1. TITLE PAGE

April 10th, 2012

Final Report Grant No: 1R03HS017740-01

Project Period: 07/01/2009 – 06/30/2010 (with 1-year no cost extension)

Title: ***Developing a Rational Clinical Approach to the Disposition of TIA Cases in the ED***

Support: Agency for Healthcare Research & Quality

Project Principal Investigator: Mathew J. Reeves BVSc, PhD

(517)-353-8623, reevesm@msu.edu

Department of Epidemiology and Biostatistics

Michigan State University

East Lansing MI 48824

Project Officer: ERNESTINE MURRAY

(301)-427-1630, emurray@**ahrq.gov**

Research Team:

Mathew J Reeves, PhD, Principal Investigator

Brian Mavis, PhD, Co- Investigator

Margaret Holmes-Rovner, PhD, Co- Investigator

Michael Brown MD, MS, Consultant

S. Claiborne Johnston, MD, PhD, Consultant

Acknowledgements:

We thank the AHRQ for their financial support of this research program. We also acknowledge the fine work of the following three MSU undergraduate Research Assistants who contributed to the success of the research: Peter Jajou, Thomas Wilkins and Jake Pratt.

2. Structured Abstract

Purpose: To develop a cost-effectiveness analysis (CEA) model to compare hospitalization versus out-patient care of TIA cases presenting to the emergency department (ED), and to assess the acceptability, feasibility, and barriers to using clinical decision rules for risk stratification to guide the disposition of TIA patients in the ED.

Scope: Patients with Transient Ischemic Attack (TIA) are at high risk of developing a stroke. However, the medical community is unsure how best to manage TIA cases that present to the ED because no clinical standard exists for determining which cases should be hospitalized and which managed on an out-patient basis (i.e., disposition). Clinical practice is therefore highly variable. This study aims to develop a more rational approach to the management of TIA cases in the emergency department through the development of cost-effectiveness models and assessments of physician and patient attitudes towards disposition and risk stratification.

Methods: Cost-effectiveness models comparing the costs and outcomes of hospitalization versus out-patient management of TIA in the ED were developed using Treeage HealthCare Software. We assessed knowledge, acceptability, and barriers to using the ABCD2 clinical decision rule for risk stratification of TIA patients by undertaking a postal survey of over 400 emergency medicine (EM) physicians who were members of the Michigan College of Emergency Physicians. We followed the survey methodology described by Dillman. We also undertook two focus groups with 22 EM physicians and 22 community members to determine attitudes towards hospitalization and out-patient management of TIA.

Results: Only about half of physicians were aware of the ABCD2 rule, and the rule was rarely used in practice. Among physicians the decision to hospitalize was relatively insensitive to cost of care and the risk of stroke only influenced the decision when reduced to virtual certainty (<1%). The decision to use out-patient care by physicians was more sensitive to cost of care, increases in stroke risk, and compliance in the out-patient setting. Preference for hospital-based care vs. out-patient care was split evenly amongst the participants in the 2 patient focus groups. Similar to the findings among physicians, out-patient care was more sensitive to increases in out-of-pocket costs and increases in stroke risk suggesting that the initial patient preference for out-patient care was not a 'firm' as the preference for hospital-base care. Interestingly, patients who chose hospital-based care reported lower QOL compared to out-patient care.

These findings suggest future studies should focus on acceptable outpatient risks and costs to increase adoption of clinical prediction rules and appropriate decision making for TIA cases.

Key Words: Transient ischemic stroke, disposition, cost-effectiveness analysis, risk stratification.

3. Purpose (Objectives of the study)

The objectives of this study were to 1) develop a cost-effectiveness analysis (CEA) model to compare hospitalization versus out-patient disposition of TIA cases presenting to the emergency

department (ED), and 2) to assess the acceptability, feasibility, and barriers to using clinical decision rules for risk stratification to guide the disposition of TIA patients in the ED through a combination of postal surveys with emergency medicine (EM) physicians and focus groups.

4. Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

Transient ischemic attacks (TIA) or mini-strokes represent an important clinical problem in the emergency department (ED) because approximately 1 in 20 cases go on to develop a major stroke within 48 hours of presentation. Moreover, the work-up of TIA cases in the ED represents a clinical dilemma because no firm guidelines exist as to their disposition i.e., whether cases should be hospitalized or managed on an out-patient basis. In the absence of clear guidelines, clinical practice in terms of hospitalization of TIA is highly variable, but evidence suggests that ED physicians are increasingly resorting to hospitalizing most TIA cases. This policy is driven by several forces including the need to obtain timely diagnostic evaluations and the desire to monitor patients for signs of impending stroke.

The trade off in terms of the costs and benefits of hospitalization of TIA patients is driven in large part by their short-term risk of stroke - clinical risk stratification should play a central role in determining the clinical management of TIA cases in the ED. The ABCD2 rule is a validated clinical decision rule (CDR) designed to risk stratify TIA patients who present to the ED based on a combination of age, blood pressure, clinical symptoms, duration of symptoms, and diabetes. External validation studies have demonstrated the rules' accuracy in predicting short-term stroke risk in TIA patients: 7-day stroke risk ranges from 0% in cases with a score of 0 up to 12% in cases with a score of 6 or 7. Although hospitalization may make sense for high risk TIA cases, it is clear that many TIA cases are at low risk and could be appropriately managed in an out-patient setting, thus saving health care costs. The management of TIA in the ED therefore represents a classic problem from the perspective of health care quality and resource allocation that calls for the development of a more evidence-based approach utilizing cost-effectiveness analysis.

This study aims to develop a more rational approach to the management of TIA cases in the emergency department through the development of cost-effectiveness models, and the assessments of attitudes towards disposition and risk stratification among both Michigan emergency medicine physicians and at-risk community members.

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

<u>Cost-effectiveness modeling</u>

Cost-effectiveness models comparing the costs and outcomes of hospitalization versus out-patient management of TIA in the ED were developed using Treeage HealthCare Software.

Data were obtained from an extensive literature search as well as local data generated from a prior cohort study of TIA, as well as local mid-Michigan hospitals.

Postal survey of physicians

We assessed knowledge, acceptability, and barriers to using the ABCD2 clinical decision rule for risk stratification of TIA patients by undertaking a postal survey of over 400 emergency medicine (EM) physicians who were members of the Michigan College of Emergency Physicians. Members who were targeted for the survey were randomly selected from the membership rolls (n= 839). We followed the postal survey methodology techniques described by Dillman sending pre-notification letters, postal card reminders and 3 separate copies of the survey tool over an 8 week period.

Focus group survey of physicians

We also assessed knowledge, acceptability, and barriers to risk stratification using the ABCD2 rule through two focus groups with 22 EM physicians from Lansing and Grand Rapids, Michigan.

Focus group survey of at-risk community members

Finally we also assessed patient attitudes towards hospitalization versus out-patient management using two focus groups that were made up of a total of 22 at-risk community members selected from a neurology out-patient and a primary care clinic in East Lansing, Michigan.

6. Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Cost-effectiveness modeling

Cost-effectiveness models are still under-development but are close to being completed. Progress has been stymied by the difficulty of finding accurate cost estimates for diagnostic testing (i.e., CT and MRI imaging, and carotid artery and cardiac ultrasound) in different care settings (i.e., in-patient, out-patient, emergency department). An abstract submission to the 2013 International Stroke Conference and draft paper are under development.

Postal survey of Emergency Medicine physicians

From an initial sampling frame of 839 members of the Michigan College of Emergency Physicians (MCEP) we drew a random sample of 480 members to be part of the mail survey. After excluding duplicates (n= 1), returned non-working addresses (n=2) and members who contacted us to explain that they were either retired (n=3) or no longer in EM practice (n=3), we had a final sample of 471 eligible members. A total of 191 (40.6%) were returned and 188 (40%) had useable data for the analysis.

Three-quarters of the physician respondents (76.6%) were male, with an average age of 46.4 years. The vast majority (87.1%) were EM Board Certified with an average of 16.5 years of experience. After excluding 6 outliers with implausibly high values, respondents reported seeing an average of 7.15 TIA patients per month. Half of the physicians (51%) were already aware of the ABCD2 rule, and of those that were aware, about 20 % calculated it 'always or most of the time' when treating a TIA patient in the ED. Of the physicians who were not aware of the rule, the majority (86%) stated that they would consider using it in the future.

After reading a brief description of the ABCD2 rule included in the survey, over 80% of the physicians thought that it would be easy to use and over 60% thought that it was easy to remember. Although only a minority of the physicians (26%) believed that the rule did not cover all important clinical factors, only half (54%) thought that the rule would actually be useful in their practice, and 20% of respondents stated that their work environment would make it difficult to use the rule. When presented with a scenario where it was stated that the ABCD2 rule had been demonstrated to safely triage low-risk patients for out-patient care, then 2/3rds (63.4%) of physicians reported that they would use the rule regularly.

There were some interesting differences between how physicians reported currently managing their TIA cases in the ED and how they believe TIA cases should be managed. The survey revealed that only half (51.6%) of physicians perform some form of carotid imaging (either Doppler ultrasound, or CT or MR angiography) "Always" or "Most of the time" on TIA patients in the ED, while almost 90% (88%) either "Strongly" or "Moderately Agreed" that all TIA patients should undergo such imaging tests. Data on brain imaging also revealed some interesting differences, especially for MRI scans - only 21% of the time did physicians report performing a brain MRI scan "Always" or "Most of the time" in the ED, whereas 40% of physicians strongly or moderately agreed that all TIA patients should undergo such scans (the equivalent figures for CT brain scan were 96.2% and 84%, respectively). Just over 43% of physicians reported that TIA patients received an echocardiogram (TEE or TTE) either always or most of the time while in the ED, and 56% strongly or moderately agreed that all TIA patients should undergo such tests.

With respect to the attitudes and practices related to hospitalizing TIA cases, about half of physicians (53.3%) either "Strongly" or "Moderately Agreed" that all TIA patients should be hospitalized. These results closely matched the actual patterns of hospitalization use where respondents reported that 59% of TIA cases were typically hospitalized, 26% were admitted under observation status, and 15% were discharged home. Almost 70% of physicians strongly or moderately agreed that risk stratification of TIA patients in the ED was an essential component of TIA care and management, but only 48% agreed that it was acceptable for low-risk TIA patients to be managed as out-patients.

Physicians were also questioned about their opinions on the potential benefits of hospitalizing TIA cases (as opposed to the use of out-patient care or observation stays). Over three-quarters of physicians (78%) regarded the ability to complete carotid imaging

during the hospitalization as a very important benefit of hospitalization, this was followed by the ability to avoid poor patient compliance with follow-up out-patient care which was identify by 74% of physicians as being important or very important. Other benefits of hospitalization identified by at least 60% of physicians as being important or very important included the ability to complete cardiac imaging (TEE or TTE), the ability to refer to an in-patient neurology service, and the ability to give tPA should the patient developed a stroke during hospitalization (there were reported by 69%, 68%, and 65% of physicians, respectively). Just over half of the physicians (52%) reported that avoiding potential lawsuits was an important reason for hospitalizing TIA cases.

An abstract on our MECP results will be submitted to the 2013 International Stroke Conference and a draft paper is near completion.

Focus group survey of physicians

The following abstract has been accepted as a poster presentation to the American Heart Association Quality of Care and Outcomes Research (QCOR) meeting in Atlanta, GA. May 9-11th, 2012.

Use of Risk Stratification for the Management of TIA in the Emergency Department: Focus Group Results.

Mathew J. Reeves PhD, Brian Mavis PhD, Thomas Wilkins BSc, Margaret Holmes Rovner PhD, Michael Brown MD MS, Mary Hughes DO.

From the Departments of Epidemiology (Reeves, Wilkins), Medical Education (Mavis), Ethics and Humanities (Holmes Rovner), Emergency Medicine (Brown), College of Human Medicine, and the Department of Osteopathic Medical Specialties (Hughes), College of Osteopathic Medicine, Michigan State University, East Lansing, Michigan.

Background: Evaluation of TIA cases in the emergency department (ED) represents a clinical dilemma because no firm guidelines exist as to their disposition (hospitalization vs. out-patient care). The ABCD2 clinical prediction rule risk stratifies patients but little is known about how Emergency Medicine physicians (EMPs) use the rule in clinical decision making. We undertook focus groups with EMPs to determine their attitudes and use of the ABCD2 score, and to understand how information on baseline risk, costs, compliance, and feasibility affect their decision making.

Methods: Physicians from 2 EM practice groups in Michigan were invited to attend a focus group meeting. Data were collected on their knowledge, attitudes, and use of the ABCD2 clinical prediction rule in the evaluation of TIA cases. Using a case vignette of a moderate risk patient (ABCD2 score = 4, 7-day stroke risk = 6%), physicians were asked to choose between hospitalization or discharge for out-patient care. We then changed several baseline conditions, including 7-day stroke risk, health care costs, and compliance with out-patient follow-up, to determine under what conditions they altered the initial disposition decision.

Results: Twenty two EMPs participated; all worked in community-based hospitals, 91% were male, 95% were EM board certified with an average of 16.5 years of EM experience. Respondents reported seeing an average of 6.7 (SD= 4.6) TIA patients per month. Sixty four percent (14/22) were familiar with the ABCD2 score, but only 9% (2/22) used it regularly. Almost 60% (13/22) initially chose to hospitalize the moderate risk patient. Increasing the cost of the episode of care (from $3000 to $9000) did not change the decision to hospitalize for the majority (8/13, 62%) of EMPs. Only when 7-day stroke risk was lowered from 6% to 1% did the majority of EMPs (11/13, 85%) change their decision from hospitalization to outpatient care. Forty percent (9/22) initially chose to manage the moderate risk patient as an out-patient. A small increase in the cost of care (from $3000 to $3500) resulted in 56% (5/9) EMPs switching their decision from out-patient care to hospitalization, while a modest increase in stroke risk (from 6% to 10%) resulted in 78% (7/9) switching their initial decision. The choice of out-patient care was also influenced by the likelihood that patients would complete testing in the out-patient setting; if compliance dropped from 100% to 80% then half of the EMPs switched their decision from out-patient care to hospitalization. Increasing the number of hours that a patient would need to complete testing (from 4 to 12 hours) only had a modest impact on physician decision making.

Conclusions: The ABCD2 score was rarely used in practice. The decision to hospitalize was relatively insensitive to cost of care; 7-day stroke risk only influenced the decision when reduced to virtual certainty (1%). The decision to use out-patient care was more sensitive to cost of care, increases in stroke risk, and compliance in the out-patient setting. These data suggest future studies should focus on acceptable outpatient risks and costs to increase adoption of clinical prediction rules and appropriate decision making for TIA cases.

Focus group survey of at-risk community members

A total of 22 community members were included in 2 patient focus groups; one group consisted of 7 patients with a recent history of TIA who was being managed in an out-patient neurology clinic, and 15 patients were selected from a general family practice clinic. Patients were 64% female and 90.9% Caucasian. Eight-two percent were married with 18.2% living alone. Almost 60% had private insurance, 27.3% Medicaid, 9% Medicare. About half of the patients had 5 or more visits to the doctor in the last 12 months, and 41% had at least 1 visit to the ER in the past year. Subjects rated their own general health rating as: 14% Excellent, 41% Very Good, 32% Good, and 14% Very Poor.

When presented with a typical scenario of a TIA patient visiting the emergency department, 55% (n= 12) picked hospitalization as their preferred treatment location, while 45% (n= 10) picked outpatient (OP) care. To determine the impact of out-of-pocket medical costs on this decision, patients were tested to see when they would change their initial decision in response to an increase in out-of-pocket costs. Of the 12 patients who picked hospitalization, 9 (75%) changed their position when personal costs increased from $200 to $1000, but 2 patients did not change decision even when costs increased to $5K. Compared

to the hospitalization group the 10 patients who picked outpatient (OP) care changed their position earlier; 6 (60%) had switched to in-patient care once costs had increased to $600. Only 1 patient did not change their initial decision even if costs increased to $5K. Patients were also tested to see when they would change their initial decision in response to an increase in stroke risk. Most patients choosing hospitalization did not change their decision despite increase in stroke risk; 7 (58.3%) did not change despite risk increasing to 20%. The 10 patients who picked outpatient care initially were slightly more responsive to increases in stroke risk; 5 (50%) of patients changed decision to hospital care after risk had increased to 10%. In summary the patients who picked out-patient care initially were more likely to shift to in-patient care with increased out-of-pocket expenses or a relative increase in stroke risk, suggesting that the decision for out-patient care was not as firm as those that picked hospital based care.

When length of stay was increased from the baseline of 1 day, 58% of patients choosing hospitalization did not change their initial decision despite an increase to greater than 4 days. Likewise, 50% of patients choosing outpatient care would not change their position despite a change from 4 hours to more than 16 hours required for completing outpatient testing.

Patients selecting hospitalization reported a lower overall QOL 7 days after the episode of care (assuming no adverse outcomes occurred), compared to patients who chose OP care (mean QOL 0.80 vs. 0.90). Under the assumption of not suffering an adverse outcome, when patients were forced to take the alternative option (i.e., OP care when initial choice was hospitalization, and vice versa) they reported a lower QOL score, however the magnitude of the decrement was similar – median scores were 0.1 units lower for the OP group (if they had to take hospitalization) and was 0.08 units lower if the hospitalization group had to take OP care. When all subjects were combined the overall median QOL score 7 days after the event (0.81) was very similar to the subjects current QOL (measured by asking the subjects to rate their current health (0.82)). This finding suggests that an uncomplicated TIA event had no measureable impact on overall QOL.

7. List of Publications and Products (Bibliography of Outputs) from the study. Follow the AHRQ Citation Style Format at http://dev.ahrq.gov/fund/refstyle.htm.

Several publications are under development.