorization of each hospital as metropolitan or non-metropolitan was based on the 2000 Rural-Urban Commuting Ares (RUCA) Code[11] for the census tract in which the hospital was located, with RUCA Codes <4 categorized as metropolitan and RUCA codes ≥ 4 categorized as non-metropolitan. The area of the coastal plain in Georgia is the area of the state with the highest stroke mortality rates.[12] A hospital was classified as serving the coastal plain of Georgia if the county in which the hospital is located is primarily in the Sea Island or East Gulf Coastal Plain physiographic sections, based on a physiographic map of Georgia.[13]

Statistical Analysis

Data entered into the GCASR database by participating hospitals for stroke discharges during November 1, 2005 through October 31, 2007 were included in the analysis. Cases entered by hospitals with discharge dates prior to a hospital's GCASR start date, in-hospital stroke cases, entries for patients aged <19 years, cases with no clinical diagnosis related to stroke, and duplicate entries were excluded from the analysis.

To assess the degree to which hospitals that submitted data were representative of all hospitals in Georgia, characteristics of hospitals that submitted data were compared with characteristics of hospitals in Georgia that did not submit data but were eligible for the registry (defined as non-federal, acute care or critical access hospitals providing adult hospital care during 2007). Differences between groups were assessed using the chi-squared test for categorical variables and the Wilcoxon Rank sum test for continuous variables.

The analyses for this evaluation focused on four of the 10 registry quality indicators, including receipt of tPA, dysphagia screening, DVT prophylaxis, and smoking cessation counseling. These four indicators were chosen for detailed evaluation prior to the analyses because they represent various stages of stroke patient care, they did not have a very high level of adherence at baseline, and they included measures that had been the particular focus of registry quality improvement activities including conference calls with hospitals. The specific quality indicator calculations used in this evaluation were a modification of the initial quality indicator calculations developed by CDC for the Paul Coverdell National Acute Stroke Registry that were in use during the time period considered. In all analyses, adherence with a quality indicator was defined at the patient level as delivery of care meeting the indicator, considered among indicator-eligible patients only. Detailed descriptions of the definitions used to determine adherence for each of these four quality indicators are listed in Table 1. All analyses were conducted for each indicator separately.

To assess the impact of our quality improvement activities on stroke care processes, we used a three-stage analytic strategy. The first stage of the analysis consisted of descriptive analyses of the overall adherence percentage for each indicator. In the second stage of the analysis, logistic regression models were used to identify hospital characteristics that were associated with adherence among admissions that occurred during the first 6 months of a hospital's registry participation (baseline models). In the third stage of the analysis, conditional logistic regression models were used to quantify within-hospital trends over time in adherence by cohort, and to identify hospital characteristics that were associated with differing rates of change in adherence over time (trend models).

In the descriptive analyses, the overall adherence percentage for each indicator was calculated for each registry cohort by month and for the first and last six months of any hospital participation for each cohort. This descriptive analysis included all indicator eligible-patients without regard to the number of eligible patients per hospital, and aggregated patients across hospitals within cohorts.

Baseline models first assessed associations between adherence and each hospital characteristic alone among admissions that occurred during the first 6 months of a hospital's registry participation. These models were followed by multivariate models that included all of the considered hospital characteristics. Hospital characteristics considered included the hospital's registry cohort, registry selection status (selected or volunteer), number of beds (<median of 250 vs. ≥250), type of ownership (private versus not for profit or hospital association ownership), location in metropolitan or non-metropolitan area, teaching status, number of stroke admissions during 2006 (<median of 258 vs. ≥258), and location in or outside the coastal plain area. Because in these analyses patients are nested within hospitals, the baseline models accounted for clustering of patients within hospitals through inclusion of a random intercept for hospital in generalized linear mixed models. Baseline models included only hospitals with at least 10 admissions entered

for the relevant quality indicator over the time period under consideration in the analyses (November 1, 2005 through October 31, 2007).

In trend models, conditional logistic regression, conditioning on hospital, was used to assess the average within-hospital monthly change in adherence. The conditional logistic regression analysis accounts for clustering of patients by hospital, and controls for unmeasured hospital characteristics.[14] In these models, the primary interest was in the association between the patient's month of discharge and the odds of adherence. The month of discharge was considered as a continuous variable (1-24) to determine the average monthly change in the odds of adherence. Terms for interactions between month and hospital characteristics were used to estimate average monthly changes in adherence for separate groups by hospital characteristics, and to determine the statistical significance of differences in trends between groups. The initial trend models included a term for the interaction between discharge month and hospital cohort only, to assess overall trends in adherence for each cohort. Subsequent models considered interactions between discharge month and each of the hospital characteristics separately (characteristics defined as in the baseline models), to identify hospital characteristics that were individually associated with different rates of change in adherence. A multivariate model was then fit that included terms for all two-way interactions between hospital characteristics and discharge month. Finally, models were fit that included terms for the interaction between a hospital's baseline adherence level (in quartiles) and discharge month to determine whether, overall, hospitals with different baseline adherence levels had different rates of change in adherence. All trend models, like the baseline models, included only hospitals with at least 10 admissions entered for the relevant quality indicator over the time period under consideration in the analyses (November 1, 2005 through October 31, 2007).

All p-values are two sided. P-values less than 0.05 were considered statistically significant. All analyses were performed using SAS software version 9.2 (SAS Institute, Cary, NC).

RESULTS

Hospital Characteristics

The characteristics of the 45 hospitals with data are shown in Table 2. Twenty-four hospitals were in cohort 1 and 21 were in cohort 2. Eight of the hospitals with data were selected with certainty, 25 were randomly selected, and 12 were volunteer hospitals. Thirty of the hospitals had also participated in the pilot registry. A higher percentage of cohort 1 hospitals had participated in the pilot registry than cohort 2 hospitals (83% and 48% respectively, p=0.01). Although 36% of the hospitals were located in non-metropolitan areas, non-metropolitan hospitals were under-represented in the registry compared with other eligible hospitals in state (Table 1). Among hospitals with data, 51% had less than 250 beds, compared with 89% of other hospitals in the state (p<0.01). The number of 2006 stroke admissions was <258 for 51% of hospitals with data, compared with 91% of other hospitals in the state (p<0.01). Hospitals that submitted data included 15 of the 18 Joint Commission Certified Primary Stroke Centers in Georgia during 2007, with a higher percentage of cohort 1 hospitals being primary stroke centers than cohort 2 hospitals (50% vs. 14%, p=0.01). Hospitals submitting data did not significantly differ from other registry-eligible hospitals in location relative to the coastal plain, type of ownership, and teaching status.

Patient Characteristics

The final patient-level data set included 12,690 stroke admissions. The number of patients entered per hospital ranged from 1 to 1136, with a median of 178. Among the admissions with data, 53% were for females. Fifteen percent of admissions were for patients aged <50 years, 41% for patients aged 50 years - 69 years, and 44% were for patients aged 70 years or older; 59% were for patients of white race, 36% were for patients of black race, 2% were for patients of other race, and 3% were for patients of unknown race. The health insurance status was Medicare only for 43% of admissions, other insurance only for 31%, Medicare and other insurance for 12%, and no insurance or not documented for 14%. The final hospital diagnosis

related to stroke was ischemic stroke (alone or with TIA) for 61% of the admissions, transient ischemic attack for 18%, intracerebral hemorrhage (alone or with TIA or subarachnoid hemorrhage) for 14%, subarachnoid hemorrhage alone for 6%, stroke not otherwise specified for 1%, hemorrhagic stroke not otherwise specified for 0.5%, and ischemic and hemorrhagic stroke for 0.3%. Documented previous medical history included hypertension for 74% of admissions, diabetes mellitus for 30%, dyslipidemia for 29%, previous stroke for TIA for 28%, myocardial infarction for 22%, smoking for 20% and atrial fibrillation for 12%. The discharge destination was discharge to home (with or without home health services) for 55% of admissions, transfer to another institution (hospital, rehabilitation facility, or long term care facility) for 33%, hospice (home or in a medical facility) for 3%, and left against medical advice or missing for 1%; 8% died during the admission.

Descriptive Analyses of Overall Adherence

Graphs of overall trends in the adherence percentage for the four quality indicators considered are shown in Figure 1 by hospital cohort. The overall adherence percentage among admissions during the first 6 months of any participation for cohort 1 (November 2005-April 2006), the first 6 months of any participation for cohort 2 (October 2006-March 2007), and the last 6 months of the time period considered (May 2007-October 2007) are shown, by cohort, in Table 3. Cohort 2 hospitals started at a lower level of adherence than cohort 1 for all of the indicators except smoking cessation counseling. The graphs and percentages by time period show overall improvement in all four indicators in both cohorts, except possibly smoking cessation in cohort 2, which started at a relatively high baseline adherence level. The improvement appeared particularly rapid for dysphagia screening during the few months after the start of participation for cohort 2.

Comparison of Baseline Adherence Levels by Hospital Characteristics

The results of the assessment of associations between baseline adherence and hospital characteristics are shown in Table 4. The odds ratios presented compare the odds of adherence

for admissions at hospitals with the listed characteristic with the odds of adherence for admissions at hospitals without the listed characteristics. Because the number of beds and the number of stroke admissions were highly correlated, and the number of stroke admissions was felt to be the most relevant measure of hospital volume, all multivariate baseline models included only the number of stroke admissions and not the number of beds. For tPA administration, it was not possible to include the hospital's metropolitan/non-metropolitan status in baseline models due to very few t-PA eligible patients being entered by non-metropolitan hospitals.

For tPA administration, a significantly higher odds of baseline adherence was seen for admissions to cohort 1 hospitals compared with cohort 2 hospitals. For dysphagia screening, a higher baseline odds of adherence was seen in the multivariate model for admissions at cohort 1 hospitals compared with cohort 2 hospitals, at hospitals with a high number of stroke admissions compared with hospitals with fewer stroke admissions, and at hospitals in the coastal plain compared with hospitals not in the coastal plain. For DVT prophylaxis and smoking cessation, none of the hospitals characteristics were significantly associated with baseline adherence in the multivariate models.

Trends in quality indicators

The results of models of trends in adherence over time by single hospital characteristics are shown in table 5. The odds ratios compare the odds of quality indicator adherence in a given month compared with the previous month, on average. As for the baseline models, it was not possible to include the hospital's metropolitan/non-metropolitan status in trend models for t-PA. For all four quality indicators, conditional logistic regression models with a term for the interaction between cohort and month showed general within-hospital improvement in adherence over time in both cohorts, with odds ratios for the monthly change in adherence ranging from 1.01 to 1.08. This improvement was statistically significant for dysphagia screening in both cohorts, and for DVT prophylaxis and smoking cessation in cohort 1.

When models comparing trends over time by other hospital characteristics were considered individually, there were no significant interactions between hospital characteristics and change in adherence over time for t-PA administration or DVT prophylaxis. In single interaction models for dysphagia screening, the rate of improvement in adherence was significantly higher among selected hospitals than among volunteer hospitals, among hospitals with fewer beds compared with larger hospitals, and among hospitals with not-for-profit or hospital association ownership compared with privately owned hospitals. In single interaction models for smoking cessation counseling, the rate of improvement in adherence was significantly higher among hospitals with not-for-profit or hospital association ownership compared with privately owned hospitals, and among teaching hospitals compared with non-teaching hospitals.

The results of models for within-hospital trends in quality indicator adherence that simultaneously included two way interaction terms between month and all of the hospital characteristics except the number of beds are shown in Figure 2. As for the baseline models, multivariate trend models included only the number of stroke admissions and not the number of beds. In the multiple interaction models, hospitals with a number of stroke admissions below the median had a higher rate of improvement than those with a higher number of stroke admissions for all four quality indicators, although this difference was statistically significant only for the dysphagia screening and DVT prophylaxis quality indicators. Metropolitan hospitals also had a higher rate of improvement than non-metropolitan hospitals for the three indicators for which this could be assessed, with this difference being statistically significant for the dysphagia screening and DVT prophylaxis quality indicators. Hospitals with not for profit or hospital association ownership had a significantly higher rate of improvement than privately owned hospitals for dysphagia screening and smoking cessation. For dysphagia screening selected hospitals had a significantly higher rate of improvement than volunteer hospitals, and teaching hospitals had a significantly higher rate of improvement than non-teaching hospitals.

The results of models that included terms for the interaction between a hospital's baseline adherence level, considered in quartiles, and month are shown in Figure 3. These models showed that the rate of improvement was inversely related to the baseline adherence level for t-PA administration and DVT prophylaxis, with hospitals with the lowest baseline adherence levels having the greatest rate of improvement in adherence. For t-PA administration and DVT prophylaxis, statistically significant improvement in adherence was seen among hospitals in the lowest quartile of baseline adherence, but not among hospitals with higher levels of baseline adherence. The inverse relationship between baseline adherence and rate of improvement was not seen as clearly for dysphagia screening or smoking cessation counseling.

DISCUSSION

There was evidence of overall improvement in adherence with all four quality indicators in both cohorts over the time period examined. The improvement was statistically significant for dysphagia screening in both cohorts, and for DVT prophylaxis and smoking cessation in cohort 1. The significant increase in DVT prophylaxis among cohort 1 hospitals may reflect the fact that hospitals were asked to particularly focus on DVT prophylaxis during the time period under consideration.

Although odds ratios for the monthly within-hospital change in adherence were generally low in magnitude (1.01-1.08), the observed rate of improvement can result in substantial improvements in adherence over time. For example, the monthly odds ratio of 1.04 for dysphagia screening in cohort 2 is equivalent to an odds ratio over a 6 month period of approximately 1.27, indicating a 27% increase in the odds of adherence over a 6-month period. Given a baseline adherence percentage of 33.9%, this would result in 39.4% adherence after 6 months, a 5.5 percentage point increase in adherence over a 6 month period. Among patients for whom data was entered into the registry, 72% were eligible for the dysphagia screening indicator. If this is representative of all 2006 stroke admissions at registry-eligible hospitals in Georgia, 16,619

stroke patients at these hospitals during 2006 would have needed dysphagia screening. On a state-wide level, an increase in adherence of 5.5 percentage points, if sustained over the period of a year, would mean that an additional 914 patients would receive the needed screening. The rates of improvement for the four indicators are overall comparable to or higher than the overall rate of improvement reported by Schwamm et al for the American Heart Association's nation-wide Get with the Guidelines Program,[8] although the results from that study are somewhat different because that study did not focus on within-hospital changes.

Cohort 2 hospitals joined the implementation phase registry with lower baseline adherence levels than cohort 1 hospitals for all four indicators, despite the fact that they joined the registry later in calendar time. This may reflect the fact that a higher percentage of cohort 1 hospitals had participated in the pilot registry and a higher percentage of cohort 1 hospitals were Joint Commission certified primary stroke centers. It is not possible to determine how those two factors and other factors may have interacted to lead to higher baseline performance among cohort 1 hospitals.

When the multivariate baseline and trend models are considered together, several patterns emerge. In many cases, groups of hospitals by various hospital characteristics that had lower baseline performance had higher rates of improvement, but this was not consistently observed. When the relationship between baseline adherence and rate of change in adherence was assessed apart from other hospital characteristics, an inverse relationship between baseline adherence and rate of change in adherence was observed for t-PA administration and DVT prophylaxis, but not as clearly for dysphagia screening and smoking cessation counseling.

Hospitals with a lower number of stroke admissions had a lower baseline adherence level and a higher rate of improvement for all four indicators. In multivariate models, the lower baseline level was statistically significant for the dysphagia indicator, and the higher rate of improvement was statistically significant for the dysphagia and DVT indicators. This may indicate that this group of hospitals can particularly benefit from the registry, and continued

efforts should be made to recruit additional hospitals with a low number of stroke admissions. Hospitals with a lower number of stroke admissions are significantly underrepresented among registry hospitals. During 2006, 78.9% of all hospitals in the state that were potentially eligible for the registry had less than 258 admissions; these hospitals admitted more than 7,700 stroke patients during 2006, accounting for 33.7% of all stroke admissions in Georgia. In addition, 53% of the hospitals with a lower number of stroke admissions are located in the coastal plain, the area of the state with the highest stroke mortality rates; and hospitals with a lower number of stroke admissions in the coastal plain account for 15% of stroke admissions in the state. Therefore, hospitals with a lower number of stroke admissions account for a substantial number of stroke patients each year. Transfer of acute stroke patients to higher volume hospitals may not always be feasible. Of the hospitals with <258 stroke admissions during 2006, 71% are located outside of metropolitan areas, with lower volume hospitals in rural areas accounting for >4,300 stroke admissions during 2006 (19% of the stroke admissions in the state). A long distance to a larger volume hospital can make transfer before treatment infeasible for administration of tPA, which must be given within 3 hours of stroke onset. Therefore, the quality of stroke care at lower volume hospitals is of public health importance in Georgia.

After controlling for other characteristics, non-metropolitan hospitals had a lower rate of improvement for all three indicators for which this characteristic could be assessed, with the lower rate of improvement being statistically significant for the dysphagia and DVT quality indicators. These hospitals also had a lower baseline adherence level for two of the three indicators (dysphagia screening and smoking cessation) although these differences were not statistically significant. Similarly, the rate of improvement was lower for hospitals with private ownership for three of the four indicators, with the lower rate statistically significant for dysphagia screening and smoking cessation, despite the fact that these hospitals also had lower rates of baseline adherence for dysphagia screening and smoking cessation (not statistically significant). These patterns may indicate that registry quality improvement initiatives have been

less successful in reaching non-metropolitan and privately owned hospitals. Exploring ways of more effectively tailoring registry interventions to the needs of these hospitals may help to increase the impact of the registry.

By design, the models used in these analyses did not control for patient characteristics. Quality indicator definitions take relevant patient characteristics into account to identify eligible patients, and given quality indicator qualification, adherence should ideally not vary by other patient characteristics. In addition, any impact of differences in patient mix on trend analyses was minimized through use of within-hospital comparisons in conditional logistic regression models. The use of conditional logistic regression was not possible in baseline models, which did not have within-hospital variation in the characteristics in the baseline models.

Several previous studies have also found improvements in stroke care processes during hospital participation in stroke registries or stroke quality-of-care improvement programs.[8,9,15,16,17,18,19,20,21] Several of the previous studies differed from this study in that they focused on evaluation of time-limited quality improvement initiatives using a pre-intervention/post-intervention study design,[15,17,18,19,20,21] and many used centralized medical chart abstraction during only selected time periods rather than ongoing hospital-based data collection.[15,16,17,19] Two previous studies reported on registries that were similar in overall design to this study. Hills and Johnston reported significant improvement in three stroke care quality indicators associated with duration of registry participation in a web-based acute stroke registry with continuous hospital-based data collection, data feedback, and benchmarking.[9] Schwamm et al reported significant improvement in seven pre-specified stroke quality of care performance measures associated with hospital participation in the AHA's Get With the Guidelines (GWTG) registry, which includes ongoing data collection, data feedback with benchmarking, and ongoing quality improvement initiatives to help hospitals improve stroke care quality.[8] However, GCASR is unique in that the two previous registries with ongoing data collection did not seek to recruit a representative sample of hospitals. In addition, both previous studies required a fee for hospital participation,

while GCASR paid the costs of the data collection tool for hospitals that were selected for the registry to encourage participation by a broad range of hospitals.

Although the goal of having GCASR-participating hospitals be representative of hospitals in the state was not completely achieved, as hospitals from non-metropolitan areas and smaller hospitals with fewer stroke admissions were under-represented, GCASR has included a substantial number of smaller hospitals and hospitals from non-metropolitan areas. Representation of non-metropolitan hospitals and smaller hospitals with fewer stroke admissions was expanded with the more active recruitment of hospitals used in the second recruitment phase. These efforts resulted in higher representation of smaller, non-academic hospitals than was seen in the previously reported registries. The hospitals participating in GCASR also participate in the GWTG registry because GCASR data collection is done through the tool used by the GWTG registry. However, 84% of GCASR hospitals with data were non-academic compared with 48% of the overall population of hospitals participating in the GWTG program as reported by Schwamm et al; and the median number of beds for GCASR hospitals was 248 (25^{th}-75^{th} percentile 53-413) compared with a median of 300 beds (25^{th}-75^{th} percentile 195-441) among GWTG hospitals overall.[8] The hospitals participating in the registry reported by Hills and Johnston were predominantly non-rural, and half were academic hospitals.[9] Among GCASR hospitals with data, 36% were in non-metropolitan areas. Inclusion of non-metropolitan hospitals in stroke quality improvement efforts is particularly important in Georgia, where stroke mortality and hospitalization rates are highest in rural areas.[22]

The differences between the populations of hospitals participating in GCASR and the nationwide GWTG program are accompanied by differences in the types of hospitals with the highest rates of improvement in quality indicator adherence. Schwamm et al reported greatest improvement among academic hospitals, hospitals with the highest number of beds, and hospitals with the highest number of annual stroke admissions.[8] In contrast, we found higher rates of

improvement for hospitals with a lower number of stroke admissions, which also tended to have a lower baseline adherence level.

This study had several limitations. First, there were potential limitations in the quality of registry data. Although the quality of the patient-level data entered by hospitals was monitored for a sample of cases in the registry and was found to be adequate, the data were used as they were entered by the hospitals without verification the information for each patient. In addition, registry data did not allow identification of repeat admissions for the same patient. In this analysis, each admission was considered separately, although it is possible that some patients may have had more than one admission in the data set.

There were also limitations in the completeness of registry data. During April 2007 through October 2007, 10 selected hospitals discontinued registry participation, including 5 that had entered data for discharges during the time period included in the analysis. In addition, not all hospitals entered data for all eligible patients during the time period under consideration. The impact of these factors on the analysis was minimized through consideration of within-hospital trends in adherence through conditional logistic regression models. Consideration of within-hospital changes ensures that observed changes in adherence are not due to changes in the population of participating hospitals. However, the analysis could be impacted by any systematic differences within hospitals between entered cases and cases that were not entered, and by systematic differences between hospitals that discontinued participation and those that did not.

There are also limitations in the conclusions that can be drawn based on these analyses. While the indication of overall within-hospital improvement in temporal association with registry participation is encouraging, it is not possible to separate registry effects from temporal trends due to other influences. Results relating to baseline and trend associations with hospital characteristics should be interpreted as being descriptive of the experience of hospitals in GCASR, and not as being representative of a wider group of hospitals. There were important differences between participating hospitals and non-participating hospitals, and some categories

in the multivariate analyses were represented by few hospitals. In addition, in the trend models, the number of hospitals in the analysis did not allow consideration of interactions involving more than two terms. Finally, although the level of significance of the interaction terms is instructive in identifying groups with significantly different rates of improvement, the specific odds ratio estimates are dependent on the choice of the reference group. In this case, the group with the highest number of entered admissions was chosen as the reference group.

Despite these limitations, this study has some important implications for public health practice. Evidence of improvement in stroke care processes among hospitals participating in GCASR suggests that GCASR has been successful in its mission of contributing to improvement in the quality of acute stroke care in Georgia. In addition, this study identified some future directions for the registry including the importance of continued efforts to recruit smaller hospitals with fewer stroke admissions, and the need for exploration of ways of more effectively addressing the stroke care quality improvement needs of non-metropolitan and privately owned hospitals in particular. Some of these results have already been used in discussions of future registry recruitment strategies. In addition, although some of the examined indicators, such as smoking cessation counseling, have achieved a high overall level of adherence, others, such as tPA administration have not. Therefore, there is the potential for further improvements in the quality of care overall in relation to some indicators, in addition to the potential for addressing variability in quality of care by hospital characteristics. Further studies to determine whether the observed care-process improvements have led to improvements in stroke patient outcomes, and to identify the effectiveness of particular registry quality improvement efforts, would be helpful to more completely evaluate the success of the registry and to guide future registry activities.

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Table 1. Quality Indicator Definitions

Indicator	Indicator -eligible patients (Denominator)	Patients receiving care meeting the indicator (Numerator)
Dysphagia Screening	-Any stroke type except TIA (includes ischemic stroke of uncertain type, ischemic stroke, subarachnoid hemorrhage, intracerebral hemorrhage, hemorrhagic stroke not otherwise specified, or stroke not otherwise specified). AND -Not NPO for entire hospital stay.	-Received dysphagia screening prior to any oral intake.
Smoking Cessation	-Any stroke type (as defined for dysphagia screening plus TIA). AND -Discharge destination **not**: transferred to another short term general hospital for inpatient care, left against medical advice or discontinued care, expired, expired in medical facility (such as hospital, SNF, ICF or freestanding hospice), hospice-home, hospice- medical facility, or missing. AND -Medical history of smoking, defined as smoking at least one cigarette in past year.	-Received counseling to stop smoking, smoking cessation advice, or smoking cessation therapy.
DVT Prophylaxis	-Any stroke type (as defined for smoking cessation). AND -Admitted for more than 2 days. AND -Not documented to be ambulating within 48 hours (documented not to be ambulating within 48 hours, ambulation status recorded as “not documented”, or ambulation question blank).	-DVT prophylaxis started within 48 hours after arrival. Acceptable prophylaxis included heparin (including low dose, subcutaneous heparin), low molecular weight heparin, a trial-based antithrombin agent, warfarin (or other agent with similar action), and pneumatic compression stockings. TED hose alone did not meet the criteria.

Table 1 (continued)

Indicator	Indicator -eligible patients (Denominator)	Patients receiving care meeting the indicator (Numerator)
tPA	-Ischemic stroke of uncertain type or ischemic stroke and **NOT** a diagnosis of subarachnoid hemorrhage, intracerebral hemorrhage, or hemorrhagic stroke not otherwise specified. AND -Time from onset to hospital arrival is not missing, and is > 0 and ≤2 hrs. AND -The patient did not receive tPA at a transferring hospital, was not on a thrombolytic investigational protocol, and did not receive another type of intervention within 3 hours after onset. Other interventions include intra-arterial clot removal, intra-arterial thrombolytic, or a thrombolytic for which the type was not specified. AND -No documented valid contraindication checked. (NONE of the following: uncontrolled hypertension; rapid improvement; CT findings contraindicating tPA; severity too mild or too severe; seizure at onset; recent surgery/trauma; recent IC surgery (3 mo.), head trauma, or stroke; patient or family refused; consent not obtainable; history of intracranial hemorrhage, brain aneurysm, vascular malformation, or brain tumor; age; active internal bleeding (<22 days); platelet count <100,000, abnormal PT or aPTT; glucose <50 mg/dl or >400 mg/dl; no IV access; life expectancy less than 1 year or severe co morbid illness; investigative therapy for acute ischemic stroke). AND -No other written-in contraindication related to the patients clinical condition. (Reasons for not giving tPA related only to hospital processes were not considered valid contraindications.)	-Patient received IV tPA within 3 hours of onset.

Table 2. Hospital Characteristics among hospitals submitting data to the Georgia Coverdell Acute Stroke Registry for patients discharged during November 2005 through October 2007

	Hospitals with data (n=45)		Other eligible hospitals in Georgia in 2007 (n=102)		
Characteristic	**#**	**%**	**#**	**%**	**p-value**
Cohort					
Started on 11/1/05 (cohort 1)	24	53			
Started on or after 10/1/06 (cohort 2)	21	47			
In Phase I Sample with certainty					
Yes	8	18	0	0	
No	37	82	102	100	
In Phase I Sample randomly (among those not selected with certainty)					
Yes	25	68	22	22	<0.0001
No	12	32	80	78	
Pilot Participant					
Yes	30	67	16	16	<0.0001
No	15	33	86	84	
Primary RUCA code (1 missing)					
Metropolitan (RUCA codes 1 and 2)	29	64	34	34	0.0005
Non-Metropolitan (RUCA codes 4,7,9,10	16	36	67	66	
Coastal Plain					
Yes	19	42	54	53	0.2325
No	26	58	48	47	
Type of Ownership (7 missing)					
Not for Profit or Hospital Association	37	82	74	78	0.5566
Private	8	18	21	22	
Teaching Hospital					
Yes	7	16	7	7	0.0991
No/Unknown	38	84	95	93	
Joint Commission Certified Primary Stroke Center during 2007					
Yes	15	33	3	3	<0.0001
No	30	67	99	97	
Number of beds					
<250	23	51	91	89	<0.0001
≥250	22	49	11	11	
Number of 2006 Stroke Admissions					
<258	23	51	93	91	<0.0001
≥258	22	49	9	9	

Note: two hospitals in the original sample were not among eligible hospitals in 2007.

Table 3. Overall Quality Indicator Adherence Percentage among all indicator-eligible admissions during first 6 months of GCASR participation for cohorts 1 and 2, and during last 6 months of time period considered

	November 2005-April 2006			October 2006-March 2007			May 2007-October 2007		
	Numerator	Denominator	%	Numerator	Denominator	%	Numerator	Denominator	%
tPA									
Cohort 1	51	123	41.5	53	141	37.6	58	118	49.2
Cohort 2				15	83	18.1	14	62	22.6
Dysphagia Screening									
Cohort 1	1156	1716	67.4	1294	1923	67.3	1231	1620	76.0
Cohort 2				297	877	33.9	356	822	43.3
DVT Prophylaxis									
Cohort 1	1115	1291	86.4	1309	1453	90.1	1048	1157	90.6
Cohort 2				537	683	78.6	503	578	87.0
Smoking Cessation									
Cohort 1	315	433	72.7	415	498	83.3	402	440	91.4
Cohort 2				169	197	85.8	209	252	82.9

Table 4. Associations between hospital characteristics and quality indicator adherence at baseline (first 6 months of a hospital's registry participation), Georgia Coverdell Acute Stroke Registry, generalized linear mixed models with a random effect for hospital

	Single Characteristic Models			Multivariate Model		
	OR	**95% CI**	**p**	**OR**	**95% CI**	**p**
tPA administration (n=619; 22 hospitals)						
Cohort 2	0.29	0.12-0.69	**0.005**	0.21	0.09-0.47	**<0.001**
Volunteer	0.77	0.28-2.13	0.606	0.52	0.24-1.12	0.095
Less than 250 beds	1.03	0.27-3.87	0.971			
Private Ownership	1.75	0.45-6.77	0.417	1.9	0.64-5.61	0.244
Teaching Hospital	0.90	0.32-2.54	0.843	0.95	0.36-2.52	0.909
Stroke Admissions below median	0.55	0.05-6.02	0.626	0.23	0.02-2.94	0.254
Located in Coastal Plain	0.66	0.15-2.98	0.584	0.66	0.18-2.45	0.535
Dysphagia Screening (n=9118; 36 hospitals)						
Cohort 2	0.24	0.10-0.61	**0.003**	0.23	0.10-0.49	**<0.001**
Volunteer	1.14	0.42-3.12	0.797	1.43	0.56-3.62	0.454
Less than 250 beds	0.16	0.06-0.39	**<0.001**			
Private Ownership	0.97	0.29-3.29	0.958	0.72	0.25-2.03	0.530
Non-Metropolitan	0.15	0.05-0.49	**0.002**	0.40	0.07-2.28	0.301
Teaching Hospital	1.61	0.43-5.97	0.478	0.55	0.19-1.61	0.277
Stroke Admissions below median	0.19	0.07-0.54	**0.002**	0.24	0.11-0.54	**<0.001**
Located in Coastal Plain	1.83	0.41-8.15	0.431	3.29	1.16-9.34	**0.025**
DVT Prophylaxis (n=6740; 35 hospitals)						
Cohort 2	0.91	0.39-2.13	0.833	0.71	0.32-1.60	0.411
Volunteer	1.65	0.62-4.36	0.314	1.57	0.66-3.72	0.307
Less than 250 beds	0.94	0.33-2.69	0.909			
Private Ownership	1.23	0.28-4.51	0.871	1.39	0.44-4.33	0.574
Non-Metropolitan	0.41	0.13-1.27	0.122	1.49	0.27-8.29	0.650
Teaching Hospital	2.26	0.89-5.77	0.087	1.82	0.77-4.31	0.173
Stroke Admissions below median	0.36	0.15-0.88	**0.024**	0.36	0.09-1.36	0.131
Located in Coastal Plain	0.70	0.30-1.66	0.421	0.68	0.30-1.57	0.371
Smoking Cessation (n=2276; 29 hospitals)						
Cohort 2	0.92	0.31-2.73	0.867	0.85	0.31-2.35	0.750
Volunteer	0.51	0.15-1.72	0.275	0.49	0.15-1.55	0.222
Less than 250 beds	0.99	0.35-2.80	0.984			
Private Ownership	0.37	0.15-0.93	**0.034**	0.36	0.10-1.25	0.107
Non-Metropolitan	1.18	0.51-2.74	0.696	0.64	0.12-3.47	0.606
Teaching Hospital	0.64	0.23-1.78	0.395	0.44	0.15-1.23	0.118
Stroke Admissions below median	0.73	0.25-2.09	0.555	0.73	0.19-2.78	0.643
Located in Coastal Plain	1.46	0.65-3.27	0.364	1.63	0.65-4.10	0.299

*Metropolitan/Non-metropolitan status could not be included in t-PA models due to small numbers of tPA eligible patients at non-metropolitan hospitals.

Table 5. Within-hospital trends in quality indicator adherence by hospital characteristics, Georgia Coverdell Acute Stroke Registry, November 2005 through October 2007, single interaction conditional logistic regression models, conditioning on hospital

t-PA	OR for 1 month change	95% CI
Cohort 1	**1.01**	**0.98-1.04**
Cohort 2	**1.07**	**0.94-1.21**
Selected	1.01	0.98-1.05
Volunteer	1.01	0.97-1.06
≥250 beds	1.01	0.98-1.04
Less than 250 beds	1.04	0.97-1.12
Not Private	1.01	0.98-1.05
Private Ownership	1.00	0.94-1.07
Metropolitan	NA	
Non-Metropolitan	NA	
Non-Teaching	1.01	0.98-1.05
Teaching Hospital	1.02	0.96-1.07
Stroke Admissions at or above median	1.01	0.98-1.04
Stroke Admissions below median	1.09	0.98-1.21
Not coastal Plain	1.02	0.99-1.05
Located in Coastal Plain	0.98	0.92-1.06

Dysphagia Screening	OR for 1 month change	95% CI
Cohort 1	**1.02**	**1.01-1.03**
Cohort 2	**1.04**	**1.01-1.08**
Selected *	1.04	1.03-1.05
Volunteer*	1.00	0.98-1.01
≥250 beds*	1.02	1.01-1.03
Less than 250 beds*	1.06	1.04-1.08
Not Private*	1.03	1.02-1.04
Private Ownership*	1.00	0.99-1.02
Metropolitan	1.03	1.02-1.03
Non-Metropolitan	1.01	0.96-1.06
Non-Teaching	1.02	1.01-1.03
Teaching Hospital	1.04	1.02-1.05
Stroke Admissions at or above median	1.02	1.01-1.03
Stroke Admissions below median	1.04	1.02-1.07
Not coastal Plain	1.02	1.01-1.03
Located in Coastal Plain	1.03	1.00-1.06

*Indicates $p<0.05$ for term for interaction between hospital characteristic and month (statistically significant difference in trends between groups) in single interaction models

Table 5 (continued)

DVT Prophylaxis	OR for 1 month change	95% CI
Cohort 1	**1.01**	**1.01-1.03**
Cohort 2	**1.03**	**1.00-1.08**
Selected	1.02	1.01-1.04
Volunteer	1.02	1.00-1.05
≥250 beds	1.02	1.01-1.04
Less than 250 beds	1.00	0.97-1.04
Not Private	1.02	1.00-1.03
Private Ownership	1.03	1.00-1.07
Metropolitan	1.02	1.01-1.04
Non-Metropolitan	0.98	0.93-1.03
Non-Teaching	1.03	1.01-1.04
Teaching Hospital	1.00	0.98-1.03
Stroke Admissions at or above median	1.02	1.00-1.03
Stroke Admissions below median	1.04	1.01-1.08
Not coastal Plain	1.02	1.01-1.04
Located in Coastal Plain	1.02	0.99-1.04

Smoking Cessation	OR for 1 month change	95% CI
Cohort 1	**1.08**	**1.05-1.10**
Cohort 2	**1.03**	**0.96-1.12**
Selected	1.07	1.04-1.10
Volunteer	1.08	1.04-1.12
≥250 beds	1.07	1.04-1.10
Less than 250 beds	1.08	1.02-1.15
Not Private *	1.09	1.07-1.12
Private Ownership*	1.02	0.98-1.06
Metropolitan	1.07	1.05-1.10
Non-Metropolitan	1.02	0.91-1.15
Non-Teaching *	1.05	1.01-1.08
Teaching Hospital*	1.09	1.06-1.12
Stroke Admissions at or above median	1.08	1.05-1.02
Stroke Admissions below median	1.03	0.97-1.09
Not coastal Plain	1.07	1.05-1.10
Located in Coastal Plain	1.07	1.03-1.12

*Indicates $p<0.05$ for term for interaction between hospital characteristic and month (statistically significant difference in trends between groups) in single interaction models

Figure 1. Trends in quality indicator adherence over time by hospital cohort, among all entered indicator-eligible admissions, Georgia Coverdell Acute Stroke Registry, November 2005 through October 2007

Cohort 2 hospitals started registry participation in November 2006.

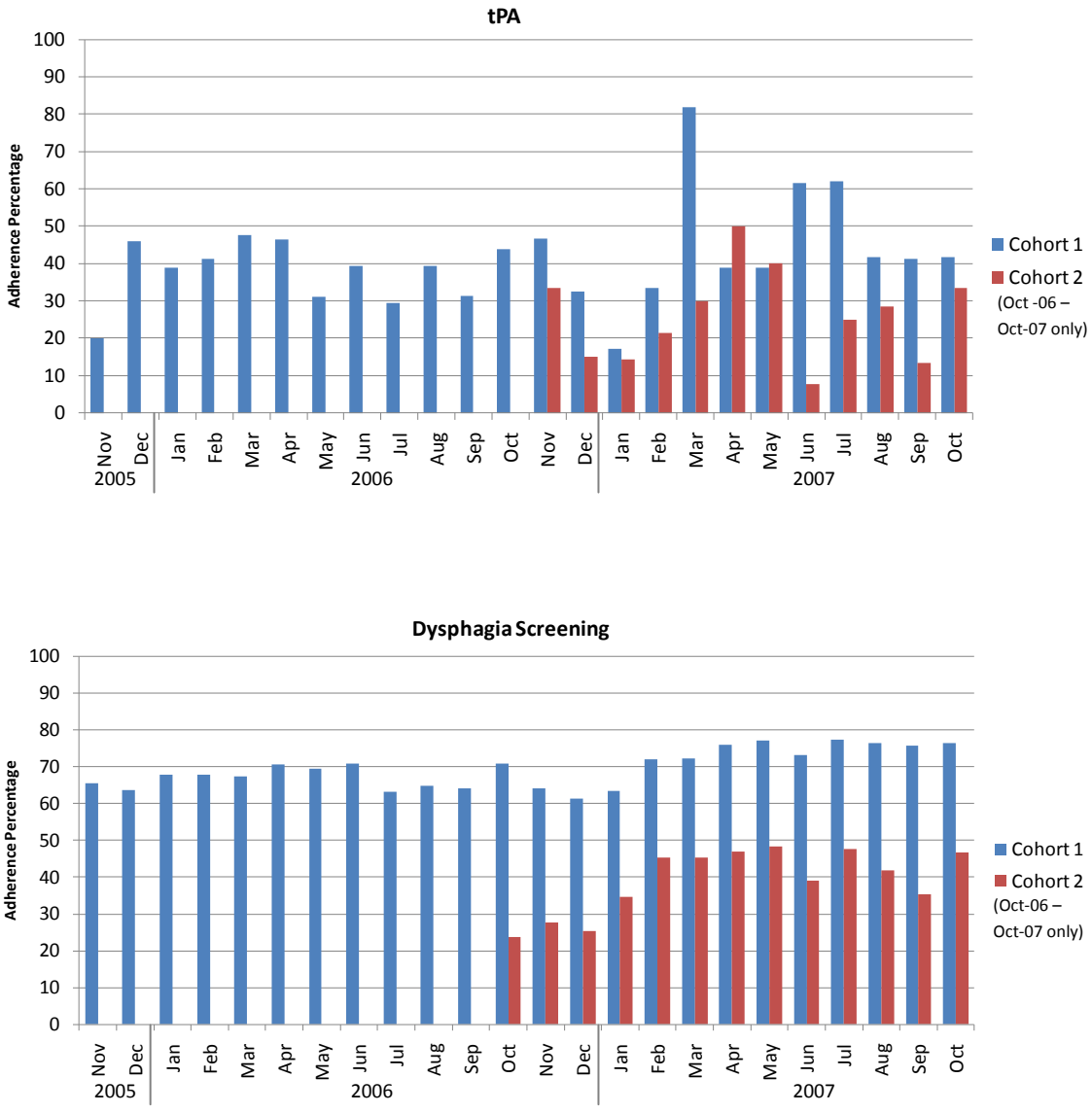
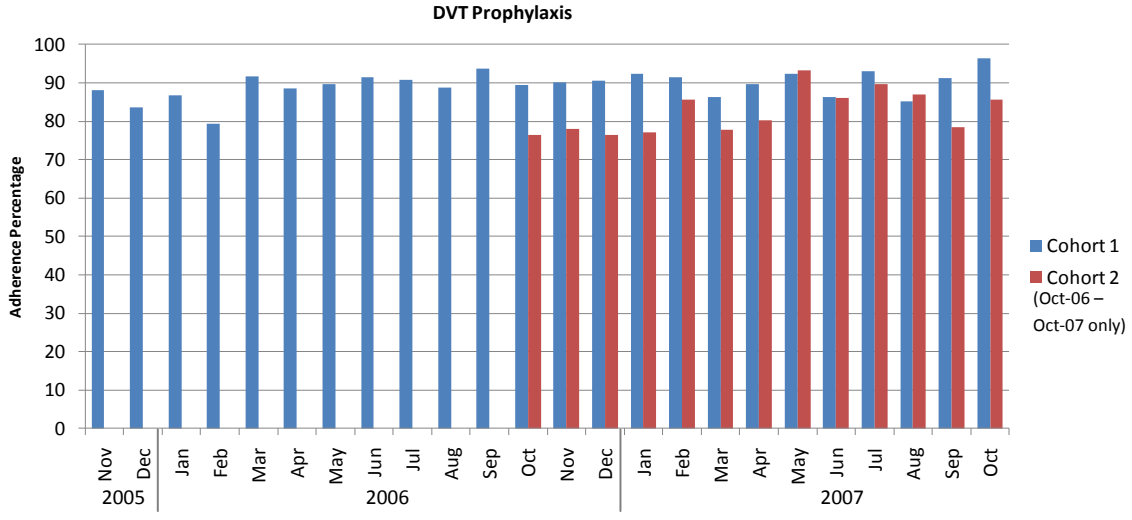


Figure 1 (continued)



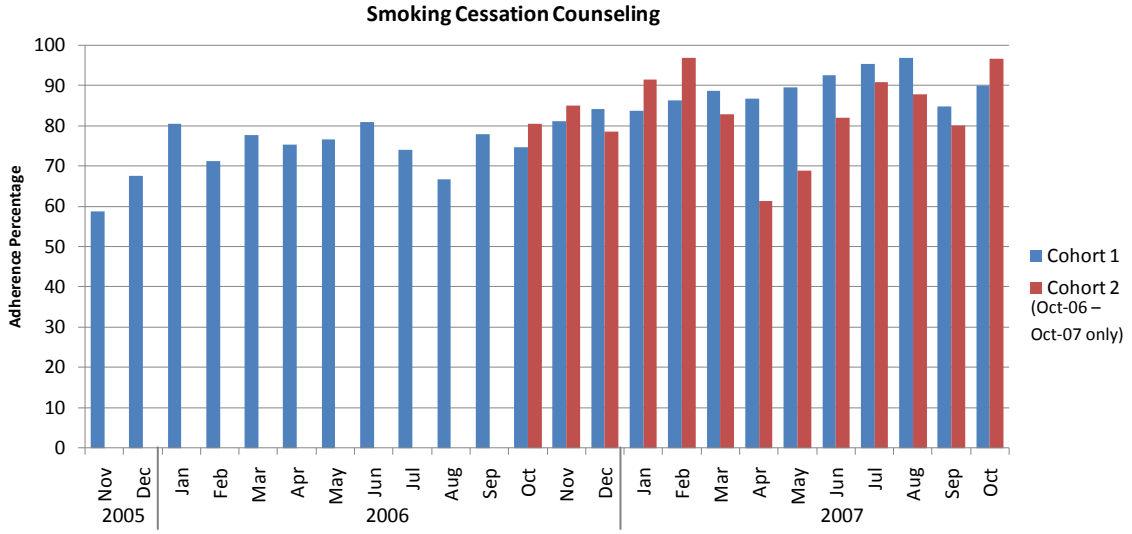


Figure 2. Within-hospital trends in quality indicator adherence by hospital characteristics, Georgia Coverdell Acute Stroke Registry, November 2005 through October 2007, multiple interaction conditional logistic regression trend models, conditioning on hospital

The odds ratios compare the odds of quality indicator adherence in month x compared with month x-1. The reference category consisted of hospitals in the group with the highest number of entered admissions (cohort 1, selected, not for profit or hospital association owned, metropolitan, non-teaching, high stroke admissions, not located in the coastal plain). Categories marked with an asterisk show hospital characteristics for which the p-value for the term for the interaction between month and the hospital characteristic was <0.05, indicating significantly different odds ratios for month among hospitals with the listed characteristic (other characteristics as in the reference group) compared with hospitals with all of the reference characteristics.

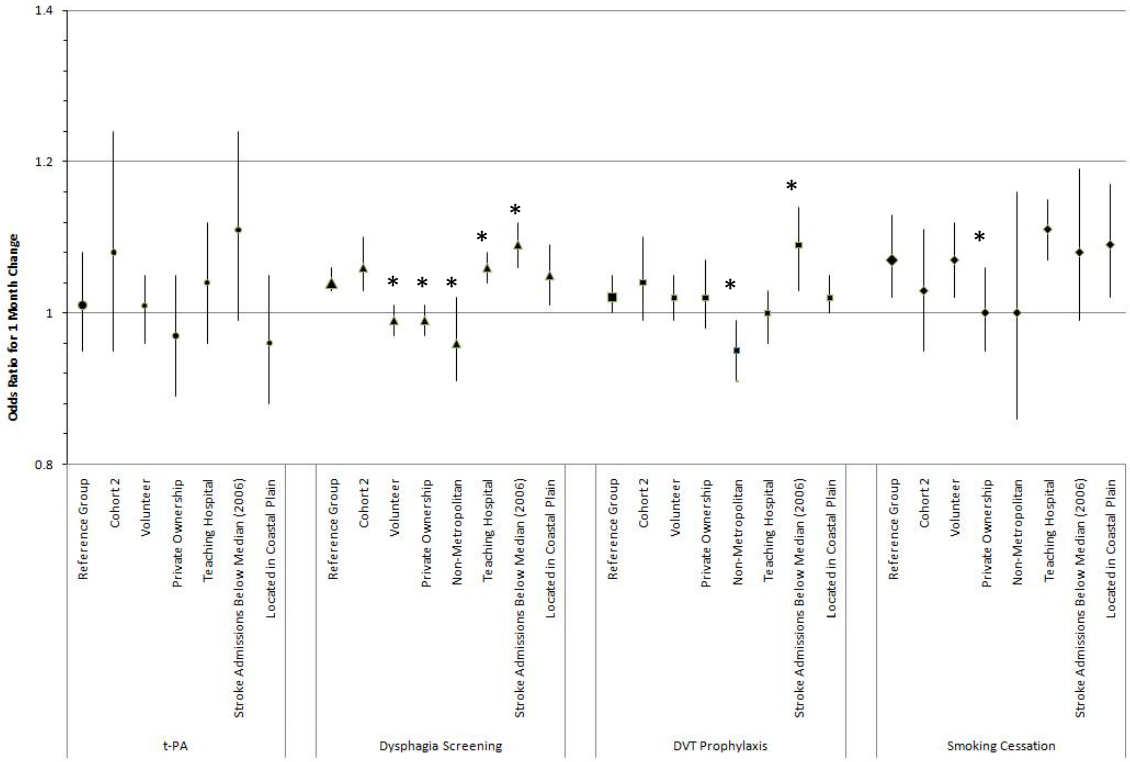
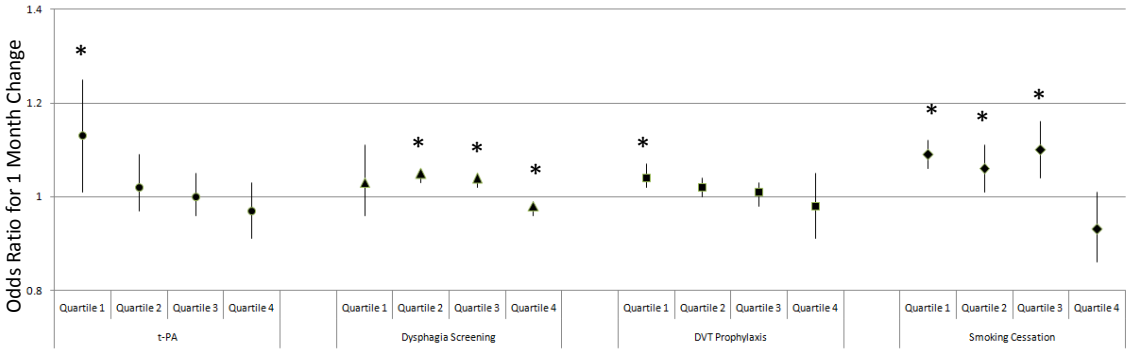


Figure 3. Within-hospital trends in quality indicator adherence by baseline adherence level in quartiles, Georgia Coverdell Acute Stroke Registry, November 2005 through October 2007, conditional logistic regression trend models, conditioning on hospital

The odds ratios compare the odds of quality indicator adherence in month x compared with month x-1. Quartiles marked with an asterisk show hospital characteristics for which the p-value for month was <0.05, indicating a statistically significant trend (positive or negative).



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Chapter 6: Manuscript for Study 2

(References, tables, and figures not continuous with larger document.)

Did educational conference calls contribute to stroke care quality improvement in a registry context?

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References: 325 (11 references)

ABSTRACT

Background: Improvement over time in adherence with evidence-based stroke care recommendations has been seen among hospitals participating in the Georgia Coverdell Acute Stroke Registry, but the impact of particular registry interventions is unknown. This study examined changes in quality indicator adherence in association with the five registry-wide educational conference calls conducted during the first 2 years of registry operation that addressed dysphagia screening, deep vein thrombosis prophylaxis, and smoking cessation counseling.

Methods: Conditional logistic regression models were used to examine within-hospital changes in adherence with the quality indicator on which each call focused. For each call, average adherence with the call-related indicator during the four months before the call was compared with average adherence during two follow-up periods (four month periods starting 1 and 3 months after the call). To help separate call effects from the effects of other registry interventions, we modeled the within-hospital monthly rate of change in adherence, using linear splines with a knot at the start of each follow-up period, to look for acceleration in the rate of change in temporal relation to each call. The association between overall trends in adherence for each indicator and the percentage of all registry calls in which a hospital participated was also assessed.

Results: Although post-call improvement in the average level of adherence with the relevant quality indicator was seen for all calls, there was no evidence of a call-specific effect on adherence in temporal relation to the calls. A more global association between a hospital's call participation percentage and trends in quality indicator adherence was seen for two of the three quality indicators.

Conclusions: Although there was no evidence of a temporal effect of the calls on quality indicator adherence, call participation may help keep hospitals engaged with stroke care quality

improvement. Alternatively, call participation may simply be a marker for a hospital's level of interest in stroke care quality improvement.

Key Words: stroke, Quality of Health Care**,** registries

INTRODUCTION

Each year, approximately 795,000 people in the United States experience a stroke, with approximately 185,000 of those strokes being recurrent strokes.[1] Among those who survive a stroke, approximately 15-30% are permanently disabled.[1] Preventable medical complications of stroke such as deep vein thrombosis[2] and pulmonary complications resulting from dysphagia[3] can lead to poorer clinical outcomes in stroke patients. Several measures have been shown to improve outcomes in acute stroke patients,[4] but evidence-based recommendations for stroke care are not always followed in clinical practice.[5]

The Georgia Coverdell Acute Stroke Registry (GCASR) is funded by the Centers for Disease Control and Prevention (CDC) as part of the Paul Coverdell National Acute Stroke Registry.[6] GCASR seeks to reduce stroke case- fatality, disability due to stroke, and the incidence of recurrent stroke in Georgia by monitoring and improving the quality of acute stroke care in the hospital setting. GCASR works with hospitals to improve acute stroke care through a multifaceted approach involving several interventions. Hospital participation in GCASR has been found to be associated with an increase over time in adherence with evidence-based stroke care recommendations[7]. However, since GCASR involves several simultaneous interventions, it is of interest to clarify the contributions of particular interventions to the observed improvement.

One of the interventions that GCASR has used to help to improve implementation of evidence-based stroke care recommendations has been a series of educational conference calls with participating hospitals, addressing specific aspects of stroke care. The aim of this study was to evaluate the contribution of educational conference calls to the impact of registry participation by determining 1) whether average adherence with call-related stroke care quality indicators improved in temporal relation to educational conference calls relating to selected evidence-based stroke care quality indicators, 2) whether the average monthly rate of change in call-related indicator adherence changed in temporal relation to the conference calls, and 3) whether there

was evidence that conference call participation overall was associated with improvements in adherence with the selected quality indicators.

Although the primary aim of this study was evaluation of the registry calls to help guide future plans for the registry, the findings may also help shed light on the way in which educational conference calls can contribute in the context of multifaceted quality improvement interventions. Several reviews of studies of the effectiveness of educational interventions, when considered as a sole intervention, have found that educational interventions can be effective in improving clinical practice, and that educational interventions involving an interactive component are generally more effective than purely didactic educational interventions.[8,9,10] However, less is known about the contribution of educational meetings within the context of a larger multifaceted intervention.

METHODS

Hospital selection and recruitment

Hospitals were invited to participate in GCASR if they were in a representative sample of 57 hospitals selected among the 151 hospitals in Georgia with at least one admission for acute stroke during 2000, or if they had volunteered to participate in an earlier pilot-phase registry.[5] Hospitals that were not actively invited were also welcomed to participate if they desired. Recruitment was done in stages, with 26 hospitals starting participation in November 2005, 25 hospitals starting in October 2006, and 2 additional hospitals starting in December 2006 and March 2007. Hospitals that joined the registry in November 2005 are considered cohort 1, and those joining in October 2006 or later are considered cohort 2. This analysis focused on discharges during the first two years of the registry (November 2005-October 2007). Of the 53 hospitals that participated in the registry, 45 entered at least some patient data into the registry for discharges during this time period, and this evaluation focuses on those 45 hospitals ("fully participating hospitals").

Quality Improvement Activities

GCASR quality improvement interventions included collection of patient-level data from hospitals relating to stroke care processes, feedback of summary data to hospitals with benchmarking against other hospitals, individualized quality improvement consultations, monthly individualized telephone calls, site visits, and general availability of registry staff (including a registry neurologist and hospital coordinator) to help answer stroke quality improvement questions or connect hospitals with resources available through other registry hospitals. Additional registry-wide interventions included monthly conference calls and newsletters, annual workshops in collaboration with American Heart Association's "Get With the Guidelines" program, and encouragement for hospitals to share stroke care quality improvement resources with each other.

Registry-Wide Conference Calls

The registry-wide monthly conference calls were designed to facilitate interaction among registry hospitals regarding stroke care quality improvement. Each month, a topic related to stroke care was selected based on interests expressed by hospitals and needs identified through analysis of registry data. Some calls focused on specific stroke care quality indicators, while others focused on broader topics related to stroke care quality improvement. During most months, a speaker proficient in the topic was asked to prepare a presentation to start the teleconference. Active interaction among hospitals related to the topic was encouraged after the presentation. Calls had varying levels of interaction. For some calls, a more explicitly interactive format was followed, with the selected presenter conducting a guided discussion rather than starting with a didactic presentation. Each call lasted 1 hour. Presenters were often from one of the GCASR participating hospitals that had experienced success with a particular area of stroke care. The types of hospital personnel who participated in the calls varied with the call topic, but most often included nurses involved with stroke care quality improvement at their institutions. A few days before each call, copies of the slides used in the presentations were distributed to all

registry hospitals, regardless of the hospital's call attendance, and highlights of the calls were briefly summarized in the registry's newsletters. Call topics were usually announced a few weeks to 1 month before each call. For each call, a record was kept of the hospitals that had at least one staff member attend the call, but the specific attendees from each hospital and the number of attendees at each hospital were not recorded.

Data collection

Hospitals that participated in the registry were asked to enter data for all admitted patients with a clinical diagnosis of acute stroke or transient ischemic attack (TIA) into an on-line, secure data entry system (Outcome, Inc., Cambridge, MA). The data collected included patient demographic and clinical characteristics; diagnostic procedures, treatments and counseling received while in the hospital and at discharge; and in-hospital outcomes. Data abstraction was done by hospital staff members who were trained in data abstraction for the registry at kick off workshops and through individual telephone training sessions. To protect patient confidentiality, the registry data did not include patient names, medical record numbers, or other direct identifiers. Data for separate admissions for the same patient could not be linked.

Quality of Care Measures

The registry used 10 quality indicators, developed by CDC, to measure the quality of stroke care. The 10 indicators used during the first two years of the implementation phase included tissue plasminogen activator (t-PA) administration, dysphagia screening, antithrombotic administration within 48 hours, deep vein thrombosis (DVT) prophylaxis, lipid profile measurement, stroke education, smoking cessation advice and counseling, assessment of the need for rehabilitation, discharge with antithrombotic therapy, and anticoagulation for atrial fibrillation. Each indicator identified an intervention that had been previously shown to be effective in improving outcomes among stroke patients with relevant characteristics ("eligible patients"). The adherence percentage for each indicator was calculated among eligible patients. Patients eligible for each intervention were identified based on the data elements entered into the

registry database, forming the denominator for percentages calculated. Patients with documented contraindications for a measure, or for whom eligibility could not be determined, were considered ineligible and were removed from the denominator for each measure. Patients for whom receipt of the intervention was documented in the medical record were considered to have received care meeting the quality indicator and were included in the numerator of the percentages. Hospitals had continuous on-line access to information about the adherence percentage for each indicator among the patients for whom they had entered data.

Statistical Analysis

Statistical analyses were conducted to examine within-hospital changes in adherence with three of the 10 registry quality indicators in temporal relation to the registry-wide conference calls that focused on those indicators, using an interrupted time series design. The calls included in this evaluation were selected a priori, before the analyses were conducted, and included all calls related to dysphagia screening, DVT prophylaxis, and smoking cessation counseling conducted during November 1, 2005 through October 31, 2007. Calls relating to these three indicators were chosen for detailed evaluation because these indicators had been the particular focus of registry quality improvement efforts and of analyses for previous registry evaluation studies. Conference calls related to these quality indicators were held in April 2006 (DVT prophylaxis), August 2006 (dysphagia screening), March 2007 (dysphagia screening), April 2007 (DVT prophylaxis), and May 2007 (smoking cessation counseling) (Figure 1).

The specific quality indicator calculations used in this evaluation were a modification of the initial quality indicator calculations developed by CDC for the Paul Coverdell National Acute Stroke Registry that were in use during the time period considered. In all analyses, adherence with a quality indicator was defined at the patient level as delivery of care meeting the indicator, considered among indicator eligible-patients only. The detailed definitions used to determine adherence with each of these four quality indicators have been previously described.[11] All analyses were conducted separately for each indicator and call.

Descriptive Analyses

For each of the calls in the analysis, hospital characteristics were compared for hospitals that attended the call and hospitals that did not attend, among fully participating hospitals that were participating in the registry on the call date ("eligible for the call"). Among hospitals that were eligible for each call, hospital characteristics were also compared for hospitals that did and did not have adequate data for the evaluation, defined as having entered data for at least 5 admissions for indicator-eligible patients with discharge dates during the baseline period and both follow-up periods for the respective call. Finally, hospital characteristics were examined in relation to the percentage of all registry conference calls which the hospital attended among calls for which the hospital was eligible. The statistical significance of differences between groups for continuous variables was assessed using the Wilcoxon Rank Sum test. The statistical significance of differences between groups for categorical variables was assessed using the Fisher's Exact Test.

Models for Changes in Quality Indicator Adherence

To examine within-hospital changes in quality indicator adherence in temporal relation to the calls, conditional logistic regression models were used, conditioning on hospital. In all models, adherence during the 4 months preceding the call (pre-call period), was compared with adherence during the 4 months after two lag periods (follow-up periods). The lag periods lasted 1 month and 3 months after the call to account for the time needed for hospitals to implement changes based on learning during the call before any effect on quality indicator adherence would be expected. For the May 2007 call, the follow-up period after the 3 month lag was only 3 months in duration due to the end of the available data at the end of October 2007.

Two types of models for change over time were used. Initial models ("pre-post average models") simply compared a hospital's average level of adherence during the two follow-up periods with that hospital's adherence during the pre-call period. Observations during the lag periods were excluded from these analyses. Initial pre-post average models did not consider a

hospital's call attendance status, as "intent to treat" models. Models were then considered that included terms for the interaction between the time period and the hospital's call attendance status.

The second type of models for change over time ("trend models") evaluated a hospital's average monthly rate of change in adherence during the two follow up periods compared with the average monthly rate of change in adherence during the pre-call and lag periods. The odds ratios obtained from these models compare the odds of quality indicator adherence in a given month with the odds of adherence during the previous month, on average, within each period. The trend models were considered the primary analysis. The trend models assumed that after a lag period, there would be acceleration in the rate of improvement in quality indicator adherence if the calls had the desired impact. These models included a continuous variable for the month of discharge, and a spline, with one knot at the end of the lag period, allowing for an increase or decrease in the average monthly change in the odds of adherence starting at the end of the lag period. The average monthly change in the odds of adherence during each follow up period was compared with the average monthly change in the odds of adherence during the pre-call period and lag period combined. Trend models were first fit that did not consider a hospital's call attendance status, as "intent to treat" models. Models were also fit that included interactions between the terms for baseline and follow-up monthly change in adherence and the hospital's call attendance status.

For both types of models, separate models were constructed for each call. The analysis included only hospitals that were eligible for each call and that had adequate data for the evaluation, to allow stable estimates of average adherence and the rate of change in adherence during each period.

Consideration of global effect of calls

The possibility that the calls may have had an impact that cannot be detected in temporal relation to specific calls was considered. To examine the more global association between call

participation and quality indicator adherence, we examined the overall within-hospital monthly rate of change in quality indicator adherence in relation to the overall percentage of registry-wide calls which each hospital attended, among calls for which the hospital would have been eligible. This analysis was conducted using conditional logistic regression models for adherence with each of the three selected quality indicators that included a term for the month of discharge and terms for the interaction between discharge month and categories of hospital call attendance percentage. For this analysis, hospitals were divided into 4 groups by the percentage of calls that they attended among calls for which they were eligible. The four groups were selected to achieve balance between groups in relation to both the number of hospitals and the number of admissions in the analysis. The models controlled for two-way interactions between month and other hospital characteristics, including the hospital's registry cohort, the annual number of stroke admissions (at or above the median versus below the median), metropolitan location, and teaching status.

Human Subjects Review

The Emory University institutional review board (IRB) determined this study to be exempt from IRB review as a non-research activity, because it was designed as an evaluation of a public health program. The Georgia Department of Human Resources IRB approved this study through its "Approval Without Detailed Review" process, which has criteria similar to criteria for IRB exemption under federal regulations.

RESULTS

Hospital call Participation

The number of hospitals that were eligible to attend each of the 5 calls based on the hospital's registry start and end dates, and the number of hospitals that attended each call, are shown in Table 1. The percentage of eligible hospitals attending the calls ranged from 47% (April 2007) to 67% (April 2006 and October 2006). In a few cases, hospitals reported data for

their smaller affiliates with data for the larger facility. In these cases, the larger hospital and the smaller affiliate are counted as one hospital, as they often shared stroke quality improvement staff and the data for the two facilities could not be separated. For the April 2006, October 2006, and April 2007 calls, there were no statistically significant differences between attendees and non-attendees, although there was a general trend towards call-attending hospitals being larger and having more stroke admissions than non-attending hospitals. For the March 2007 and May 2007 calls, compared with hospitals that did not attend, hospitals that attended the calls were significantly larger, had a significantly higher number of stroke admissions during 2006, and were more likely to be in metropolitan areas. For the March 2007 call, call-attending hospitals were more likely than non-attending hospitals to be located outside the coastal plain area (Table 1).

The number of call-eligible hospitals with sufficient patient-level data available for the evaluation is shown at the bottom of Table 1. The difference between the number of call-eligible hospitals and the number with sufficient data is particularly notable for the October 2006 call, which was in the first month of participation for cohort 2 hospitals, and the May 2007 call on smoking cessation for which many hospitals may not have had sufficient numbers of indicator-eligible patients (because the smoking cessation indicator includes smokers only). In general, call attendees were more likely to have sufficient data than non-attendees. In addition, hospitals with a number of beds above the median, a number of stroke admissions above the median, and located in metropolitan areas were significantly more likely to have sufficient data than hospitals with fewer beds, fewer stroke admissions, and those located in non-metropolitan areas (data not shown).

Pre-call Average Adherence vs. Post-call Average Adherence

The results of the conditional logistic regression analysis comparing average adherence in the pre-call period with average adherence in the two post call periods for hospitals overall and by call attendance status are shown in Figure 2. Overall, hospitals showed increased average

adherence during both follow-up periods compared with the baseline period for all of the calls, with this increase being statistically significant for the April 2006 call on DVT prophylaxis (both lag periods), the October 2006 call on dysphagia screening (3 month lag only), and the March 2007 call on dysphagia screening (both lag periods).

When considered by call attendance status, increased average adherence during both follow up periods compared with the pre-call period was generally seen for both hospitals that attended the calls and hospitals that did not. The one exception was the April 2007 call, on DVT prophylaxis, for which there was a decrease in average adherence with the DVT prophylaxis indicator among call participants during the post-call period after a 1 month lag that was not statistically significant. In many cases, the increase in performance in the post call period was actually higher among call non-attendees than among call-attendees (statistically significant for the April 2007 call on DVT prophylaxis). The exceptions were the October 2006 call considering a 3 month lag, and the May 2007 call considering both 1 and 3 month lags.

Non-attending hospitals had lower average baseline adherence than call-attendees for the October 2006, March 2007 and April 2007 calls (Table 1). When comparing adherence at baseline and follow-up for hospitals overall, there was a clear trend towards hospitals with lower baseline performance to have higher follow-up vs. pre-call odds ratios for the April 2006, October 2006 and April 2007 calls. Higher performance increases among call non-attendees appeared to be related to lower average baseline performance among non-attendees in some, but not all, cases (results not shown).

Changes in Rates of Improvement over Time

The results of the models of the monthly rates of change in adherence are shown in Figure 3 for the 3 month lag. Results for the 1 month lag were similar. For the April 2006, March 2007, and May 2007 calls, quality indicator adherence was increasing each month, on average, during the baseline periods (pre-call and lag periods combined), as evidenced by odds ratios >1 for a 1 month change, for hospitals overall and for both call-attendees and non-attendees

considered separately. For each of these calls, the post-call monthly rates of improvement were generally lower than the pre-call rates of improvement (except for the April 2006 call-attendees). For the October 2006 and April 2007 calls, there was evidence of little monthly change in adherence at baseline (odds ratios for 1 month change close to 1) for hospitals overall. For the October 2006 call, both call attendees and non-attendees showed little monthly change in adherence at baseline. For the April 2007 call, attendees showed decreasing adherence at baseline, and non-attendees showed increasing adherence at baseline. Post-call monthly rates of improvement were higher than baseline rates for the October 2006 call (overall, and for call-attendees and non-attendees), and for the April 2007 call for hospitals overall and for call-attendees. For the April 2007 call among non-attendees, monthly rates of change were lower in the follow-up periods than at baseline.

The change in slope at the end of the lag period for hospitals overall was statistically significant only for the March 2007 call on dysphagia screening, for which the slope decreased, and for the October 2006 call, for which the slope increased. When considered by call participation status, the interaction between the change in slope and call participation status was statistically significant only for the April 2007 call on DVT prophylaxis, for which call participants showed an increasing slope and call non-participants showed a decreasing slope.

Consideration of Global Effect of Call Attendance

The overall percentage of calls which hospitals attended, among those for which they were eligible, ranged from 0% to 100%, with a median of 54% among the 45 hospitals that fully participated in the registry. The overall call attendance percentage was significantly higher among hospitals in cohort 1 compared with cohort 2, among hospitals with a number of beds at or above the median compared with hospitals with fewer beds, among hospitals with a number of 2006 stroke admissions at or above the median compared with hospitals with fewer stroke admissions, and among metropolitan hospitals compared with non-metropolitan hospitals (results not shown). When we examined the monthly rate of change in quality indicator adherence by the overall call

attendance percentage, in models adjusting for interactions between month and other hospital characteristics, higher rates of improvement in quality indicator adherence were observed for dysphagia screening and smoking cessation counseling among hospitals with higher call participation (trend statistically significant only for dysphagia screening). This trend was not seen for DVT prophylaxis (Figure 4).

DISCUSSION

This study examined the specific effectiveness of one component, educational conference calls, within a multifaceted quality improvement intervention. While many of the calls were well attended, call attendance was lower among smaller hospitals with fewer stroke admissions than among larger hospitals with more stroke admissions, indicating that the registry may need to identify different strategies for engaging smaller hospitals

The trend models were considered the primary analysis on a theoretical basis, because it was felt that the calls would most likely cause a gradual increase in adherence rather than a sudden jump in adherence. In addition, the pre-post average models will detect improvement that may be simply due to a continuation of underlying improving adherence that may have started before the call as a result of other registry efforts. The trend models look for a change in adherence, above the pre-existing underlying rate of change and in temporal relation to the calls. Therefore, the trend models are better suited to identifying an effect of the calls apart from the effect of other registry interventions. Further, the comparisons that do not include consideration of call participation status were preferred. Those models can be considered as “intent to treat” analyses, because they include data for all hospitals for which the intervention was intended. There is also some justification for preferring this type of analysis due to the fact that presentation slides were sent to all hospitals, potentially leading to an impact of the call on non-attendees. While these analyses may be expected to be biased toward the null, they will not be confounded by other factors related to call attendance, including baseline compliance rate.

Although the pre-call vs. post-call average comparisons showed overall improvement in quality indicator adherence, there was no clear evidence that the improvement was a result of the conference calls. The intent-to-treat trend models showed evidence of a post-call increase in the rate of improvement in adherence only for the October 2006 call. The intent-to-treat trend models also showed a significant decrease in the rate of improvement after the March 2007 call on dysphagia screening. Overall, these findings do not provide consistent evidence of a benefit of the calls. The findings of analyses including consideration of call participation status support these conclusions, as there was no evidence of greater improvement among call participants in any of the pre-post average models. Although there was evidence of a greater post-call increase in the rate of improvement among call participants for one call (the April 2007 call on DVT prophylaxis), models that include participation status are susceptible to confounding by factors that may be related to call participation.

The findings of this study are consistent with the findings of a review of multiple studies of the effectiveness of professional education meetings by Forsetlund et al.[10] That review of 81 studies found that educational meetings can improve adherence with desired practices, particularly if they include an interactive component. However, the additional benefit of educational interventions in the context of other interventions was less clear. The effect of educational interventions was not found to be substantially different from the effect of other types of interventions, such as educational outreach visits; and multifaceted interventions that included educational meetings were not found to have an effect substantially different from educational meetings alone. The current study examined the question from a slightly different perspective, seeking to detect an effect of educational interventions above the underlying effect of other components of a multifaceted intervention, but did not find evidence of such an effect. A review of multiple studies of various types of interventions to encourage implementation of best medical practices found several of the other types of interventions used in the registry to be either variably effective (including audit and feedback), or generally effective (including academic detailing and

multifaceted interventions in general),[9] which is in agreement with the overall improvement in adherence over time that has was seen in this study.

This study had several limitations. The representativeness of the findings is limited by lack of adequate data for evaluation for all hospitals. Insufficient data could be due to overall low numbers of stroke patients, low numbers of patients eligible for the relevant quality indicator, lags in the start of data entry, or low adherence with data entry. Adequate data for the evaluation was less likely to be available for smaller hospitals and non-urban hospitals, limiting the generalizability of the findings for those hospitals. In addition, call attendance percentages varied with hospital characteristics for some calls, and overall interest in stroke care quality improvement may play a role in both call attendance and quality indicator adherence. Within-hospital comparisons minimize the impact of between-hospital factors, particularly in the analysis examining the effect among all hospitals without regard to call participation status. However, the analyses that include interaction with call attendance may still be influenced by other hospital factors associated with attendance. In addition, it is possible that the models for change over time did not accurately reflect the true patterns of change that may have resulted from the calls. Due to limitations in the amount and duration of the available data, more complex models for change and models for change over time that included longer lag periods were not considered.

Data quality is another potential limitation of this study. The data used to assess quality indicator adherence was self-reported by hospitals without verification. The registry conducted an evaluation of data quality overall, and found adequate inter-rater reliability for most quality indicators, although reliability for the dysphagia screening indicator was lower than that found for other indicators. Changes in data abstraction practices at hospitals could have influenced the observed trends, particularly for dysphagia screening, as accurate data abstraction was also emphasized during the calls. If the calls had a positive impact in encouraging more accurate recording of instances in which recommended care was not delivered, this could paradoxically

lead to an appearance of decreased quality of care. This may, in part, explain the decrease in the rate of improvement observed for the second dysphagia screening call.

Strengths of this study include the examination of within-hospital changes in adherence through conditional logistic regression models that control for all hospital characteristics that are not temporally varying, which minimizes the impact of between-hospital differences in the analysis, particularly for analysis that included all hospitals without consideration of call participation status. In addition, the use of models examining changes in trends in adherence allows the effect of the calls to be considered apart from the underlying effect of other concurrent registry interventions. Ignoring the underlying rate of improvement could lead to an overestimation of the effectiveness of the calls.

It appears that factors other than the calls have had a more powerful influence than the conference calls on trends in adherence. Based on these observations, one might ask whether the calls could be eliminated to save resources. However, the findings of this study should be interpreted cautiously. Call attendance appeared to have a more global association with improved quality indicator adherence, which may be due either to a positive effect of the calls in general, or to other unmeasured hospital characteristics that cause a hospital to both have a higher rate of improvement in adherence and to participate in calls. The call attendance percentage may simply serve as a measure of registry engagement. However, the calls may also encourage and sustain registry engagement. A survey of hospitals evaluating hospital perceptions of registry quality improvement interventions found that hospitals value the conference calls. The calls may serve a stronger function in keeping hospitals engaged in stroke care quality improvement and helping hospitals network with each other than in providing specific educational value.

Based on these analyses, it does not appear that hospitals implement specific strategies discussed on the calls shortly after the calls. At the time of the calls, hospitals may have different stroke care quality improvement priorities than those discussed on the calls. It is possible that a more general emphasis on encouraging interaction between hospitals about stroke care quality

improvement would be more useful than calls intended to target specific quality indicators. It is also possible that greater coordination of calls with the quality improvement focus of hospitals at the time could lead to greater implementation of the information from the calls. A survey of hospitals asking about the ways in which they use the information from the conference calls, and about their call format preferences could help guide decisions about possible changes to the conference calls. Further studies could also be considered after seeking further input from hospitals, such as an evaluation of a trial period during which the calls were discontinued or changed in format, or a randomized trail assigning hospitals to groups with different call formats, possibly including a group with no calls.

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Table 1. Characteristics of Hospitals Attending and Not Attending each Call

Call Date	Apr-06	Oct-06	Mar-07	Apr-07	May-07
Quality Indicator on which call focused	DVT Prophylaxis	Dysphagia Screening	Dysphagia Screening	DVT Prophylaxis	Smoking Cessation
Number of call-eligible hospitals	24	43	44	45	43
	# (%) Attending	# (%) Attending	# (%) Attending	# (%) Attending	# (%) Attending
Overall # (%) attending	16 (67%)	29 (67%)	23 (52%)	21 (47%)	22 (51%)
Cohort					
1	16 (67%)	19 (79%)	14 (58%)	7 (33%)	15 (63%)
2	0	10 (53%)	9 (45%)	14 (58%)	7 (37%)
Recruitment Status					
Recruited	13 (68%)	21 (64%)	16 (48%)	15 (45%)	15 (48%)
Volunteer	3 (60%)	8 (80%)	7 (64%)	6 (50%)	7 (58%)
Bed Size					
<250	7 (70%)	14 (61%)	7 (30%)*	11 (48%)	9 (43%)
≥250	9 (64%)	15 (75%)	16 (76%)	10 (45%)	13 (59%)
Number of stroke admissions, 2006					
<258	6 (55%)	13 (57%)	7 (30%)*	10 (43%)	8 (38%)
≥258	10 (77%)	16 (80%)	16 (76%)	11 (50%)	14 (64%)
Teaching Status					
Yes	4 (100%)	6 (86%)	5 (71%)	4 (57%)	5 (71%)
No	12 (60%)	23 (64%)	18 (49%)	17 (45%)	17 (47%)
Ownership Type					
Private	2 (40%)	7 (88%)	3 (38%)	4 (50%)	3 (38%)
Not-for Profit or Hospital Association	14 (74%)	22 (63%)	20 (56%)	17 (46%)	19 (54%)
Metropolitan Location					
Metropolitan	12 (67%)	21 (78%)	20 (71%)*	15 (52%)	19 (66%)*
Non-Metropolitan	4 (67%)	8 (50%)	3 (19%)	6 (38%)	3 (21%)
Location in State					
Coastal Plain	7 (78%)	10 (53%)	6 (32%)*	10 (53%)	9 (50%)
Non-coastal Plain	9 (60%)	19 (79%)	17 (68%)	11 (42%)	13 (52%)

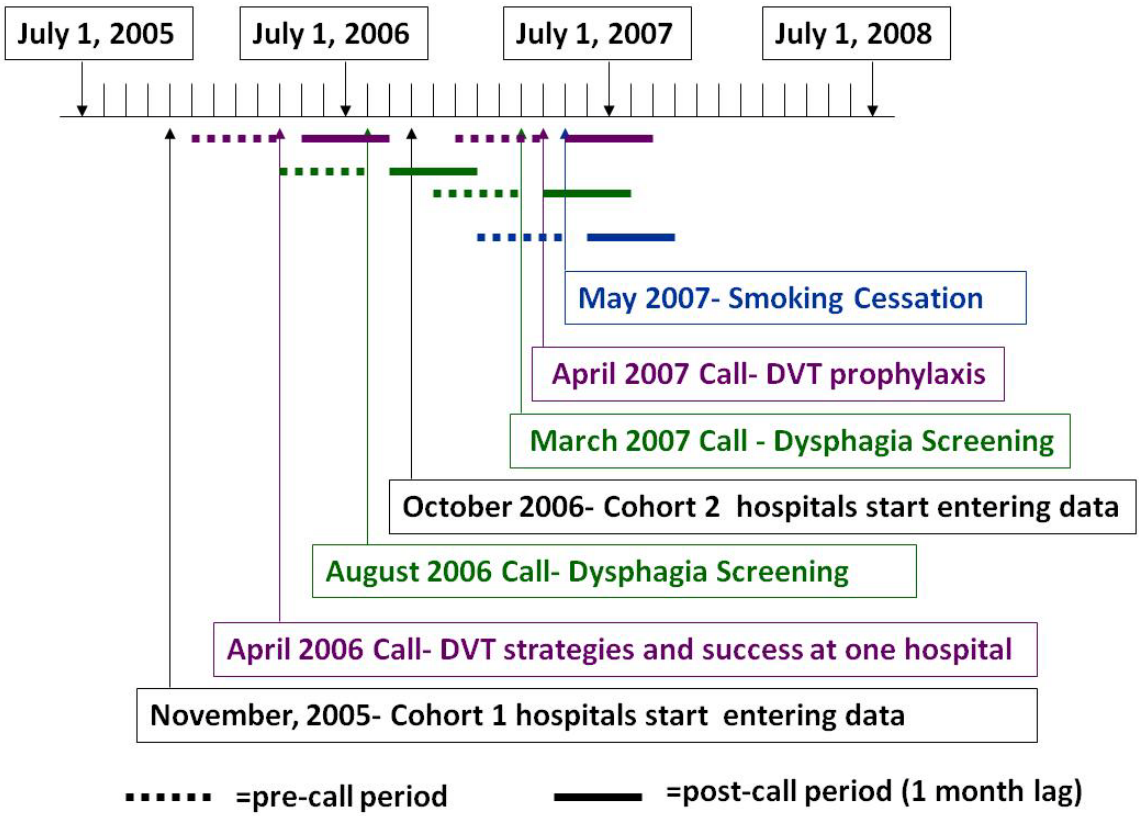
Table 1. (continued)

Call Date	Apr-06		Oct-06		Mar-07		Apr-07		May-07	
Quality Indicator on which call focused	DVT Prophylaxis		Dysphagia Screening		Dysphagia Screening		DVT Prophylaxis		Smoking Cessation	
Call Attendance	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Bed Size										
Median	293.5	355	282	113.5	356*	127*	248	256	356.5	143*
Range	25-953	25-458	25-953	25-633	25-953	25-511	25-953	25-633	25-953	25-470
Number of stroke admissions, 2006										
Median	321	218	310	84.5	437*	74*	259	168.5	444*	92*
Range	4-1171	13-695	0-1171	16-736	0-1171	4-523	10-907	0-1171	4-1171	5-785
Sufficient data for evaluation during baseline and follow up periods (% of call-eligible hospitals with data)	12 (75%)	5 (63%)	15 (52%)	3 (21%)	17 (74%)*	8 (38%)*	15 (71%)*	9 (38%)*	11 (50%)	5 (24%)
% of eligible patients receiving care meeting the indicator during the baseline period among all hospitals with any data										
Median	81.3	92.6	64.3	52.9	52.6	11.9	90.3	84.9	92.6	94.7
Range	20-98.9	27.8-100	11.1-100	0-76.9	16.7-100	0-80.7	0-100	0-100	0-100	7.7-100

*p<0.05 for comparison of call attending hospitals and call non-attending hospitals.

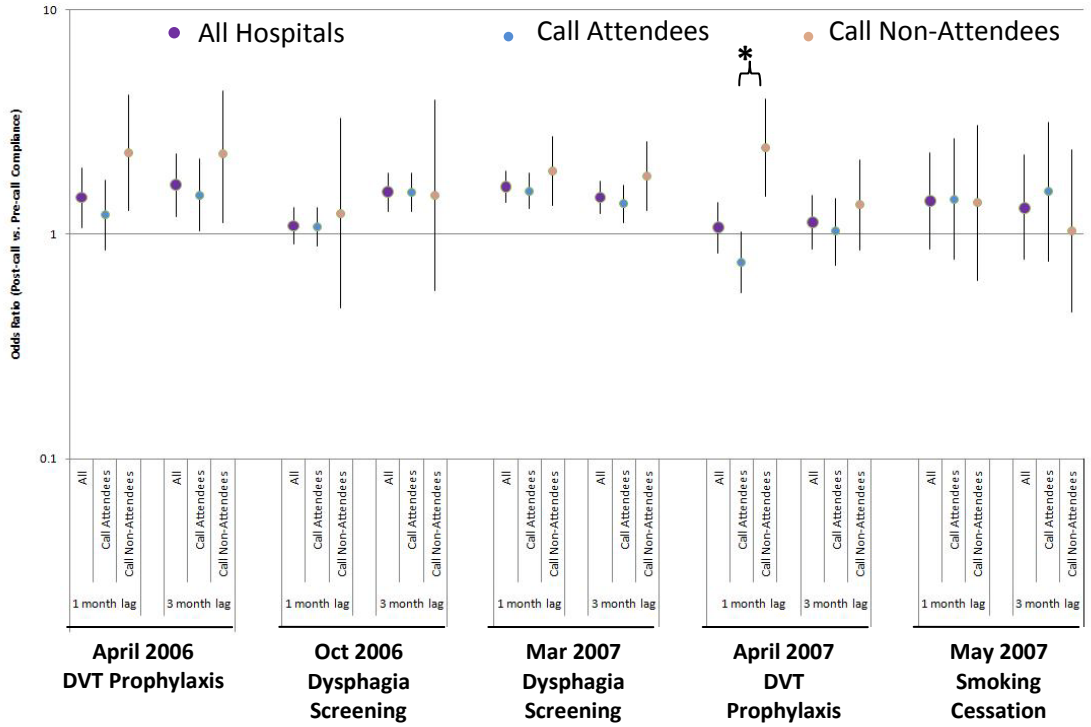
Data on number of beds and type of hospital ownership were obtained from the Georgia Hospital Association's 2007 directory. The number of stroke admissions during 2006 for each hospital was calculated using hospital discharge data from the Georgia Hospital Association (ICD-9 CM codes 430-438). Teaching status and census tract information was obtained from a Georgia hospital database maintained by the Georgia Division of Public Health, Office of Health Information and Policy. Metropolitan/non-metropolitan categorization was based on the 2000 Rural-Urban Commuting Ares (RUCA) Code for the census tract in which the hospital was located (Metropolitan: RUCA Code <4, Non-Metropolitan: RUCA code ≥4). Georgia's coastal plain is the area of the state with the highest stroke mortality rates. A hospital was considered in the coastal plain if the county in which the hospital is located is primarily in the Sea Island or East Gulf Coastal Plain physiographic sections of the state.

Figure 1. Timing of evaluated GCASR Registry-wide educational conference calls and topics covered



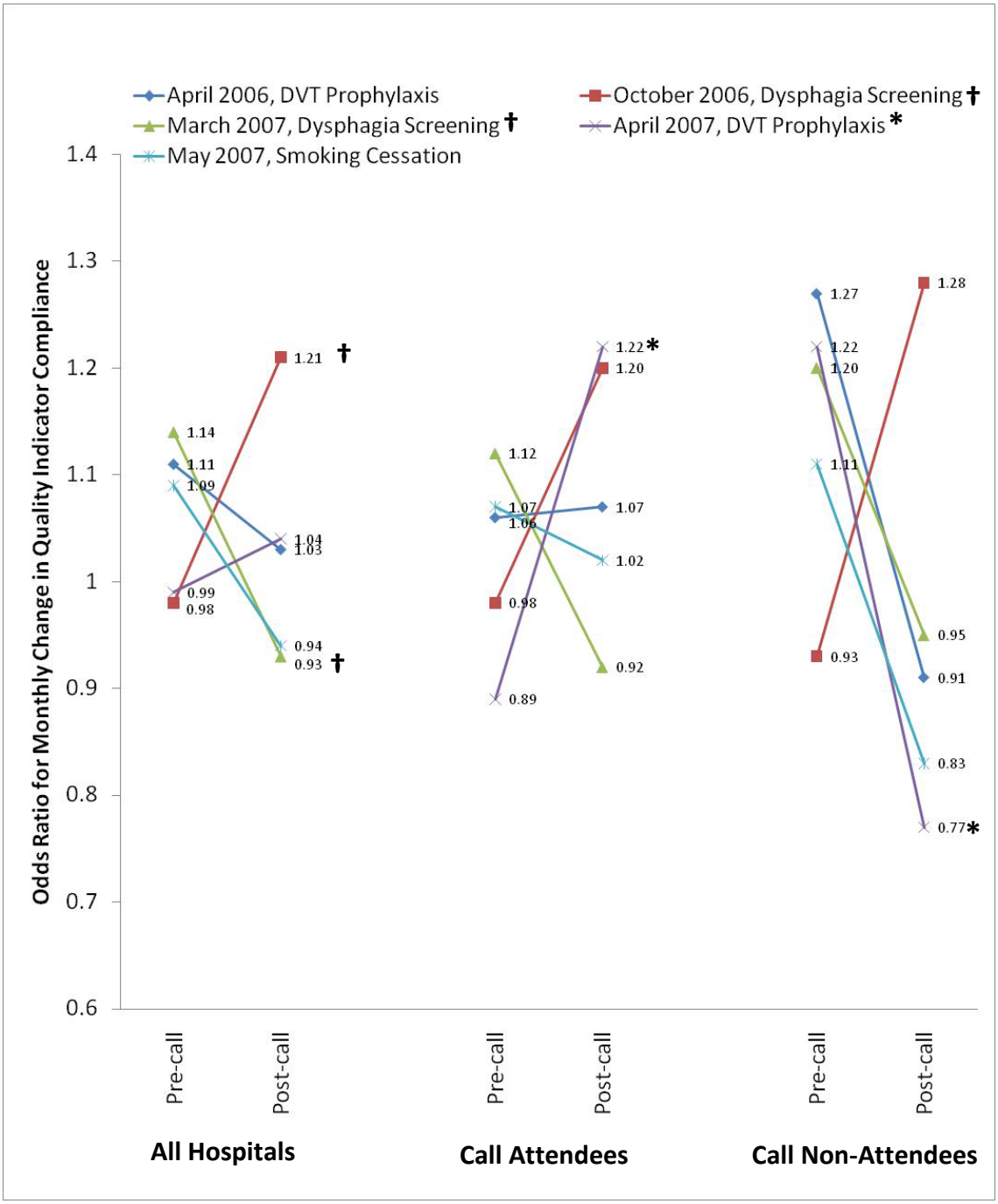
*Only the post-call periods after a one month lag are shown. The post-call periods after a three month lag are not shown.

Figure 2. Results of pre-post conditional logistic regression models comparing average adherence before calls with average adherence during follow-up periods after 1 month or 3 month lags among all hospitals, and hospitals by call attendance status



***P-value for interaction between participation and time period <0.05**

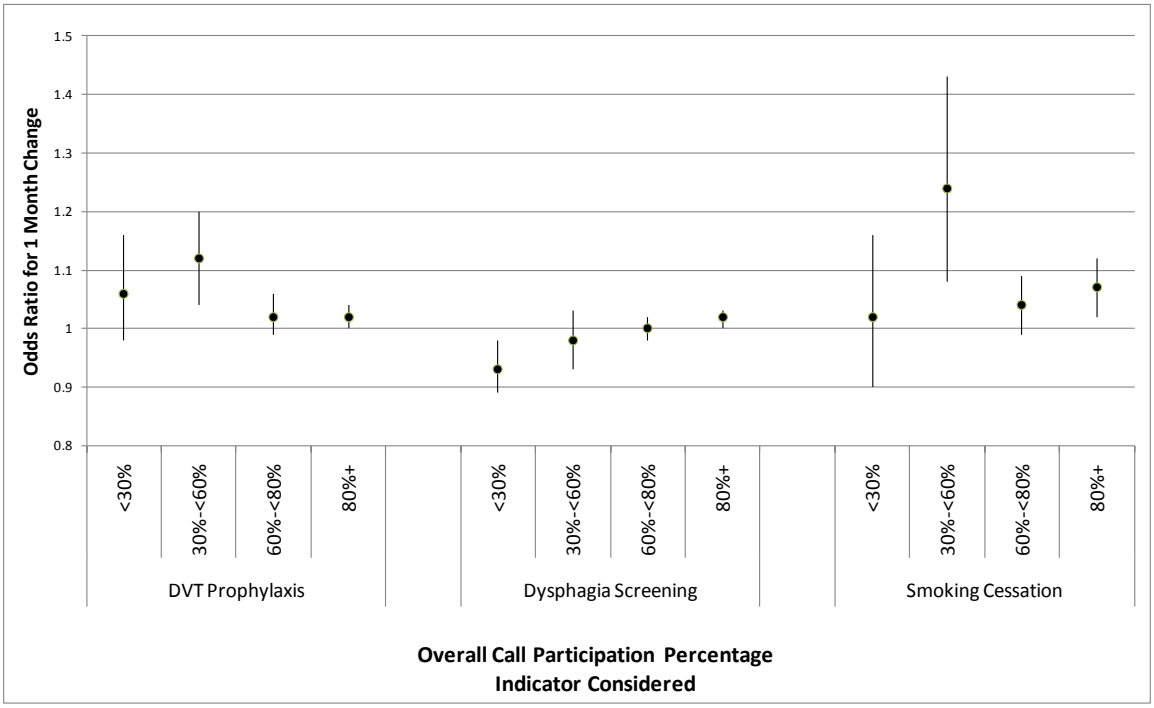
Figure 3. Results of conditional logistic regression models comparing the monthly change in the odds of adherence (slope) during pre-call periods and post call periods, after 3 month lag, among all hospitals and by call attendance



***P-value for participation/post-call trend interaction <0.05**
†P-value for slope change among all hospitals <0.05

Figure 4. Overall odds ratio for monthly change in quality indicator adherence by hospital call attendance percentage

Odds ratios are from conditional logistic regression models conditioning on hospital and including terms for the interactions between month and the hospital's registry cohort, the annual number of stroke admissions (at or above the median versus below the median), metropolitan location, and teaching status.



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Chapter 7: Manuscript for Study 3

(References, tables, and figures not continuous with larger document.)

Evaluation of the Impact of the Georgia Coverdell Acute Stroke Registry Prototype on Stroke Outcomes in Georgia

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ABSTRACT

Background: The Georgia Coverdell Acute Stroke Registry (GCASR) seeks to monitor and improve the quality of acute stroke care in Georgia. This study was conducted to evaluate the association between stroke patient outcomes and the operation of the GCASR pilot registry during 2001-2005.

Methods: Hospitals were randomly selected for invitation to participate in the GCASR pilot registry among hospitals in Georgia. We linked hospital discharge data for patients with index ischemic stroke admissions to Georgia hospitals with Georgia mortality records. In an intent-to-treat analysis, the hazard of death within 1 year of an index stroke admission and the hazard of readmission within 1 year of discharge, censoring at the time of death, were compared for patients admitted to randomly selected hospitals and non-selected hospitals during the 6 months before the registry (baseline) and the last 6 months of the pilot registry (follow-up). Within-hospital trends between these time periods in the hazard of these outcomes were also compared by hospital selection and participation status.

Results: During the follow-up period, the hazard of readmission was lower for patients admitted to randomly selected hospitals compared with those admitted to non-selected hospitals (HR=0.81, 95% CI 0.67-0.98). There was a slight increase in the hazard of death within 30 days among patients admitted to selected hospitals compared with those admitted to non-selected hospitals, but this difference was not seen at 1 year. There was a within-hospital decrease in the hazard of readmission among selected hospitals when comparing the follow-up and baseline periods.

Conclusions: Operation of the GCASR pilot registry was associated with a reduction of the hazard of readmission for recurrent stroke among patients admitted to hospitals randomly selected for registry participation. Repeating this study for the current implementation phase registry will help to further clarify the impact of the registry on patient outcomes.

Key Words: stroke, Quality of Health Care**,** registries

INTRODUCTION

Stroke causes > 140,000 deaths each year, and is the third leading cause of death in the United States. Each year, approximately 795,000 people in the United States experience a stroke, with approximately 185,000 of those strokes being recurrent strokes.[1] Stroke disproportionately affects residents of Georgia, which in 2006 had a stroke mortality rate 16% higher than the national average.[2] Several measures have been shown to improve acute stroke patient outcomes,[3] but evidence –based recommendations for stroke care are not always followed in clinical practice.[4]

The Georgia Coverdell Acute Stroke Registry (GCASR) is funded by the Centers for Disease Control and Prevention as part of the Paul Coverdell National Acute Stroke Registry.[5] GCASR seeks to monitor and improve the quality of acute stroke care in the hospital setting by helping hospitals to increase adherence to evidence-based stroke-care recommendations, with the ultimate goal of reducing stroke case- fatality, disability due to stroke, and the incidence of recurrent stroke in Georgia. GCASR started in 2001 as a pilot project, administered through Emory University, involving 46 hospitals in Georgia. Full implementation, after incorporation into the Georgia Division of Public Health, began in November 2005.

Several studies have found that GCASR,[6] other stroke registries,[7,8,9] and other types of single-hospital[10] and multi-hospital stroke quality improvement programs [11, 12, 13, 14, 15] can improve adherence to evidence-based stroke care recommendations. However, since the ultimate goal of the registry is to improve stroke patient outcomes, assessment of the impact of GCASR on post-discharge stroke patient outcomes is a critical part of registry evaluation. There is increasing emphasis on measurement of patient outcomes as well as care processes when assessing quality of care,[16] as process measure improvements do not always lead to outcome improvements.[17] We used state-wide hospital discharge data linked with mortality data to evaluate whether a change in the hazards of death within 1 year of admission and readmission for stroke within 1 year of

discharge, for admitted ischemic stroke patients, was seen in association with operation of the GCASR pilot registry.

METHODS

Hospitals were selected for recruitment for the pilot registry though a random sample of hospitals in the state. Hospitals that were not selected were welcomed to participate, if they desired, although they were not actively recruited. This evaluation included all non-federal, adult acute care general hospitals in Georgia. Facilities that were not primarily general acute care hospitals or that had no stroke admissions during 2001-2006 were excluded from the evaluation, leaving 149 eligible hospitals (Figure 1). Of the 149 eligible hospitals, 47 had been randomly selected for participation in the pilot registry, of which 26 (55%) participated in the registry. An additional 5 hospitals had also been randomly selected but were not included in the evaluation because they had closed before the end of the pilot period (2 hospitals), or they were considered ineligible for the evaluation (1 pediatric facility, 2 long term care facilities). Eight hospitals had been selected with certainty for participation in the pilot registry because they had the highest annual number of acute stroke admissions in the largest county. All eight hospitals selected with certainty met the evaluation criteria and participated in the registry. Ninety-four non-selected hospitals met the evaluation criteria, of which 12 (13%) participated in the pilot registry.

Quality Improvement Activities

Hospitals participating in the pilot registry were asked to submit medical charts to the Georgia Medical Care Foundation for centralized data abstraction related to acute stroke care for acute stroke patients discharged during December 2001-February 2002 and February 2003-March 2003. Hospitals received feedback from the chart abstractions and participated in in-person stroke quality improvement workshops during September 2002 and November 2003. Other registry quality improvement activities included monthly calls with hospitals starting in December 2002, and availability of registry staff to provide stroke care quality improvement

resources and facilitate networking between hospitals. In early 2003, some hospitals also started participation in the American Heart Association/American Stroke Association's "Get With The Guidelines- Stroke" program.

Evaluation Data Set Preparation

The evaluation linked patient-level data for patients discharged from hospitals in Georgia ("hospital discharge data") with Georgia death certificate data for the years 2000-2006. The hospital discharge data included a unique longitudinal patient identifier, based on the patient's name, date of birth and sex. Stroke admissions (principal ICD-9 diagnosis codes 430-438) were selected from the hospital discharge data. For each patient, the first stroke admission during 2000-2006 was the index admission. The primary analysis considered the hospital of first presentation to be the index hospital. A secondary analysis considered the index hospital to be the hospital at which the patient was finally admitted after a series of early transfers (on the same day or the day following the previous admission). Both analyses included only index admissions during 2001-2005 with a primary diagnosis of ischemic stroke (primary ICD-9 code 433.01, 433.11, 433.21, 433.31, 433.81, 433.91, 434.01, 434.11, 434.91, or 436). Admissions through 2006 for all stroke types were included in identification of stroke readmissions.

An identifier matching the longitudinal identifier in the hospital discharge data was created in the death certificate data set using decedent identifying information, after which identifiers were removed. De-duplicated, de-identified mortality records were linked with hospital discharge records using a deterministic linkage based on the longitudinal identifier. The accuracy of the linkage was assessed by examining the percentage of patients dying before discharge or discharged to hospice who had linked death data, the percentage of linked cases for which the race was the same in both data sets, and the percentage of linked cases for which the final stroke admission was after the date of death from the linked death certificate.

Outcome variables

The primary outcomes of interest were death within 1 year of the index admission date, and readmission within 1 year of the index admission discharge date. A patient was considered to have died if either the last stroke admission indicated in-hospital death or there was a death date from a linked death certificate. If dates of death from the hospital discharge data and the death certificate data were not the same, the date of death from the hospital discharge data was used. Time to readmission was calculated as the time from the index admission discharge date to the admission date for the next admission that was not part of an initial chain of transfers for the index event.

Regression Models

To determine whether changes in these outcomes were seen in association with operation of the GCASR pilot registry, two types of models were used. The primary models were intent-to-treat Cox proportional hazards models, that compared the hazard of the outcomes for patients admitted to selected and non-selected hospitals during each of three time periods separately, accounting for correlation between patients admitted to the same hospital through robust variance estimation. The three time periods were the 6 months prior to the start of the pilot registry (January-June 2000), the last 6 months of the pilot registry (January-June 2004), and the 6-month period 1 year after the last 6 months of the pilot registry but before hospital participation in the implementation phase registry started (January-June 2005). Admissions to hospitals selected with certainty were excluded from the intent-to-treat analyses.

As secondary analyses, Cox proportional hazards models were considered that compared outcomes of patients admitted during Jan-June 2001 with outcomes of patients admitted to the same hospitals during Jan -June 2004 or Jan-June 2005. These models were stratified by hospital to create within-hospital comparisons that account for clustering of patients within hospitals and control for all hospital characteristics. These models included a term for the time period and a

term for the interaction between time period and hospital selection status (for intent-to treat analyses) or combined selection and participation status (for complier's analyses).

All models considering the outcome of death within 1 year of admission censored patients 1 year after the index admission date. Models considering the outcome of readmission within 1 year of discharge censored patients at the time of death or 1 year after the index admission discharge date. All models controlled for patient-level characteristics including age (in 7 categories: 18-39, 40-49, 50-59, 60-69, 70-79, 80-89, and 90+ years), race (white, black and other) and gender. To ensure a consistent set of hospitals in all analyses, all models excluded admissions to hospitals that did not have at least 1 index admission during each time period under consideration. This led to exclusion of admissions to 18 hospitals (1 randomly selected participating, 2 randomly selected non-participating, and 15 non-selected non-participating) (Figure 1). All analyses excluded admissions for patients aged <18 years.

Several sensitivity analyses were done. All analyses were repeated considering the index hospital to be the hospital at which the patient was admitted after early transfers rather than the hospital at which the patient first presented. The proportional hazards assumption was assessed graphically for each variable in the models through examination of log –log survival curves, and through examination of correlations between Schoenfeld residuals and failure time rankings. Based on these assessments, the proportional hazards assumption was considered reasonable for the patient-level covariates (age category, sex and race). However, to assess the sensitivity of the results to this decision, all proportional hazards models were repeated, stratifying on these patient characteristics. In addition, to further assess the proportional hazards assumption for the main exposures of interest (hospital selection and participation status), all survival analyses were repeated examining the outcomes within 30 and 90 days of admission or discharge.

All analyses were performed using SAS software version 9.2 (SAS Institute, Cary, NC). Cox proportional hazards models used SAS PROC PHREG. All p-values are two sided. P-values less than 0.05 were considered statistically significant.

Human Subjects Review

The Emory University institutional review board (IRB) determined this study to be exempt from IRB review as a non-research activity. The Georgia Department of Human Resources IRB approved this study through its "Approval Without Detailed Review" process, which has criteria similar to criteria for IRB exemption under federal regulations.

RESULTS

Data Set Linkage

After de-duplication and restriction to index admissions, the hospital discharge data set had 134,132 records (Figure 2). The initial death certificate data set had 471,008 records, of which 697 had duplicate longitudinal identifiers. For 65% of sets of mortality records with duplicate longitudinal identifiers, all records in the set had the same death date. Initially, hospital discharge records for 41,155 patients linked with death certificates. Of 11,403 patients for whom the discharge status for the last available stroke admission indicated in-hospital death, 84% linked with death certificates, with 94% of these linkages having the same death date from both data sets. Of 1,994 patients for whom the last available discharge status indicated hospice care, 79% linked with records in the death certificate data set. Among all linkages, 97% had the same race in both data sets. The linked death certificate death date was before the last available discharge date for only 1.3% of linkages, with the death certificate death date being only 1 day before the last discharge date in 81% of those cases. Linkages with death certificate records that were based on longitudinal identifiers for which there had been duplicate death certificate records with discrepant death dates (same longitudinal identifier but different death dates) appeared substantially less reliable using these measures, and linked mortality data for records with those longitudinal identifiers (n=51) were deleted (i.e. patients were considered to not have reliable evidence of death unless there was an in-hospital death date from hospital discharge data). Linked mortality data were also deleted for 76 records for which the date of death from the death

certificate was more than 1 day before the final stroke discharge date. These deletions had minimal impact on the percentage of cases with in-hospital death or discharge to hospice that linked with mortality data (83% and 79% respectively after deletions); however, the percentage of linked in-hospital death cases for which the date of death was the same in both data sets increased to 99%. After all exclusions, the data set included 47,604 records for patients with ischemic stroke admissions during 2001-2005,of which 16,502 linked with a death certificate. Of these, 5,175 admissions were during Jan-June 2001, 4,368 were during Jan-June 2004, and 4,738 were during Jan-June 2005.

Hospital Characteristics

Characteristics of hospitals included in the evaluation by random selection status are shown in Table 1. There were no meaningful differences between randomly selected and non-selected hospitals. Considering hospitals by combined selection and participation status (data not shown), hospitals selected with certainty were the largest facilities, followed by hospitals that were not selected but participated. Among selected hospitals, participating hospitals tended to be larger than non-participating hospitals. Non- selected non-participating hospitals tended to be the smallest hospitals. Hospitals selected with certainty and non-selected participating hospitals were more likely than other hospitals to be located in metropolitan areas and less likely to be located in the coastal plain.

Patient Characteristics

Characteristics of patients by index hospital selection status are shown in Table 1. Compared with patients admitted to non-selected hospitals, patients admitted to selected hospitals were slightly less likely to be of white race. Characteristics of patients admitted during each time period in the analysis are shown in Table 2. Patient age, median length of stay, the percentage of patients who were female, and the percentage of patients who were of white race slightly but progressively decreased from Jan-June 2001 to Jan-June 2004 and Jan-June 2005.

Frequencies of patient outcomes by time period

The frequencies of patient outcomes are shown by hospital selection status in Table 1 and by time period in Table 2. In the 2001-2005 index ischemic stroke admission data set overall, 22.6% died within 1 year of admission, 10.7% were readmitted within 1 year of discharge, and 30.9% either died or were readmitted within 1 year of discharge, with these percentages decreasing over time.

Intent to treat models

During the last 6 months of the pilot registry (Jan-June 2004), patients admitted to randomly selected hospitals had a 19% lower hazard of readmission within 1 year of discharge compared with patients admitted to non-selected hospitals (Table 3). There was no significant difference in the hazard of readmission with in 1 year of discharge between patients admitted to selected and non-selected hospitals during the 6 months before the pilot registry started (Jan-June 2001), or during the period 1 year after the pilot registry ended (Jan-June 2005). There was no significant difference in the average hazard of death within 1 year of admission between patients admitted to selected and non-selected hospitals during any of the time periods.

Comparing January-June 2004 with January-June 2001, there was within-hospital improvement in the hazard of readmission within 1 year after discharge among patients admitted to selected hospitals, but not among patients admitted to non-selected hospitals (Table 4). There was no within-hospital improvement in the hazard of death within 1 year of admission at selected or non-selected hospitals.

Complier's analyses

Comparing January-June 2004 with January-June 2001, within-hospital improvement in the hazard of readmission within 1 year of discharge was observed for all selected groups, regardless of participation status, although none of the hazard ratios were statistically significant (Table 4). Improvement was greatest for selected hospitals that participated in the registry. Similar improvement was not seen among the non-selected hospital groups.

Sensitivity Analyses

The results of the analyses were not substantially changed if the index hospital was the hospital at which the patient was admitted after early transfers rather than the hospital at which the patient first presented, but the percentage of patients with early transfers was low (2.1% overall). The results were also unchanged in proportional hazard models that stratified on patient characteristics rather than controlling for such characteristics in the model.

Considering the outcomes at 30 and 90 days rather than at 1 year did substantially impact the results (Table 3). In intent-to treat proportional hazards models, patients admitted to selected hospitals during the last 6 months of the pilot registry had a higher hazard of death within 30 and 90 days compared with patients admitted to non-selected hospitals (statistically significant for the 30-day outcome). Patients admitted to selected hospitals during the last 6 months of the pilot registry also had a lower hazard of readmission within 30 and 90 days compared with patients admitted to non-selected hospitals (statistically significant for both 30 and 90 day outcomes). Higher hazard ratios for death were associated with lower hazard ratios for readmission, suggesting competing risks.

DISCUSSION

This study suggests that the Georgia Coverdell Acute Stroke Pilot Registry had a positive impact in decreasing readmission for recurrent stroke within 1 year of discharge for admissions during the last 6 months of pilot registry operation. This improvement in outcomes was not seen 1 year after the registry ended. However, these findings must be interpreted with caution.

The apparent effect on readmission was strongest among randomly selected hospitals that participated in the registry, but some improvement in this outcome was also seen among randomly selected hospitals that did not participate. Selected hospitals that were invited to participate, but chose not to, may have declined participation due to already being involved in

other stroke care quality improvement programs, or the invitation may have prompted them to start such a program apart from the pilot registry.

However, there was also a suggestion that there may have been an increased risk of death within the early days after ischemic stroke admission in association with pilot registry operation; although the difference in mortality was not apparent after 1 year. The reason for this finding is not entirely clear. One possible explanation is that it could truly have been a result of the registry, if the registry increased thrombolytic therapy use. A review of trials of thrombolytic therapy use in acute ischemic stroke found that although treatment reduced the odds of death or dependency at 3-6 months, there was an increase the odds of death among treated groups within the first 10 days after stroke which persisted to the 3-6 month follow up point (not statistically significant for r-tPA trials).[18] Despite the risks, t-PA use in properly selected patients is recommended because the substantial benefits of t-PA use in improving functional outcomes have been judged to outweigh these risks.[3] The increase in early mortality observed in this evaluation might be expected only if the pilot registry led to a substantial increase in thrombolytic therapy use during the last 6 months of registry operation. The extent to which this was the case cannot be assessed because centralized chart abstractions were not done during that time period. An alternate explanation could be that severity of illness was differentially increased among selected hospitals during the last 6 months of the pilot registry, but not during the 6-month period one year later. It is not clear why that would have been the case. If the hazard of mortality in the few days immediately following admission was increased among selected hospitals during the last 6 months of the pilot registry, competing risks could have contributed to the apparent decrease in the hazard of readmission for selected hospitals during this period. Another possible explanation of the finding of an increase in early mortality is chance.

Several studies have found improvement in care processes associated with hospital participation in stroke registries[6,7,8,9] and other types of single[10] and multi-hospital [11,12,13,14,15] stroke care quality improvement programs; however, less is known about the impact of these

types of interventions on stroke patient outcomes. Although it might seem logical that improvements in care processes would improve patient outcomes, this cannot be taken for granted.[19] The experience with quality of care measures for heart failure suggests that improvements in care processes are not always associated with improvements in patient outcomes.[17] In the case of stroke care, several studies have documented improved outcomes at the patient-level with specific interventions for stroke patients,[3] and with specific organizational components of stroke care such as treatment in a stroke unit,[20] a dedicated stroke service,[21] and combinations of such measures at the patient level.[22] Studies of stroke patients admitted to Danish hospitals found an association at the patient level between measures of the quality of care delivered to individual patients and outcomes for those patients, including length of stay[23] and 30 and 90 day mortality rates.[24] At the hospital level, Ovbiagele et al, found that a single-hospital intervention implemented to improve use of secondary prevention measures for hospitalized stroke patients was associated with an increase in utilization rates for specific secondary prevention measures,[25,26] and was also associated with a lower rate of vascular events during the 90 days after stroke admission among patients admitted to the intervention hospital compared patients admitted to a similar control hospital.[27] Several studies have found that multi-hospital quality improvement programs for myocardial infarction[28] and heart failure[29] have led to improvements in in-hospital mortality rates. Fonarrow et al. found that a multi-hospital quality-of-care improvement program for heart failure was associated with a non-significant trend toward improvements in 60 and 90 day mortality for heart failure patients.[30] However, to our knowledge, this is the first reported study of the effect of a multi-hospital stroke registry on stroke patient outcomes at the hospital level.

This study had several limitations. Some non-selected hospitals participated in the registry, and some selected hospitals did not participate. This would be expected to bias the results of intent-to-treat analyses towards the null. In addition, although the within-hospital comparisons used in some analyses would be expected to give consistent estimates, estimates

from such models may not be maximally efficient. Evidence of changes in stroke patient outcomes in association with registry operation- both positive and negative- was observed despite these limitations in the efficiency of the study.

The analyses controlled for patient characteristics including age, sex and race, but information about co-morbidities and severity of illness was not available. Although the use of random selection in some analyses, and within hospital comparisons in the others, would be expected to minimize the impact of differences between hospitals in patient mix, random selection at the hospital-level does not guarantee randomization of patient mix. In addition, based on the increase in age over time observed in this study, and data from previous national and multinational studies of patients with myocardial infarction that spanned the time period in this study,[31, 32] one might have expected the prevalence of co-morbidities to have generally increased over the study time period covered. However, other factors may have decreased underlying risk over time. The likelihood that a patient had a previous stroke may not have been constant between time periods. For the baseline period (Jan-June 2001), the process used to create the data set would have ensured that a patient did not have a previous stroke admission in Georgia during the previous 1-1.5 years (during 2000). However, for the later time periods, the number of years for which the patient would not have had a prior stroke admission in Georgia progressively increased. This could have led to a decreased underlying level of risk for death or readmission over time. If changes in patient mix over time were different in selected and non-selected hospitals, this could have affected the conclusions of the study. For example, it is possible that there could have been an increase in admissions of more severely ill patients to participating hospitals because of recognition of the hospital's stroke quality improvement efforts. However, while the apparent impact of the registry reversed 1 year after the end of the pilot registry, it is unlikely that trends in severity would have reversed. In addition, the impact of changes in the prevalence of prior strokes may have been minimized by the presence of a 1-1.5 year period for identification of previous strokes prior to the baseline period. Each year, approximately 23% of

stroke admissions are for recurrent strokes,[1] but the risk of recurrent stroke is highest during the first months after a stroke.[33]

There was also a potential for misclassification of the outcomes considered. The accuracy of the longitudinal identifier in identifying readmissions for the same patient was likely imperfect due to factors such as name changes and data entry errors. In addition, readmissions for stroke that occurred at federal facilities or at facilities outside Georgia would not have been detected. It is also possible that the longitudinal identifier may not be entirely patient-specific, although restriction of the data set to stroke admissions may have helped improve the specificity of the longitudinal identifier in this study. Little information is available regarding the sensitivity and specificity of the specific type of longitudinal identifier used in this study. In the current study, there were few duplicate longitudinal identifiers in the mortality data (697 duplicates out of 471,008 total records, 0.15%), and many of those may have been true duplicate records as they had the same death date as other records with the same identifier. Sensitivity problems due to name changes would be expected to be less common for the population in the current study than for younger populations.

Ascertainment of death was also likely imperfect due to imperfect linkage of hospital admission data and mortality data. Since the hospital discharge data set was restricted to stroke admissions, information from other admissions that may have helped determine the date of death was not available. Deaths outside of Georgia were also not detected. The approach used for record linkage in this study was designed to optimize linkage specificity, perhaps at the cost of some loss of sensitivity, through exclusion of all linkages that appeared to be suspect. A strategy of maximizing linkage specificity in cohort studies involving data base linkage was recommended by Howe[34], because false positives with a rate unrelated to exposure status will attenuate risk ratios toward the null, while false negatives with a rate unrelated to exposure status will minimally impact risk ratios, although there will be a loss of power. In this study, there is no reason to think that misclassification of outcomes would have been differential between hospital

groups. In this study, the percentage of ischemic stroke patients who died within 1 year of admission (23.7% overall) was lower than that observed in some previous studies,[33, 35] but similar to that observed in a study of patents enrolled in the Registry of the Canadian Stroke Network during 2003-2005 (23.6%).[36] The percentage of ischemic stroke patients who were readmitted for stroke within 1 year (11.5% overall) was higher than that found in a study of Connecticut Medicare beneficiaries during 1995 (6.1%),[33] but similar to that found in a study of first ischemic stroke patients in Scotland during 2004-2008 (10.8%). [35] These comparisons provide reassurance that identification deaths and readmissions in our study was reasonably accurate.

This study also has several important strengths. Many previous evaluations of the impact of quality-of-care improvement programs have been limited by availability of data only for hospitals participating in the program. Participating hospitals may be influenced by secular trends apart from the intervention being studied, limiting causal inferences. Even if data on non-participating hospitals is available, participating hospitals may be different from non-participating hospitals in important ways other than participation in the intervention. This study included both participating and non-participating hospitals, and made use of random selection of hospitals to avoid confounding by factors associated with the choice to participate. In addition, this study examined the association between hospital registry participation and patient outcomes beyond discharge. Several previous studies have been limited to looking at in-hospital mortality, which can be influenced by general discharge practices and local availability of various types of post-hospitalization care, such as hospice care.[37,38]

In summary, this study suggests that the GCASR pilot registry may have led to reduced rates of readmission for recurrent stroke, but may also have been associated with increased early mortality after ischemic stroke. Although mortality and readmission for recurrent stroke are only two of the outcomes that stroke patients would value, and readmission for recurrent stroke represents only a portion of all causes for readmission among stroke patients,[33] improvement in readmission for recurrent stroke is important. It will be important to repeat this type of analysis

to determine whether the trends observed for the pilot registry are also seen with the more intensive and longer duration quality improvement interventions used in the current implementation phase registry.

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Figure 1. Hospital Selection and Participation, Georgia Coverdell Acutre Stroke Pilot Registry, 2001-2004

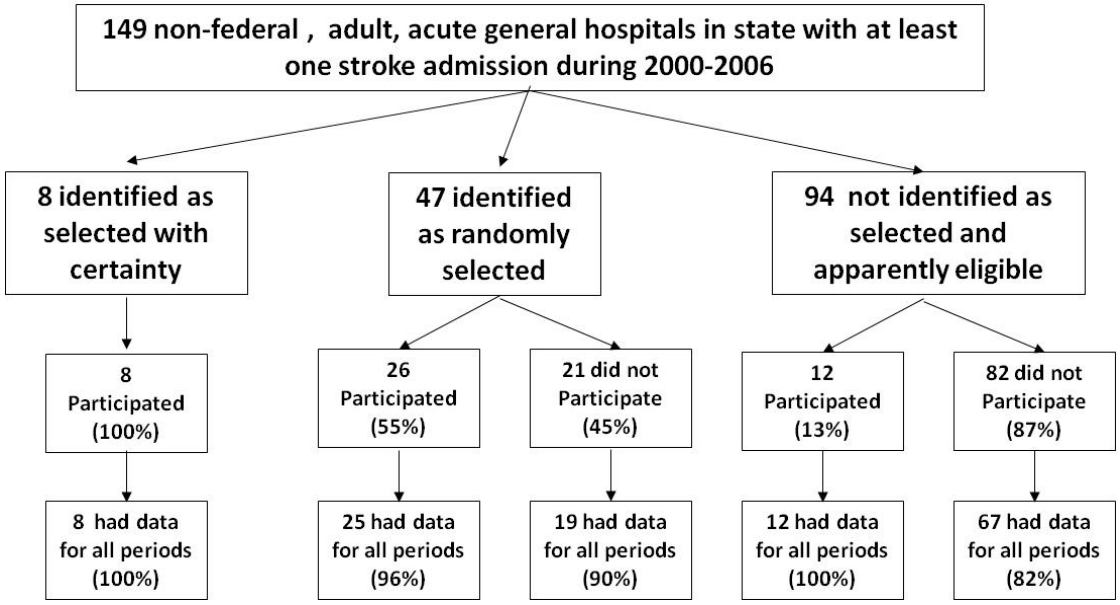

Figure 2. Results of data set linkage

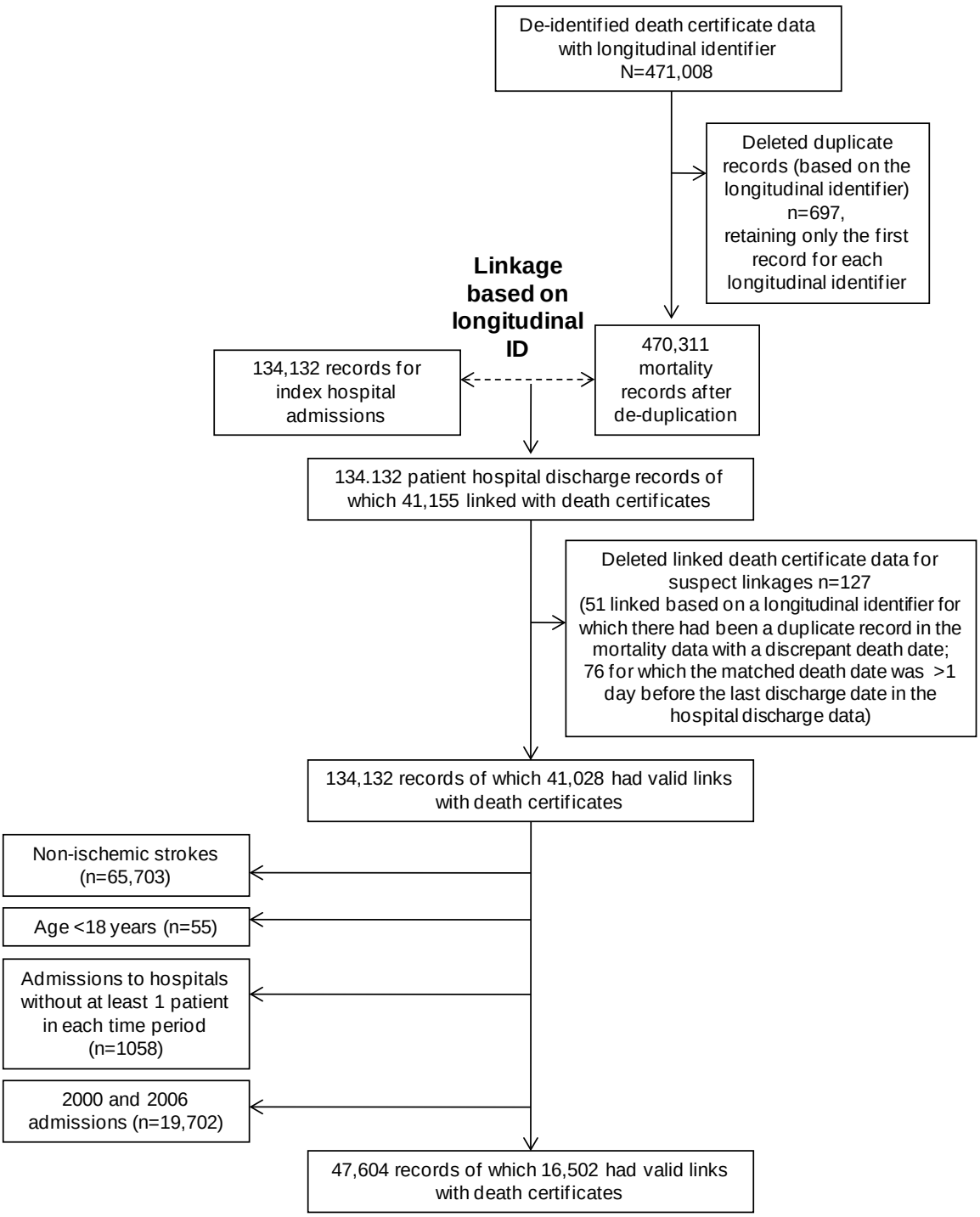

Table 1. Hospital and patient characteristics by hospital registry selection status

		Overall (including selected with certainty)		Randomly Selected		Not Selected	
HOSPITAL CHARACTERISTICS							
Number of Hospitals		131		44		79	
# of 2005 Stroke Admissions (2 unknown)	Median (25%-75%)	87 (34-254)		74 (34-289)		73 (24-203)	
# of beds (2 unknown)	Median (25%-75%)	88 (40-248)		84 (39-282)		79 (37-215)	
		N	**%**	**N**	**%**	**N**	**%**
Primary RUCA Code	Metropolitan Area (RUCA code 1-4)	81	61.8	24	54.5	49	62.0
	Non-Metropolitan (RUCA code >4)	50	38.2	20	45.5	30	38.0
Ownership (5 unknown)	Investor Owned/Other Private	25	19.8	6	14.3	16	21.1
	Not for Profit or hospital authority	101	80.2	36	85.7	60	79.0
Coastal Plain	Yes	63	48.1	26	59.1	37	46.8
	No	68	51.9	18	40.9	42	53.2
Teaching Status	Teaching	13	9.9	3	6.8	7	8.9
	Non-Teaching/Unknown	118	90.1	41	93.2	72	91.1
PATIENT CHARACTERISTICS							
Overall number of Patients		47,604		16,208		25,067	
# of patients per facility	Median (25%-75%)	237 (81-518)		224.5 (87.5-549)		203 (67-482)	
		N	**%**	**N**	**%**	**N**	**%**
Age Category (years)	18-39	1,143	2.4	362	2.2	595	2.4
	40-49	3,512	7.4	1,183	7.3	1,731	6.9
	50-59	7,354	15.4	2,467	15.2	3,729	14.9
	60-69	9,771	20.5	3,283	20.3	5,168	20.6
	70-79	12,175	25.6	4,169	25.7	6,516	26.0
	80-89	10,940	23.0	3,783	23.3	5,916	23.6
	90+	2,709	5.7	961	5.9	1,412	5.6
Sex	Male	20,920	43.9	7,147	44.1	10,854	43.3
	Female	26,684	56.1	9,061	55.9	14,213	56.7
Race	White	30,557	64.2	10,681	65.9	16,969	67.7
	Black or African American	16,023	33.7	5,155	31.8	7,677	30.6
	Asian	311	0.7	85	0.5	155	0.6
	American Indian/Alaska Native	52	0.1	24	0.1	16	0.1
	Native Hawaiian/Pacific Islander	4	0.0	2	0.0	2	0.0
	Multiracial	657	1.4	261	1.6	248	1.0
Principal Ischemic Stroke Diagnosis	433.X1	3,240	6.8	1,242	7.7	1,541	6.15
	434.X1	34,687	72.9	11,642	71.8	18,176	72.5
	436	9,677	20.3	3,324	20.5	5,350	21.3
PATIENT OUTCOMES							
Discharge Status	Died in hospital	2,892	6.1	997	6.2	1,533	6.1
	Hospice	865	1.8	340	2.1	425	1.7
	To another institution	17,143	36.0	6,131	37.8	9,141	36.5
	Home (with or without home health care)	25,386	53.3	8,361	51.6	13,094	52.2
	Other	1,252	2.6	356	2.2	847	3.4
	Unknown	66	0.1	23	0.1	27	0.1
Longer term outcomes	Died within 1 year of admission	10,757	22.6	3,650	22.5	5,803	23.1
	Readmitted within 1 year of admission	5,073	10.7	1,737	10.7	2,704	10.8
	Death or Readmission within 1 year of admission	14,722	30.9	5,001	30.9	7,909	31.6

Table 2. Patient Characteristics by Time Period

		Jan-June 2001		Jan-June 2004		Jan-June 2005	
Overall Number of Patients		5,175		4,368		4,738	
		N	%	N	%	N	%
Hospital Selection Status	Selected with certainty	738	14.3	562	12.9	624	13.2
	Randomly selected	1,751	33.8	1,488	34.1	1,636	34.5
	Not selected	2,686	51.9	2,318	53.1	2,478	52.3
Hospital Selection and Participation Status	Selected with certainty-Participated	738	14.3	562	12.9	624	13.2
	Randomly Selected- Participated	1,071	20.7	916	21.0	1,079	22.8
	Randomly Selected- Did not Participate	680	13.1	572	13.1	557	11.8
	Not Selected-Participated	735	14.2	609	17.0	632	13.3
	Not Selected-Did not Participate	1,951	37.7	1,709	39.1	1,846	39.0
Age	Median (25%-75%)	72 (61-81)		71 (59-81)		71 (58-81)	
Length of Stay	Median (25%-75%)	5 (3-7)		4 (3-7)		4 (3-7)	
		N	%	N	%	N	%
Age Category	18-39	108	2.1	114	2.6	113	2.4
	40-49	332	6.4	309	7.1	404	8.5
	50-59	712	13.8	699	16.0	756	16.0
	60-69	1,041	20.1	943	21.6	979	20.7
	70-79	1,484	28.7	1,044	23.9	1,115	23.5
	80-89	1,219	23.6	1,006	23.0	1,088	23.0
	90+	279	5.4	253	5.8	283	6.0
Sex	Male	2,193	42.4	1,921	44.0	2,162	45.6
	Female	2,982	57.6	2,447	56.0	2,576	54.4
Race	White	3,431	66.3	2,771	63.4	2,963	62.5
	Black or African American	1,649	31.9	1,495	34.2	1,676	35.4
	Other	95	1.8	102	2.3	99	2.1
Principal ICD-9-CM code	433.X1	433	8.4	253	5.8	292	6.2
	434.X1	3,232	62.5	3,058	70.0	4,346	91.7
	436	1,510	29.2	1,057	24.2	100	2.1
Discharge Status for the index admission	Died in hospital	349	6.7	269	6.2	285	6.0
	Hospice	46	0.9	98	2.2	132	2.8
	To another institution	1,981	38.3	1,513	34.6	1,623	34.3
	Home (with or without home health care)	2,735	52.9	2,340	53.6	2,546	53.7
	Other	64	1.2	141	3.2	152	3.2
	Unknown	0	0.0	7	0.2	0	0.0
Outcomes	Died within 1 year of admission	1,231	23.8	979	22.4	1,048	22.1
	Readmitted within 1 year of discharge	594	11.5	472	10.8	510	10.8
	Death or Readmission within 1 year of discharge	1,709	33.0	1,362	31.2	1,455	30.7

Table 3. Intent-to-Treat proportional hazards models with between-hospital comparisons

Outcome Definition			Hazard ratio comparing selected and non-selected hospitals		
Event	**Censoring**	**Time Period**	**Hazard Ratio**	**95% CI**	**p-value**
Death within 1 year	End of 1 year follow up	Jan-June 2001	1.00	0.89-1.11	0.930
		Jan-June 2004	1.05	0.92-1.19	0.475
		Jan-June 2005	1.01	0.87-1.17	0.884
Readmission within 1 year	Death or end of 1 year follow up	Jan-June 2001	1.03	0.85-1.24	0.771
		Jan-June 2004	**0.81**	**0.67-0.98**	**0.026**
		Jan-June 2005	1.18	0.97-1.44	0.105
Death within 90 days	End of 90 day follow up	Jan-June 2001	0.97	0.85-1.10	0.594
		Jan-June 2004	1.15	0.99-1.33	0.070
		Jan-June 2005	0.93	0.77-1.13	0.450
Readmission within 90 days	Death or end of 90 day follow up	Jan-June 2001	1.15	0.93-1.42	0.198
		Jan-June 2004	**0.77**	**0.59-0.99**	**0.043**
		Jan-June 2005	1.11	0.87-1.41	0.424
Death within 30 days	End of 30 day follow up	Jan-June 2001	0.95	0.79-1.14	0.574
		Jan-June 2004	**1.19**	**1.01-1.39**	**0.035**
		Jan-June 2005	0.94	0.76-1.15	0.546
Readmission within 30 days	Death or end of 30 day follow up	Jan-June 2001	1.11	0.79-1.56	0.557
		Jan-June 2004	**0.58**	**0.42-0.82**	**0.002**
		Jan-June 2005	0.91	0.63-1.33	0.629

t0 for death models is the index admission date.
t0 for re-admission models is the discharge date for the index admission.
Models control for age, sex and race, and use robust standard error estimation to account for clustering of patients within hospitals

Table 4. Within-hospital comparisons using proportional hazards models stratified by hospital, considering interaction between time period and selection status

Outcome Definition		Hazard Ratio Comparison	Hazard Ratio comparing follow up period with baseline period		
Event	**Censoring**		**Hazard Ratio**	**95% CI**	**p-value**
Death within 1 year	End of 1 year follow up	Non-Selected	0.94	0.84-1.06	0.344
		Selected	0.99	0.86-1.14	0.874
Readmission within 1 year	Death or end of 1 year follow up	Non-Selected	1.01	0.86-1.19	0.896
		Selected	**0.81**	**0.66-1.01**	**0.061**
Death within 1 year of admission	End of 1 year follow up	Selected with Certainty (all participated)	1.05	0.81-1.35	0.727
		Randomly selected, participated	0.96	0.80-1.16	0.679
		Randomly selected, did not participate	1.03	0.82-1.29	0.825
		Non-selected, participated	0.96	0.77-1.20	0.735
		Non-selected, did not participate	0.94	0.82-1.07	0.353
Readmission within 1 year of discharge	Death or end of 1 year follow up	Selected with Certainty (all participated)	0.82	0.57-1.17	0.277
		Randomly selected, participated	0.79	0.60-1.04	0.087
		Randomly selected, did not participate	0.87	0.62-1.22	0.412
		Non-selected, participated	1.17	0.87-1.58	0.286
		Non-selected, did not participate	0.95	0.78-1.15	0.585

Baseline: Jan-June 2001
Follow up: Jan-June 2004
t0 for death models is the index admission date.
t0 for re-admission models is the discharge date for the index admission.
Models control for age, sex and race.

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Chapter 8: Appendix on Data Quality

Two major components of data quality in a registry like the Georgia Coverdell Acute Stroke Registry (GCASR) are data accuracy and data completeness. Data accuracy relates to how well the data entered into the registry reflects the care delivered to the patient. Data completeness relates to the extent to which information was entered into the registry for all eligible patients. A lack of data accuracy could occur because of inadequate documentation of care in the medical record, or because of inaccurate abstraction of information from the medical record. GCASR was not able to assess the degree to which documentation in the medical record reflected the care delivered to the patient. The medical record was considered as the definitive source of information about care delivered. The degree to which data abstracted from the medical record and entered into the registry accurately reflected information in the medical record was assessed through an inter-rater reliability assessment. A lack of data completeness could occur because of missing individual data elements for patients for whom data was entered, or because of lack of entry of any data for a patient who was eligible for the registry. The registry's on-line data collection tool prevented a record from being saved as complete if some of the required data elements were left blank. Therefore, for those data elements, hospitals were required to either enter a value or indicate that the information was not documented in the medical record. Since the medical record was considered as the definitive source of information about care delivered, this level of data completeness becomes an issue of data accuracy for the required data elements. Therefore, the second level of data completeness, the degree to which data was entered for all eligible patients (referred to as "reporting compliance"), was the measure of completeness that was assessed.

Data Quality Assessment Methods

Inter-rater Reliability Assessment

As part of the registry's data quality monitoring procedures, the Georgia Medical Care Foundation (GMCF) re-abstracted a sample of medical charts from each hospital for admissions during October 6, 2005-April 2, 2007. Charts were randomly selected for re-abstraction from monthly lists of stroke patients submitted by hospitals with corresponding hospital-assigned "Get with the Guidelines" numbers. The data for the re-abstractions were obtained from GMCF. Hospital data were downloaded from the "Get With The Guidelines" (GWTG) web site in January 2008, after hospitals had had a chance to correct some errors. Both data sets were in the GWTG data format and used GWTG variable names. Quality indicator calculations used in this dissertation were defined using the CDC variable names and formats. Therefore, all variables were translated into the CDC data format. Once data had been translated, quality indicator calculations were done for both data sets using the translated data (as described in the methods section). The data from the re-abstractions were then merged with the data from the hospitals by hospital identifier, visit identifier and discharge date. Only records with matches in both files were retained in the final data set for the inter-rater reliability analysis.

Agreement was first assessed for individual data elements involved in quality indicator calculations. For categorical variables, the percentage agreement and kappa values were calculated. For tPA contraindications, a yes/no summary variable was used to indicate whether any valid tPA contraindication was marked in each file, and agreement was calculated based on that summary variable rather than individual contraindications. Decisions about handling missing values were made on a variable-by-variable basis with consideration of the meaning of missing values for each variable to determine if they should be included or excluded from the calculations. In some cases missing values are meaningful, in some cases they may be equivalent to a "no" or "not documented" response, and in some cases they are not meaningful at all (for example due to skip patterns). In general, observations with missing values for a particular

variable were excluded from analyses for that variable unless noted. For variables for which some values were used by one abstractor but not the other, observations with 0 weights were added to allow calculation of kappa values. For continuous variables such as dates and times, small differences in recorded values are likely, but they are only meaningful if they are large or if they affect quality indicator calculations. Therefore, for continuous variables, the difference between the two values was calculated and the distribution of the differences was examined.

After assessment of agreement at the individual variable level, agreement was assessed at the level of the quality indicator calculations. For quality indicator calculations, the percentage agreement and kappa values were first calculated for quality indicator qualification vs. non-qualification. The percentage agreement and kappa values were than calculated for whether or not the quality indicators were met. This was done using a three-level categorization (not eligible, eligible but did not receive care meeting indicator, eligible and received care meeting the indicator), and also a two level categorization (did or did not receive care meeting the quality indicator) for cases in which both abstractions agreed on quality indicator eligibility.

To describe variability in agreement, the percentage agreement for the quality indicators was calculated overall and by hospital. The distribution of the percentage agreement of among hospitals was examined, and hospitals were categorized as having high agreement (above median) or low agreement (below median) for each quality indicator. The percentage agreement across all hospitals was also calculated by month. Trends over time in the overall percentage agreement were assessed graphically for each quality indicator, with the graphs restricted to months with at least 5 abstractions. These assessments did not account for clustering of data by hospital.

In these analyses the statistical significance of kappa values was assessed using 95% confidence intervals and a two-sided exact test of the null hypothesis that kappa=0. All analyses were conducted in SAS using PROC FREQ for percentage agreement and kappa values, and PROC UNIVARIATE for comparison of the distribution of differences for continuous variables.

Reporting Compliance

Hospitals were asked to abstract data for all admissions with a clinical diagnosis of acute stroke. Compliance with reporting of all stroke admissions was assessed in two ways:

-Method1: The registry asked participating hospitals to submit to GMCF monthly logs of all discharges with a principal diagnosis of stroke (included discharges with principal diagnosis ICD-9 codes of 430,431,432.9, 433.01, 433.11, 433.21, 433.31, 433.81, 433.91, 434.00, 434.01, 434.10, 434.11, 434.90, 434.91, 435.0, 435.1, 435.2, 435.3, 435.8, 435.9, 436), including the corresponding GWTG tool case numbers for cases to which such numbers had been assigned. These cases were assumed to have been entered into the tool. This assessment was done for all hospitals recruited during the first recruitment cycle, but only for hospitals in the representative sample (not volunteer hospitals) among hospitals recruited during the second recruitment cycle. The final assessment was based on hospital discharge data submitted as of June 29, 2007 by 30 reporting entities for 34 hospitals, including all 26 year 1 hospitals and 8 of 20 randomly selected year 2 hospitals. The number of cases on the discharge logs that had corresponding GWTG numbers listed was calculated for each hospital. This method was limited by the fact that hospitals may have misunderstood the intent of the assessment and submitted lists only containing entered cases, or hospitals may not have been motivated to make sure that the list included cases not entered into the tool.

-Method 2: The number of stroke discharges for each hospital during 2006 was calculated from hospital discharge data based on ICD-9 CM codes 430-438. The ratio of the number of stroke patients entered into the registry database with discharge dates during 2006 to the number of stroke discharges in hospital discharge data for 2006 was then calculated for each hospital (referred to as the “reporting ratio”). Limitations of this method include the fact that some hospitals may enter cases not admitted to the hospital (patients visiting the emergency department only), and those cases would not be in the

hospital discharge data. In addition, some hospitals also entered information for their smaller affiliates into the database for the larger hospital (3 hospitals did this), and it is not possible to account for this in the analysis. Finally, discharge diagnoses of stroke do not correlate perfectly with a clinical diagnosis of acute stroke. This analysis was restricted to cohort 1 hospitals because they participated during all of 2006, while cohort 2 hospitals started in November 2006, and may not have reached a full participation level for November and December 2006 hospitalizations. The distribution of hospital-specific reporting ratios was examined.

Assessment of Registry Call Participation

The extent of a hospital's participation in registry quality improvement activities was considered as a factor potentially related to data accuracy and completeness. Participation in registry quality improvement activities may be a reflection of the level of institutional commitment to the registry, which could in turn impact data accuracy and completeness. In addition, participation in registry quality improvement activities could be a cause of improved data accuracy and completeness, because data quality and completeness were sometimes addressed through the quality improvement activities. We used hospital participation in the monthly registry-wide conference calls as a measure of participation in registry quality improvement activities.

For each hospital, the number of calls in which the hospital participated was divided by number of calls in which that hospital could have participated in based on registry start and end dates. Call dates included for this calculation ranged from January 2006 to April 2008, to allow a stable estimate of the degree of participation.

Assessment of Quality Indicator Adherence

The degree of adherence with each of the quality indicators was also considered as a factor potentially related to data accuracy. Hospitals that are more interested in stroke care quality improvement may be more careful about accuracy and completeness. Alternatively, data

quality could have a direct impact on the observed percentage adherence. For example, if a hospital systematically misinterpreted the definitions for a data element that is critical to a quality indicator, that hospital could have a falsely high or low apparent level of adherence with the indicator. Quality indicator adherence was assessed as described in the methods section.

Assessment of Relationships between Measures of Data Quality, Reporting Compliance, Hospital participation, and Hospital Characteristics

Descriptive analyses were done to look at associations between the measures of data quality and other factors. Relationships at the hospital level were examined between the following measures: (1) the hospital's percentage adherence for one quality indicator compared with the hospital's percentage adherence for each of the other quality indicators, (2) the hospital's percentage agreement from the IRR analysis for one quality indicator compared with the hospital's percentage agreement from the IRR analysis for each of the other quality indicators, (3) the hospital's percentage agreement from the IRR analysis for each of the quality indicators and the hospital's reporting ratio (from method 2 for assessment of reporting compliance), (4) the hospital's reporting ratio and the percentage adherence during 2006 for each quality indicator, (5) the hospital's overall percentage adherence with each quality indicator during 2006 and the hospital's percentage agreement from the IRR analysis for each quality indicator, (6) the hospital's call participation percentage and the hospital's reporting ratio, (7) the hospital's call participation percentage and the hospital's percentage agreement from the IRR analysis for each quality indicator, and (8) the hospital's call participation percentage and the hospital's overall percentage adherence with each quality indicator during 2006. Correlations were examined between hospital-level variables, using Spearman correlation coefficients due to non-normality of several variables. All of these analyses are of an exploratory nature. Statistical tests should be interpreted with caution because the numbers used are treated as fixed values, when they are actually estimates that vary in precision. These are approximate comparisons that do not take the variability in the estimates into account.

Finally, associations with hospital characteristics were assessed for the IRR percentage agreement and reporting ratios. Comparisons were done using the Wilcoxon rank sum test due to non-normal distributions. However, as noted above, these analyses must be considered exploratory. Statistical tests must be considered with caution because the numbers are treated as fixed values, when they actually are estimates that vary in precision. These are approximate comparisons that do not take the variability in the estimates into account.

Results

GMCF staff abstracted 822 medical charts. Of these, 11 in-hospital strokes, one duplicate record, and 2 records with missing hospital identification numbers were initially excluded. After the match between the re-abstracted data and the data from the registry database, 190 additional records that could not be matched with patient records in the registry database were also excluded, leaving 618 records with matching data for the analysis. There was at least one re-abstracted chart in the analysis for 29 hospitals, with the number of charts per hospital ranging from 1 to 67. Three hospitals had less than 5 charts with re-abstraction data.

Inter-rater Reliability

For individual categorical data elements involved in quality indicator calculations, overall agreement was generally good, with the percentage agreement >80% and kappa values >0.6, except for data elements related to dysphagia screening and DVT prophylaxis, and less specific stroke diagnoses (Table 8A). The data element for screening for dysphagia before any oral intake had the lowest percentage agreement, 46.6%, with a kappa value of 0.26. The two data elements related to DVT prophylaxis, ambulation without assistance within 48 hours and DVT prophylaxis initiated within 48 hours after arrival, had percentage agreement of 70.5% and 59.6% respectively and kappa values of 0.47 and 0.32 respectively. The less specific stroke diagnoses, ischemic stroke of uncertain duration, hemorrhagic stroke NOS, and stroke NOS had low kappa values, but were uncommon diagnoses. The diagnoses of ischemic stroke of uncertain duration and stroke

NOS were used more often by hospitals than by the central abstractors, while the diagnosis of hemorrhagic stroke NOS was used more commonly by the central abstractors. Use of an intra-arterial clot removal device also had low agreement (76.1%, kappa -0.02) but was uncommonly documented (hospitals 0%, central abstractors 0.49%).

For dates, overall agreement was lowest for date and time of arrival at the hospital and date and time of stroke onset, both of which are involved in the tPA quality indicator calculation (Table 8B). The difference between the two abstractions in the date and time of stroke onset was more than 1 hour in 37.9% of cases and greater than 2 hours in 34.8% of cases. The difference between the two abstractions in the date and time of arrival at the hospital was greater than 1 hour in 15.9% of cases and greater than 2 hours in 13.3% of cases. Differences of this magnitude would significantly impact the tPA quality indicator calculations. In contrast, agreement on the date and time of tPA administration was good, with 10 of 12 cases having the two abstracted times within 10 minutes of each other.

The results of overall agreement at the level of the quality indicator calculation, rather than at the level of individual data elements, are shown in Table 8C. Agreement on quality indicator eligibility was >85% for DVT prophylaxis, smoking cessation counseling, and tPA. However, the percentage agreement was lower, at 77.2% for dysphagia screening. If all categories of the quality indicator calculations are considered (ineligible, eligible and did not meet, and eligible and met), overall agreement was lower, particularly for dysphagia screening, for which agreement was 61.8%. When agreement on meeting the quality indicator was considered only among patients for whom both abstractions agreed on quality indicator eligibility, dysphagia screening still had the lowest agreement (68.5%), but tPA administration also had relatively low percentage agreement (71.4%). In general, agreement was higher for quality indicator eligibility than for whether or not an indicator was met given agreement on eligibility.

When inter-rater agreement at the quality indicator level was examined over time, DVT prophylaxis, smoking cessation counseling and tPA administration all had relatively stable agreement percentages (Figure 8A). Dysphagia screening, however, showed a pattern of a marked decrease in agreement over the first 7 months, followed by an increase in agreement. These trends should be interpreted with caution because the number of re-abstractions for some months were low, and because the exact mix of hospitals for which abstractions were done was not constant over time. However, there is a mix of hospitals throughout the time period, rather than data for hospitals being sequential. When considered at the hospital level, inter-rater reliability for the three-level quality indicator calculations was most consistent between hospitals for tPA administration (inter-quartile range 91.3%-100%) but varied more between hospitals for the other quality indicators (Table 8D). However, the data for hospital-level percentage agreement should be interpreted with caution given the wide range in the number of records per hospital in the analysis (1-67 with 3 hospitals having <5 records in the analysis).

Reporting Compliance

Data on completeness of reporting using method 1 were available for 30 hospitals. The time period covered by the data submitted varied by hospital. The number of months for which data were available ranged from 4 to 19, with 23 hospitals having data for ≥15 months. The hospital-specific percentage of cases on the discharge lists that had corresponding GWTG numbers ranged from 72% to 100%, with 25 having numbers for more than 90% of cases on the discharge list, and an additional 2 having numbers for at least 80% of cases on the discharge lists. The overall percentage of cases with corresponding GWTG numbers (and assumed to have been entered in to the tool) based on figures from this reporting was 94% (Table 8D). Data on completeness of reporting using method 2 were available for 23 hospitals. The hospital-specific ratio of the number of cases entered to the predicted number of stroke discharges ("reporting ratio") ranged from 0.34 to 2.77, with a median ratio of 0.79 (Table 8D).

Relationships between Data Quality (IRR), Reporting Ratio, Call Participation, Quality Indicator Adherence, and Hospital Characteristics

The results of explorations of relationships at the hospital level between inter-rater reliability percentage agreement for the four quality indicators, the reporting ratio, call participation, and quality indicator adherence are shown Table 8E. The only significant correlations observed between these measures were a significant correlation between higher call participation percentage and higher adherence with the dysphagia screening indicator (Spearman rank order correlation coefficient 0.48, p=0.003), a significant correlation between increased adherence with the dysphagia screening indicator and increased adherence with the tPA indicator (Spearman rank order correlation coefficient 0.56, p=0.001), and a significant correlation between increased adherence with the smoking cessation counseling indicator and a decreased reporting ratio (Spearman rank order correlation coefficient -0.49, p=0.03).

The results of explorations of associations between hospital characteristics and both data quality measures are shown in Tables 8F-8H. A higher number of 2006 stroke admissions was significantly correlated with a lower reporting ratio (Spearman rank order correlation coefficient -0.71, p=0.0002), higher call participation (Spearman rank order correlation coefficient 0.55, p=0.0001), and higher percentage adherence with the dysphagia screening quality indicator (Spearman rank order correlation coefficient 0.44, p=0.0075) (Table 8F). In a categorical analysis, the reporting ratio tended to be higher among hospitals with a number of beds below the median and with a number of 2006 stroke admissions below the median (Table 8G). The percentage agreement from the inter-rater reliability analysis for the t-PA quality indicator did not vary substantially by the hospital characteristics examined. The percentage agreement for dysphagia screening showed more variation in agreement between hospitals than was observed for the other indicators, and tended to be lower at teaching hospitals than at non-teaching hospitals. The percentage agreement for the DVT prophylaxis quality indicator tended to be lower among cohort 1 hospitals than among cohort 2 hospitals. The percentage agreement for the

smoking cessation quality indicator was overall lower among private hospitals, but was >80% for both private and not-for profit hospitals. All of these associations must be interpreted cautiously because they do not take into account the uncertainty in the measures of data quality, the reporting ratio, and quality indicator adherence. The number of observations on which these estimates were based varied substantially between hospitals, leading to varying degrees of uncertainty in the estimates.

Conclusions

Inter-rater Reliability

Consideration of inter-rater reliability at the level of the quality indicator calculations complements calculations at the individual data element level. For assessment of quality of care, reliability at the quality indicator level is important to accurate assessment of quality of care. In addition, consideration of agreement at this level can help address some of the limitations of assessments for individual data elements. In some cases, a lack of agreement at the data element level is not meaningful for some data elements when other data elements are considered. For example, if a patient has a hemorrhagic stroke, a lack of agreement on the specific reasons entered for non-treatment with t-PA is not important because the patient clearly is not eligible to receive t-PA. Similar situations can arise for other quality indicators as well. However, in order to understand the reasons for low agreement at the quality indicator level, it is important to examine agreement at the data element level.

The inter-rater reliability assessment does not assume that either the GMCF abstraction or the hospital abstraction is the gold standard. Both abstractions were to be based solely on information in the medical record, but staff at an individual hospital may be more familiar with methods of documentation at their institution than an outside abstractor would be. However, it is possible that the abstraction done by an outside reviewer may be more objective.

Two measures of inter-rater reliability were presented here, the percentage agreement and the kappa value. Both the percentage agreement and the kappa values have limitations. The percentage agreement is limited by the fact that a certain level of agreement can happen by chance, and this is more likely when the prevalence of a particular value is very high or very low. Kappa values take this chance agreement into consideration. However, in the situation of very high or very low prevalence, the kappa value can be low despite very good agreement between raters.

The level of agreement appeared to be generally acceptable for all of the indicators, but was lowest for dysphagia screening. It appears that understanding of the data elements involved in the dysphagia screening indicator was poor at some hospitals, and that it varied over time. Hospital abstractors tended to indicate higher percentage adherence for the dysphagia screening indicator than the GMCF abstractors, which could have inflated the apparent adherence level, especially during periods with particularly low agreement. Dysphagia screening was the focus of two separate calls during the time period covered in these analyses. Issues of correct abstraction were addressed on the calls as well as in a newsletter, and call participation appeared to be associated with higher inter-rater reliability for this data element. The variation in inter-rater reliability over time for dysphagia screening could have an impact on trends over time for this quality indicator.

When the findings of study 1 are considered in light of these findings, several points are worth noting. In general, differences in data quality do not appear to be the explanation for the differences in baseline adherence and adherence trends that were seen between groups by hospital characteristics in study 1. However, the results of analyses for dysphagia screening must be considered as more susceptible to potential data quality issues than analyses for the other indicators.

Reporting Compliance

Two methods for assessing reporting compliance were used, and both have limitations. In general, method 2 is less likely to be biased than method 1. It appeared that there was a lack of understanding among hospitals of the intent of the lists of stroke discharges used in method 1, leading to incomplete listing of admissions. The most notable association with the reporting ratio from method 2 was hospital size, with lower reporting ratios seen at larger hospitals. While the goal was entry of all stroke admissions, it is known that some of the larger hospitals used sampling procedures due to the volume of work involved in abstractions for a high number of stroke admissions. As long as these hospitals were using an unbiased method of selecting admissions for abstraction, the lower reporting ratio may not be a serious limitation for these larger hospitals, because they may still have had an adequate number of patients entered to achieve a reliable estimate of quality of care.

Comparison with Previous Publications Regarding Coverdell Data Quality

There have been two previous publications relating to the inter-rater reliability of the Coverdell data elements. Both reported on data from the Coverdell prototype registries (the pilot period). One reported on data from an audit done by the Research Triangle Institute.[113] Comparison of the results from that study and this analysis is difficult because the percentage agreement was reported for data elements in groups rather than for individual data elements. In addition, the data elements have been revised since the prototypes, and the methods used in the prototypes were different from those used in the implementation phase. For example, in Georgia, all data abstraction during the prototype phase was done centrally, by abstractors at GMCF, rather than being done at hospitals. The second published report on the inter-rater reliability of the Coverdell data elements reported on re-abstractions done by the Michigan prototype registry.[114] In comparison with that report, the kappa values for the stroke types found in this analysis were comparable or slightly higher, but the kappa values for the dysphagia screening and DVT prophylaxis data elements were lower. That study was comparable to this analysis in that the

initial abstractions were done by trained staff at hospitals and the re-abstractions were done by a central abstractor. However, as noted above, this comparison is limited by the fact that the data elements have changed since that time. In addition, that report was based on 104 re-abstractions, while this analysis uses 618 re-abstractions, and this analysis considered agreement at the quality indicator level while that report did not.

Table 8A: Inter-Rater Reliability Assessment for Individual Categorical Data Elements (n=618 unless indicated)

	% Yes		% Agreement	Measure of Inter-rater agreement (kappa)		
	Hospital	**GMCF**		**kappa**	**95% CI**	**Exact p-value (H0: kappa=0)**
Final Diagnosis of ischemic stroke	57.4	59.9	87.9	0.75	0.70-0.80	<0.001
Final Diagnosis of ischemic stroke of Uncertain Duration	1.0	0.5	98.5	-0.01	-0.01- -0.001	1.000
Final Diagnosis of TIA	20.4	21.7	93.2	0.80	0.74-0.85	<0.001
Final Diagnosis of intracerebral hemorrhage	12.3	12.1	97.9	0.90	0.85-0.95	<0.001
Final Diagnosis of subarachnoid hemorrhage	2.9	2.9	99.7	0.94	0.86-1.00	<0.001
Final Diagnosis of hemorrhagic stroke NOS	0.7	0.8	99.2	0.44	0.03-0.85	0.003
Final Diagnosis of stroke NOS	3.6	0.7	95.8	-0.01	-0.02- -0.002	1.000
Discharge Destination	---	---	83.7	0.77	0.73-0.81	<0.001*
Ambulating without assistance within 48 hours (n=616)†	36.7	41.7	70.5	0.47	0.41-0.53	<0.001
DVT prophylaxis initiated within 48 hours after arrival‡	62.6	50.5	59.6	0.32	0.26-0.38	<0.001*
Screening for dysphagia prior to any oral intake	53.2	31.7	46.6	0.26	0.21-0.31	<0.001*
History of Smoking (at least one cigarette in past year)	20.6	21.5	88.4	0.65	0.58-0.72	<0.001
Smoking cessation counseling or treatment† (n=617)	23.3	16.2	87.4	0.60	0.53-0.68	<0.001

Table 8A: (Continued)

IV tPA administered at this hospital	2.1	1.9	99.8	0.96	0.88-1.00	<0.001
IA Thrombolytic administered at this hospital	0	0	100	NA	NA	NA
IV tPA administered at a transferring hospital	0.5	0.3	99.8	0.80	0.41-1.00	<0.001
Use of an intra-arterial clot removal device	0	0.5	76.1	-0.02	-0.09- 0.06	0.732
Thrombolytic administered, type not specified	0.2	0	99.8	0	-0.00- -0.00	1
Thrombolytic Investigational Protocol (n)	0.2 (1)	1.0 (6)	----	----	----	----
Any Reason for no TPA Marked	10.5	5.8	89.2	0.28	0.16-0.41	<0.001

*Asymptotic p-value for kappa due to insufficient computational resources for exact computations.

†Records with missing values in the hospital data set were excluded from the calculation (n's indicated).

‡Missing values included in computation of agreement and kappa.

Table 8B: Inter-rater Reliability for Dates (only for records with non-missing date values for both abstractions)

			Difference (Hospital-Central)								
Variable	**n***	**% Agree**	**Percentiles**							**% >60 minutes or <-60 minutes**	**% >120 minutes or <-120 minutes**
			Min.	**10%**	**25%**	**50%**	**75%**	**90%**	**Max.**		
Hospital admission date (days)	617	93.8	-2556	0	0	0	0	0	10	---	---
Date and time of arrival at hospital (minutes)	571	56.0	-525,905	-36	0	0	1	30	216,000	15.94%	13.30%
Date and time of stroke onset (symptom onset if available, otherwise last known well) (minutes)	486	54.3	-525,592	-975	0	0	0	900	217,440	37.86%	34.78%
Date and time of IV tPA administration at this hospital (minutes)	12	99	-50	-1	0	0	4	15	960	8.3%	8.3%
Date and time of IA thrombolytic administration at this hospital (minutes)	0	--	--	--	--	--	--	--	--		
Date and time of use of IA clot device (minutes)	0	--	--	--	--	--	--	--	--		
Date and time of administration of thrombloytic (type not specified) at this hospital (minutes)	0	---	---	---	---	---	---	---	---		

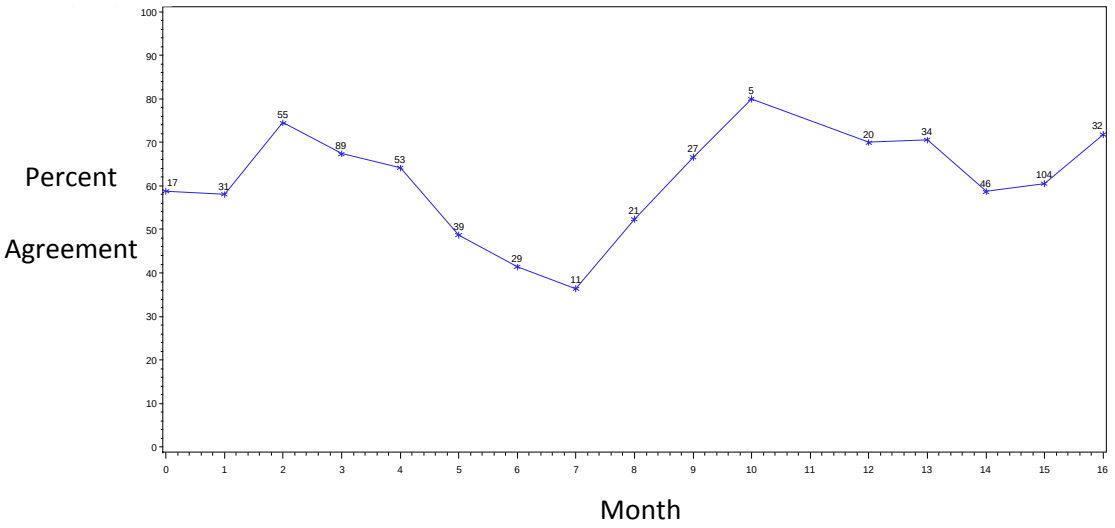
***Number non-missing for both abstractions**

Table 8C: Inter-Rater Reliability Assessment for Quality Indicators

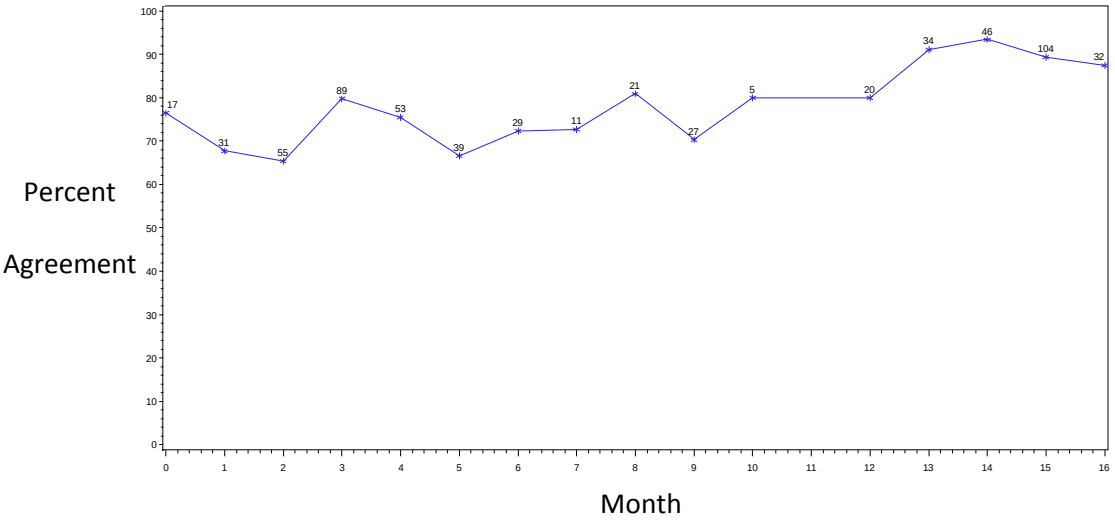
	n	% Yes		% Agree	Measure of Inter-rater agreement (kappa)		
		Hospital	GMCF		kappa	95% CI	Exact p-value (H0: kappa=0)
Quality Indicator Eligibility							
DVT eligibility	618	37.5	39.2	85.4	0.69	0.63-0.75	<0.001
Dysphagia Screening eligibility	618	67.0	53.6	77.2	0.53	0.47-0.60	<0.001
Smoking Cessation eligibility	618	17.5	17.8	90.3	0.67	0.59-0.74	<0.001
tPA eligibility	618	4.1	5.2	95.3	0.47	0.30-0.63	<0.001
Quality Indicator Met (all categories considered, including missing)							
DVT met	618	32.0	31.4	79.6	0.60	0.55-0.66	<0.001
Dysphagia met	618	42.4	26.1	61.8	0.43	0.37-0.48	<0.001
Smoking Cessation met	618	14.4	13.3	87.9	0.60	0.52-0.67	<0.001
tPA met	618	1.3	1.0	94.7	0.40	0.25-0.55	<0.001
Quality Indicator Met (when both agreed that the patient was eligible)							
DVT met	192	86.5	82.3	81.3	0.29	0.12-0.47	<0.001
Dysphagia met	302	60.9	49.3	68.5	0.37	0.27-0.47	<0.001
Smoking Cessation met	79	86.1	74.7	81.0	0.41	0.17-0.65	<0.001
tPA met	14	50	35.7	71.4	0.43	-0.03-0.88	0.266

Figure 8A. Quality Indicator IRR trends over time (restricted to months with at least 5 abstractions)

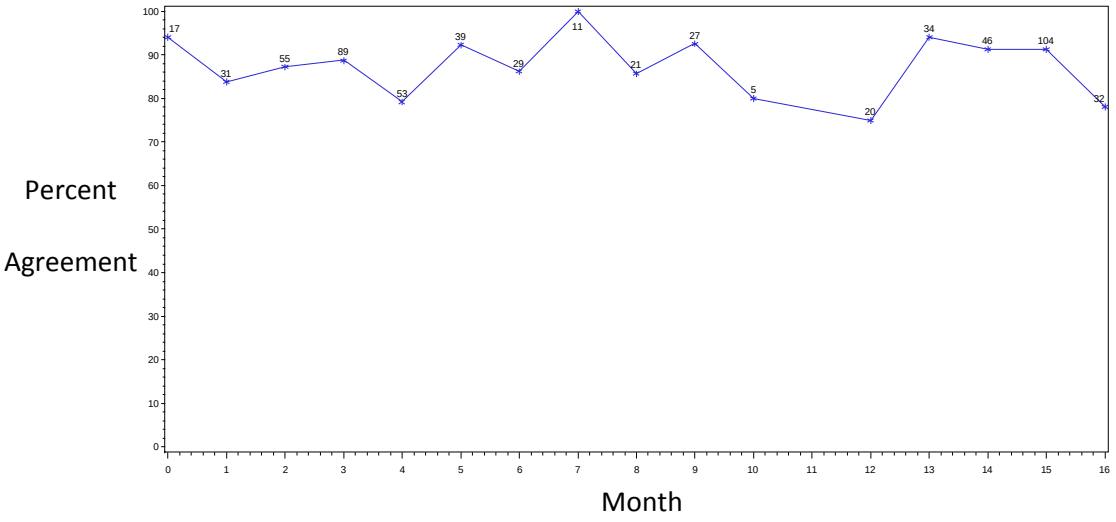
Dysphagia



DVT



Smoking Cessation



tPA

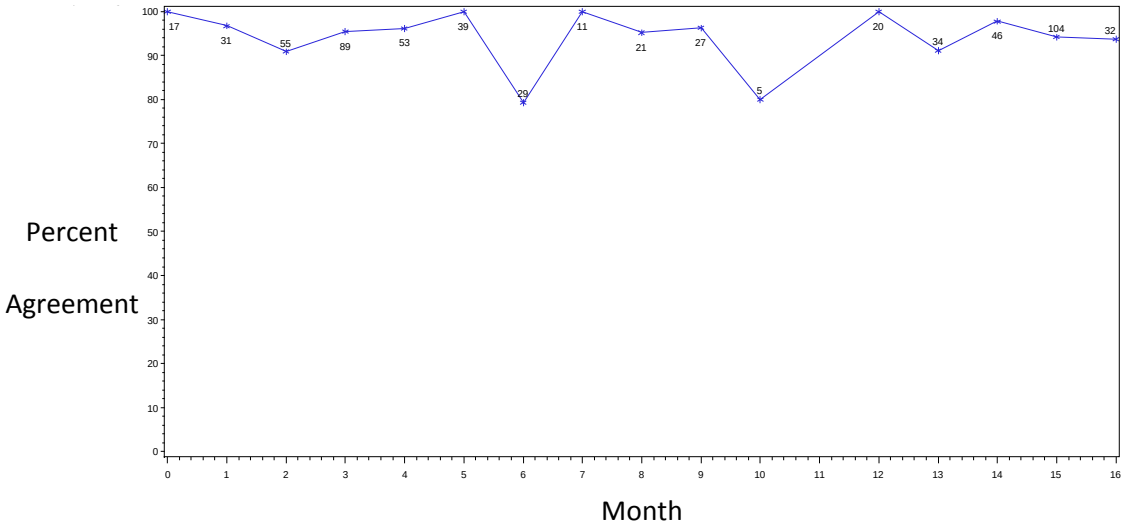


Table 8D: Distributions of Hospital-level Data Quality, Registry Participation, Quality Indicator Adherence, and Patient Outcome Measures

Measure		#of hospitals with data	Percentiles				
			Min	25%	50%	75%	Max
Reporting Compliance	Ratio of number of cases entered for 2006 admissions to number 2006 hospital discharge data (method 2)	23	0.339	0.512	0.786	0.981	2.765
	Percentage of cases on discharge logs that had corresponding GWTG numbers (method 1)*	30	71.6	94.7	99	100	100
Call Participation	Call Participation Percentage	45	0	27.8	53.8	76.9	100
Inter-rater Reliability for Quality Indicators**	Percentage agreement for DVT	29	54.5	73.7	80.8	88.2	100
	Percentage Agreement for Dysphagia	29	33.3	57.1	65.1	70.8	100
	Percentage Agreement for t-PA	29	77.8	91.3	95.8	100	100
	Percentage Agreement for Smoking Cessation	29	61.5	84.2	90.9	100	100
Quality Indicator Adherence During 2006	DVT adherence during 2006	35	0	74.2	83.6	95.7	100
	Dysphagia adherence during 2006	36	0	16	36	75	100
	t-PA adherence during 2006	30	0	0	33.7	46.2	100
	Smoking Cessation adherence during 2006	30	0	61.1	84	93.8	100
Patient Outcomes during 2005	Percentage of 2005 index admissions readmitted within 1 year (before death)	52	0	7.8	11.4	16.3	33.3
	Percentage of 2005 index admissions dying within 1 year	52	0	40	45.7	51.9	100
	Percentage of 2005 index admissions with readmission or death within 1 year	52	0	48.3	55.6	59.5	100

*The number of months for which data were available for each hospital ranged from 4 to 19, with 23 hospitals having data for ≥15 months.

**The number of records per hospital in the IRR analysis ranged from 1 to 67 with 3 hospitals having <5 records in the analysis.

Table 8E. Correlations between hospital participation, data quality, and quality indicator adherence

				IRR Agreement (October 6, 2005-April 2, 2007)				Quality Indicator Adherence, 2006			
		Reporting Ratio, 2006	Call Participation Percentage, January 2006-April 2008	DVT	Dysphagia	tPA	Smoking Cessation	DVT	Dyaphagia	tPA	Smoking Cessation
	Reporting Ratio, 2006		-0.207 p=0.344 n=23	0.145 p=0.529 n=21	-0.353 p=0.116 n=21	-0.135 p=0.559 n=21	0.211 p=0.360 n=21	-0.383 p=0.078 n=22	-0.442 p=0.40 n=22	-0.027 p=0.906 n=21	**-0.490 p=0.028 n=20**
	Call Participation Percentage, January 2006-April 2008			-0.207 p=0.281 n=29	-0.156 p=0.420 n=29	-0.098 p=0.615 n=29	-0.141 p=0.465 n=29	0.138 p=0.431 n=35	**0.4814 p=0.003 n=36**	0.291 p=0.119 n=30	0.245 p=0.192 n=30
IRR Agreement (October 6, 2005-April 2, 2007)	DVT				0.006 p=0.975 n=29	-0.212 p=0.270 n-29	0.181 p=0.349 n=29	0.315 p=0.117 n=26	-0.122 p=0.546 n=27	0.091 p=0.673 n=24	0.0678 p=0.747 n=25
	Dysphagia					0.095 p=0.625 n=29	0.075 p=0.700 n=29	0.085 p=0.679 n=26	-0.035 p=0.122 n=27	-0.284 p=0.179 n=24	0.266 p=0.198 n=25
	tPA						0.059 p=0.760 n=29	-0.218 p=0.284 n=26	-0.335 p=0.088 n=27	-0.109 p=0.611 n=24	0.128 p=0.544 n=25
	Smoking Cessation							-0.361 p=0.070 n=26	-0.005 p=0.982 n=27	0.296 p=0.160 n=24	-0.050 p=0.814 n=25
Quality Indicator Adherence, 2006	DVT								0.220 p=0.212 n=34	0.344 p=0.063 n=30	0.250 p=0.190 n=29
	Dysphagia									**0.563 p=0.001 n=30**	0.284 p=0.135 n=29
	tPA										-0.058 p=0.769 n=28
	Smoking Cessation										
	% with Readmissin or death within 1 year, 2005										

Spearman Rank Order Correlation Coefficients are used.

Table 8F. Correlations between number of 2006 stroke admissions, hospital participation, data quality, and quality indicator adherence

			IRR Agreement (October 6, 2005-April 2, 2007)				Quality Indicator Adherence, 2006			
	Reporting Ratio, 2006	Call Participation Percentage, January 2006-April 2008	DVT	Dysphagia	tPA	Smoking Cessation	DVT	Dyaphagia	tPA	Smoking Cessation
Number of 2006 Stroke Admisisons	-0.705 p=0.0002 n=23	0.545 p=0.0001 n=45	0.125 p=0.5189 n=29	0.078 p=0.6890 n=29	-0.069 p=0.7208 n=29	-0.022 p=0.9097 n=29	0.309 p=0.0707 n=25	0.438 p=0.0075 n=36	0.248 p=0.1873 n=30	0.292 p=0.1173 n=30

Table 8G. Associations between Hospital Characteristics and Reporting Ratio

	Reporting Ratio						
		Percentiles					
Hospital Characteristics	# of hospitals with data	Min.	25%	50%	75%	Max.	Wilcoxon rank sum test p-value
Cohort							
1	23	33.9	51.2	78.6	98.1	276.5	--
2	--	--	--	--	--	--	
Volunteer							
Yes	5	40.1	59.9	78.6	85.4	276.5	0.912
No	18	33.9	51.2	80.6	98.1	111.8	
Number of beds							
<250 beds	9	42.4	90	100	110.1	276.5	**0.01**
≥250 beds	14	33.9	48.4	67.3	83.2	90.3	
Number of 2006 stroke admissions							
<258 admissions	10	42.4	85.4	95	110.1	276.5	**0.013**
≥258 admissions	13	33.9	48.4	65.9	78.6	98.1	
Ownership							
Private	5	42.4	65.9	85.4	88.3	98.1	0.912
Not for Profit/Hospital Authority	18	33.9	51.2	78.3	100	276.5	
Primary RUCA Code							
Micropolitan, Small Town, Rural (≥4)	5	78	90	100	107.7	111.8	0.053
Urban (<4)	18	33.9	48.4	72.4	88.3	276.5	
Teaching Status							
Teaching	4	59.9	62.9	71	79.7	83.2	0.449
Non-teaching	19	33.9	48.4	85.4	100	276.5	
Region of State							
Coastal Plain	8	68.7	80.6	87.7	95.2	276.5	0.114
Non-coastal plain	15	33.9	42.6	65.9	98.1	111.8	

Table 8H. Associations between Hospital Characteristics and Inter-rater Reliability Percentage Agreement

		t-PA				Dysphagia			
Hospital Characteristics	# hospitals with data	Percentiles			p-value*	Percentiles			p-value*
		25%	50%	75%		25%	50%	75%	
Cohort									
1	21	90.9	95.8	97.7	0.42	54.1	63.2	70.4	0.271
2	8	92.9	97.4	100		60.7	67.5	80.4	
Volunteer									
Yes	4	92.4	97.9	100	0.546	52.2	60.8	66.2	0.492
No	25	91.3	95.5	100		57.1	65.2	75	
Number of beds									
<250 beds	11	90.9	96.3	100	0.485	53.8	63.2	75	0.86
≥250 beds	18	91.3	95.5	97.7		59.3	65.2	70.8	
Number of 2006 stroke admissions									
<258 admissions	12	93.5	100	100	0.079	55.5	62.3	72.7	0.693
≥258 admissions	17	91.3	95.7	97.3		60	65.2	70.8	
Ownership									
Private	5	95.5	96.3	100	0.402	59.3	60.7	61.5	0.294
Not for Profit/Hospital Authority	24	89.9	95.7	100		55.6	65.9	75	
Primary RUCA Code									
Non-Urban (≥4)	7	90.9	100	100	0.166	57.1	66.7	81.8	0.529
Urban (<4)	22	91.3	95.5	97.6		54.1	64.7	70.4	
Teaching Status									
Teaching	5	91.3	92.9	95.5	0.162	40.9	44.4	64.3	0.053
Non-teaching	24	91.9	96.8	100		59.6	66.7	75	
Region of State									
Coastal Plain	11	88.9	97.3	100	0.543	44.4	61.5	75	0.438
Non-coastal plain	18	92.9	95.6	97.7		60	65.9	70.8	

*Wilcoxon rank sum test

Table 8H. (Continued)

		DVT				Smoking Cessation			
Hospital Characteristics	# hospitals with data	Percentiles			p-value*	Percentiles			p-value*
		25%	50%	75%		25%	50%	75%	
Cohort									
1	21	73.3	77.8	82.1	0.008	84.2	89.3	97.3	0.296
2	8	88.2	93.8	100		78.6	100	100	
Volunteer									
Yes	4	75.1	80.1	91.7	0.851	64.1	83.3	100	0.727
No	25	73.7	80.8	88.2		85.7	90.9	100	
Number of beds									
<250 beds	11	70.4	77.8	100	0.563	84.2	96.2	100	0.236
≥250 beds	18	76.9	82.5	88.2		76.1	87.3	97.6	
Number of 2006 stroke admissions									
<258 admissions	12	68.5	76	90.4	0.155	76.5	93.5	100	0.947
≥258 admissions	17	78.4	82.9	88.2		86.1	89.3	97.6	
Ownership									
Private	5	70.4	76.9	82.1	0.224	66.7	81.5	86.4	0.031
Not for Profit/Hospital Authority	24	74.3	81.4	90.9		85.9	95.1	100	
Primary RUCA Code									
Non-Urban (≥4)	7	66.7	75	100	0.407	84.2	100	100	0.254
Urban (<4)	22	76.9	82.1	88.2		81.5	88.8	97.6	
Teaching Status									
Teaching	5	82.1	86.4	88.9	0.363	76.1	86.4	94	0.487
Non-teaching	24	73.5	79.5	87.9		85	92	100	
Region of State									
Coastal Plain	11	75	80.6	100	0.624	71.4	90.9	100	0.604
Non-coastal plain	18	72.1	81.5	87.5		85.7	91.2	100	

*Wilcoxon rank sum test

Chapter 9: Summary and Conclusions

Study 1

The findings of study 1 provide evidence that the Georgia Coverdell Acute Stroke Registry (GCASR) has been effective in improving the quality of acute stroke care in Georgia when considered from the perspective of adherence to evidence-based stroke recommendations. There was evidence of overall improvement in adherence with all four quality indicators in both cohorts over the time period examined. The improvement was statistically significant for dysphagia screening in both cohorts, and for DVT prophylaxis and smoking cessation in cohort 1. The significant increase in DVT prophylaxis among cohort 1 hospitals may reflect the fact that hospitals were asked to particularly focus on DVT prophylaxis during the time period under consideration.

Although odds ratios for the monthly within-hospital change in adherence were generally low in magnitude (1.01-1.08), the observed rate of improvement can result in substantial improvements in adherence over time. For example, the monthly odds ratio of 1.04 for dysphagia screening in cohort 2 is equivalent to an odds ratio over a 6 month period of approximately 1.27, indicating a 27% increase in the odds of adherence over a 6-month period. Given a baseline adherence percentage of 33.9%, this would result in 39.4% adherence after 6 months, a 5.5 percentage point increase in adherence over a 6 month period. Among patients for whom data was entered into the registry, 72% were eligible for the dysphagia screening indicator. If this is representative of all 2006 stroke admissions at registry-eligible hospitals in Georgia, 16,619 stroke patients at these hospitals during 2006 would have needed dysphagia screening. On a state-wide level, an increase in adherence of 5.5 percentage points, if sustained over the period of a year, would mean that an additional 914 patients would receive the needed screening. The rates of improvement for the four indicators are overall comparable to or higher than the overall rate of improvement reported by Schwamm et al[71] for the American Heart Association's nation-wide Get

with the Guidelines Program, although the results from that study are somewhat different because that study did not focus on within-hospital changes.

Hospitals with a lower number of stroke admissions had a lower baseline adherence level and a higher rate of improvement for all four indicators. In multivariate models, the lower baseline level was statistically significant for the dysphagia indicator, and the higher rate of improvement was statistically significant for the dysphagia and DVT indicators. This may indicate that this group of hospitals can particularly benefit from the registry, and continued efforts should be made to recruit additional hospitals with a low number of stroke admissions. Hospitals with a lower number of stroke admissions are significantly underrepresented among registry hospitals. During 2006, 78.9% of all hospitals in the state that were potentially eligible for the registry had less than 258 admissions; these hospitals admitted more than 7,700 stroke patients during 2006, accounting for 33.7% of all stroke admissions in Georgia. In addition, 53% of the hospitals with a lower number of stroke admissions are located in the coastal plain, the area of the state with the highest stroke mortality rates; and hospitals with a lower number of stroke admissions in the coastal plain account for 15% of stroke admissions in the state. Therefore, hospitals with a lower number of stroke admissions account for a substantial number of stroke patients each year. Transfer of acute stroke patients to higher volume hospitals may not always be feasible. Of the hospitals with <258 stroke admissions during 2006, 71% are located outside of metropolitan areas, with lower volume hospitals in rural areas accounting for >4,300 stroke admissions during 2006 (19% of the stroke admissions in the state). A long distance to a larger volume hospital can make transfer before treatment infeasible for administration of tPA, which must be given within 3 hours of stroke onset. Therefore, the quality of stroke care at lower volume hospitals is of public health importance in Georgia

After controlling for other characteristics, non-metropolitan hospitals had a lower rate of improvement for all three indicators for which this characteristic could be assessed, with the lower rate of improvement being statistically significant for the dysphagia and DVT quality

indicators. These hospitals also had a lower baseline adherence level for two of the three indicators (dysphagia screening and smoking cessation) although these differences were not statistically significant. Similarly, the rate of improvement was lower for hospitals with private ownership for three of the four indicators, with the lower rate statistically significant for dysphagia screening and smoking cessation, despite the fact that these hospitals also had lower rates of baseline adherence for dysphagia screening and smoking cessation (not statistically significant). These patterns may indicate that registry quality improvement initiatives have been less successful in reaching non-metropolitan and privately owned hospitals. Exploring ways of more effectively tailoring registry interventions to the needs of these hospitals may help to increase the impact of the registry.

Study 2

The findings of study 2 shed light on the relative impact of one quality improvement intervention used in the registry, the monthly conference calls with hospitals. The pre-call vs. post-call average comparison showed overall improvement in quality indicator adherence, but there was no clear evidence that the improvement was a result of call attendance. The trend models overall also did not do not provide consistent evidence of a benefit of the calls. Therefore, while there was evidence of increasing quality indicator adherence, there was no conclusive evidence of a specific impact of the calls in temporal relation to call timing. It appears that factors other than the calls may have had a more powerful influence on trends in adherence.

Based on these observations, one might ask whether the calls could be eliminated to save resources. However, the findings of this study should be interpreted cautiously. Call attendance appeared to have a more global association with improved quality indicator adherence, which may be due either to a positive effect of the calls in general or to other unmeasured hospital characteristics that cause a hospital to both have a higher rate of improvement in adherence and to participate in calls. The calls may serve a stronger function in keeping hospitals engaged in

stroke care quality improvement and helping hospitals network with each other than in providing specific educational value.

Study 3

This study suggests that the Georgia Coverdell Acute Stroke Pilot Registry had a positive impact in decreasing readmission for recurrent stroke within 1 year of discharge for admissions during the last 6 months of pilot registry operation. This improvement in outcomes was not seen 1 year after the registry ended. However, these findings must be interpreted with caution. There was also a suggestion that there may have been an increased risk of death within the early days after ischemic stroke admission in association with pilot registry operation; although the difference in mortality was not apparent after 1 year. The reason for this finding is not entirely clear.

Study 3 had several important limitations including the inability to adjust the analysis for severity of illness or underlying conditions, and the possibility for misclassification of the outcomes due to imperfect linkages between records. However, the study also had several important strengths. Many previous evaluations of the impact of quality-of-care improvement programs have been limited by availability of data only for hospitals participating in the program. Participating hospitals may be influenced by secular trends apart from the intervention being studied, limiting causal inferences. Even if data on non-participating hospitals is available, participating hospitals may be different from non-participating hospitals in important ways other than participation in the intervention. This study included both participating and non-participating hospitals, and made use of random selection of hospitals to avoid confounding by factors associated with the choice to participate. In addition, this study examined the association between hospital registry participation and patient outcomes beyond discharge. Several previous studies have been limited to looking at in-hospital mortality, which can be influenced by general

discharge practices and local availability of various types of post-hospitalization care, such as hospice care.[115,116]

In summary, study 3 suggests that the GCASR pilot registry may have lead to reduced rates of readmission for recurrent stroke, but may also have been associated with increased early mortality after ischemic stroke. Although mortality and readmission for recurrent stroke are only two of the outcomes that stroke patients would value, and readmission for recurrent stroke represents only a portion of all causes for readmission among stroke patients,[16] improvement in readmission for recurrent stroke is important.

Data quality

The data quality assessment indicated that overall data quality was adequate, but inter-rater reliability was lower for dysphagia screening than for the other quality indicators considered. Results of analyses for dysphagia screening may be affected by poorer data quality. In addition, the results of the data quality analysis suggest that there may be opportunities for improving understanding of some measures among hospitals, especially for dysphasia screening.

Overall Implications for the Georgia Coverdell Acute Stroke Registry

Considered together, these studies provide evidence that GCASR has been effective in improving care processes, and that the logic model on which GCASR is based, which suggests that such improvements in processes will lead to improvements in patient outcomes, is well founded. However, they also suggest some future directions for the registry including continued efforts to recruit smaller hospitals with fewer stroke admissions, and the need for exploration of ways of more effectively addressing the stroke care quality improvement needs of non-metropolitan and privately owned hospitals. They also suggest that there may be opportunities for refining the focus of the monthly calls with hospitals to take optimal advantage of the

opportunities that these calls provide for keeping hospitals engaged in stroke care quality improvement. Finally, as part of the ongoing registry evaluation, it will be important to repeat the type of analysis done in study 3 to determine whether the trends observed for the pilot registry are also seen with the more intensive and longer duration quality improvement interventions used in the current implementation phase registry.

Chapter 10: Implications for Further Research

Study 1 identified some future directions for the registry including the importance of continued efforts to recruit smaller hospitals with fewer stroke admissions, and the need for exploration of ways of more effectively addressing the stroke care quality improvement needs of non-metropolitan and privately owned hospitals in particular. Some of these results have already been used in discussions of future registry recruitment strategies.

Based on the findings of study 2, it does not appear that hospitals implement specific strategies discussed on the calls shortly after the registry-wide educational conference calls. At the time of the calls, hospitals may have different stroke care quality improvement priorities than those discussed on the calls. It is possible that a more general emphasis on encouraging interaction between hospitals about stroke care quality improvement would be more useful than calls intended to target specific quality indicators. It is also possible that greater coordination of calls with the quality improvement focus of hospitals at the time could lead to greater implementation of the information from the calls. A survey of hospitals asking about the ways in which they use the information from the conference calls, and about their call format preferences could help guide decisions about possible changes to the conference calls. Further studies could also be considered after seeking further input from hospitals, such as an evaluation of a trial period during which the calls were discontinued or changed in format, or a randomized trail assigning hospitals to groups with different call formats, possibly including a group with no calls.

The analyses used in studies 1 and 2 focused on four selected quality of care indicators including administration of t-PA, deep vein thrombosis prophylaxis, dysphagia screening, and smoking cessation counseling prevention. These four indicators were chosen among the 10 indicators used in the Paul Coverdell National Acute Stroke Registry because they represented various stages in time in acute stroke care, they did not have a very high level of adherence at baseline, and they included the measures that had been the particular focus of registry activities. After selection of the measures for the dissertation, the National Quality Forum reviewed stroke

quality-of-care measures used by various organizations,[117] and endorsed all of the measures that had been used by GCASR except dysphagia screening. Dysphasia screening was not felt to have the level of evidence supporting it that the other measures had. Future studies of registry activities may choose to focus on a different set of indicators, which may not include dysphagia screening. Alternatively, additional study of the effectiveness of dysphagia screening may be warranted, and the registry may provide opportunities for conducting that type of research.

It will be important to repeat the type of analysis used in study 3 to determine whether the trends observed for the pilot registry are also seen with the more intensive and longer duration quality improvement interventions used in the current implementation phase registry. Such an analysis would be important for evaluation of the implementation phase registry and would add to knowledge relating to the potential for registries like GCASR to impact patient outcomes. A repeated study may also allow analyses of relationships between changes in care processes and outcomes, which were not possible for the analysis for the pilot registry due to the limited time frame used for collection of stroke care process measures during the pilot registry.

In recognition of the fact that the Georgia Coverdell Acute Stroke Registry is operating in the context of many other concurrent quality-of-care initiatives and programs, which are being conducted by many different organizations, it will also be important to do further research to evaluate how GCASR fits into this overall quality-of-care context. Some of the findings of the studies in this dissertation, as well as experience in the course of registry operation, suggest that the many demands on hospital quality improvement resources may affect GCASR in terms of registry participation rates by hospitals, and the extent to which participating hospitals are able to devote resources to specific registry activities. Therefore, it will also be important to examine costs to hospitals of registry participation, and to consider possible ways of minimizing these costs. It will also be important to continuously reassess registry activities to ensure that the registry is targeting the most important areas of stroke care.

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