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IRB Proposal

Title of Project: Do Stroke Patients Present to the ED Faster for Second Strokes?

A. Study Purpose and Rationale

The greatest barrier to effective stroke treatment is delayed patient presentation to the hospital or stroke center. The only current medical treatment for ischemic stroke is intravenous tissue plasminogen activator (IV tPA), which must be administered within 4.5 hours of symptom-onset. And the sooner after symptom-onset that tPA is initiated, the more likely it is to be beneficial.ⁱ While hospitals have gone to great lengths to streamline emergency department triage and diagnosis of acute stroke, impacting the speed of patient presentation has been more difficult.

Several studies have examined factors that influence time of presentation after acute stroke. In one study of French stroke patients, female gender and transport by ambulance were found to correlate with earlier hospital arrival.ⁱⁱ Severity of symptoms (NIHSS >8) has also been associated with faster presentation to the hospital.ⁱⁱⁱ Patients who experience stroke symptoms at night have been shown to present for medical evaluation later.^{iv} What has yet to be examined, however, is the influence of prior stroke on time to presentation. It is estimated that within 5 years, 24% of women and 42% of men will experience a second stroke. Indeed, one of the greatest risk factors for stroke is a history of stroke.^v

A patient's experience of prior stroke may affect time to presentation in several ways. Patients with a history of stroke may be more likely to recognize the signs and symptoms of acute stroke, especially if they are similar to the presentation of their first stroke. These patients also hopefully received some stroke education while hospitalized for their first stroke. These factors suggest that patients with a history of stroke should present sooner for their second stroke.

However, patients who experience recurrent stroke are more likely to be disabled, aphasic, and demented. These patients are also more likely to have advanced medical comorbidities. The ability to communicate or recognize new stroke symptoms may be impaired in patients with a history of stroke. It would not be unreasonable to hypothesize that time to presentation may be increased for second time strokes.

Community stroke education and improved in-hospital education have been the focus of many academic and public health organizations. Columbia, in particular, has been dedicated to increasing stroke awareness in the Washington Heights and Harlem communities.^{vi} The results of

this study may allow clinicians and educators to more appropriately target stroke education and interventions to the post-stroke population.

Study Aim: To determine if patients who experience recurrent stroke present to CUMC sooner than they did for their first stroke. The findings of this study can be used to evaluate current in-house stroke education efforts, and to improve community stroke education in these high-risk patients.

B. Study Design

This project will be undertaken as a retrospective review of the acute stroke database maintained by the Stroke Division of the Department of Neurology at Columbia University. A five year window of time will be selected in order to adequately capture most repeat strokes. Patients who have presented to CUMC for their first and second ischemic strokes will be selected. For each admission, their “time since symptom onset” will be recorded and compared. The “time since symptom onset” is the difference between the time of admission and time of “last known well.” These times are recorded in the acute stroke template utilized by the neurology resident in the initial stroke evaluation. Though the patient’s report of symptom onset is subject to error, the procedure by which these times are used and calculated has been standardized. These times should be recorded for every acute stroke patient, as they determine eligibility for tPA. Patients who present with TIA or hemorrhagic stroke will be excluded.

Demographic data, including age, gender, race, marital status, insurance, mode of transportation to ED, distance from ED, initial ED evaluation times, and socioeconomic status (using NYC census tracts as proxies), will be collected for each stroke patient’s admission. This data will be accessed via the electronic medical record when not directly available through the stroke database. NIH Stroke Scale Score and IV tPA use will also be recorded. Patients’ personal identifiers will be removed from the data, and subjects will be coded using a unique study number. Patient data will be stored on a secure server, and identifying information will only be accessible by study personnel.

C. Statistical Analysis

Assuming $n=500$, this study has been powered to capture an effect difference of $(1/8) \times (\text{standard deviation of stroke presentation time})$. This power calculation assumes $\alpha = 0.05$ and power $(1 - \beta) = 0.80$. Time of stroke presentation for first and second strokes will be compared using a paired t-test. Because the distribution of time to stroke presentation is likely to

be right-skewed, the log(stroke time) will be used to normalize this data, and thus avoid the use of non-parametric tests. The influence of additional factors (covariates) on time to stroke presentation will be assessed using multivariate regression. The statistical program SAS will be used for these calculations.

D. Study Drugs

Not applicable.

E. Medical Devices

Not applicable.

F. Study Questionnaires

Not applicable.

G. Study Subjects

The study subjects will be adult patients at least 18 years of age who present to CUMC – NY Presbyterian for acute ischemic stroke, as diagnosed by the Stroke Service. Hospitalized patients who experience “in-house” stroke or stroke patients transferred from an outside hospital (including the Allen Hospital) will be excluded. Hemorrhagic strokes and TIAs will be excluded.

H. Recruitment of Subjects

Not applicable.

I. Confidentiality of Study Data

Only the primary investigator will have access to the decryption document that links patient identifiers to study codes.

J. Potential Conflicts of Interest

None.

K. Location of the Study

New York Presbyterian Hospital – Columbia University.

L. Potential Risks

This retrospective study poses no potential risks for study subjects, with the exception of release of confidential medical information. All efforts will be made to maintain patient confidentiality, and to protect patient information.

M. Potential Benefits

Patients whose data are used in this study will not benefit directly from this study. Future stroke patients may benefit from improved education and awareness programs.

N. Alternative Therapies

Not applicable.

O. Compensation to Subjects

None.

P. Cost to Subjects

None.

Q. Minors as Research Subjects

Not applicable.

R. Radiation or Radioactive Substances

Not applicable.

ⁱ Jauch EC et al. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke* 2013;44(3):870.

ⁱⁱ Derex L et al. Factors Influencing Early Admission in a French Stroke Unit. *Stroke* 2002;33:153-159.

ⁱⁱⁱ Lacy CR et al. Delay in Presentation and Evaluation for Acute Stroke. *Stroke* 2001;32:63-69.

^{iv} Barsan WG et al. Time of Hospital Presentation in Patients With Acute Stroke. *JAMA* 1993;153:2258-2261.

^v <http://www.stroke.org/site/PageServer?pagename=stars>

^{vi} Williams O et al. Child-Mediated Stroke Communication: Findings from Hip Hop Stroke. *Stroke* 2012;43:163-9.