Project title
Community Engagement for Early Recognition and Immediate Action in Stroke (CEERIAS)

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1. Background/Rationale/Literature Review

The disproportionate impact of stroke on minorities is well-established. Racial and ethnic disparities have been observed in all aspects of stroke including prevalence of risk factors, awareness and health-care related beliefs, access to stroke care and treatments, stroke incidence, severity, and mortality, and acute "clot-busting" treatment with tissue plasminoegn activator (tPA) and preventive medications (Cruz-Flores 2011). For example, African-Americans (AA) are more likely to die and be disabled after stroke and half as likely to receive tPA compared to non-Hispanic whites (Johnston 2001, Hsia 2011). In acute stroke, though approximately 63% of stroke patients in the US arrive to the hospital by EMS, AA and Hispanics are less likely to utilize EMS than non-Hispanic whites (Ekundayo 2013). Race-ethnic disparities in arrival to hospital and EMS use are even more staggering in Chicago, where AA patients arrive later and Hispanics utilize EMS less than non-Hispanic whites. Thus, delay in hospital arrival maybe an important driver of disparities in tPA use and post-stroke outcomes among minorities (Cruz-Flores 2011).

Given the burden of stroke and poor outcomes among minority populations, there is a critical need for effective interventions that target minorities and emphasize early arrival to the hospital after stroke onset. Key steps to reducing delays in hospital arrival are 1) early recognition of stroke symptoms and 2) immediate activation of EMS (i.e. calling 911). Calling 911 immediately not only saves time in transit but also confers other important benefits such as advanced notification of stroke centers to prepare its emergency department to treat a stroke patient promptly and emergency pre-hospital care to manage neurologic deterioration or other medical complications.

2. Hypothesis/Key Questions

The overarching goal of the Community Engagement in Early Recognition and Immediate Action in Stroke (CEERIAS) study is to utilize a patient- and community-partnered approach to develop an effective intervention aimed at increasing early hospital arrival after stroke in 2 high-risk neighborhoods in Chicago. We hypothesize that through community partnerships will we be able to bridge the gap between knowledge (i.e., recognize symptoms of stroke) and action (i.e., call 911 early after stroke).

3. Research Objectives and Purpose

Specific Aim 1 (Development): Using qualitative methods (focus groups and content analysis), we will examine and identify personal, community, and cultural barriers to EMS for stroke among 3 race-ethnic groups (AA, Hispanic, and non-Hispanic whites); test and adapt our proposed interventional model for implementation in these groups and communities; and re-test and refine the intervention for implementation in 2 large multi-ethnic, disadvantaged neighborhoods in surrounds target PSCs (Holy Cross and Advocate Trinity Hospitals).

Specific Aim 2 (Implementation): To implement a culturally-adapted stroke awareness and action program, which will be delivered by community health workers (i.e. Stroke Promoters) and monitor its penetration and adoption using the RE-AIM framework in 2 large neighborhoods in Chicago (Holy Cross and Trinity Hospital catchment areas).

Specific Aim 3 (Comparative Effectiveness): To assess change in early hospital arrival and EMS use at 2 intervention hospitals (Holy Cross and Trinity) using an interrupted time-series analysis.

4. **Research Methods**

Specific Aim 1 (Development)

Description of Focus Group/Telephone Interview Participants: Focus groups will gather a broad range of perspectives, beliefs, and experiences from persons from geographically diverse neighborhoods surrounding the 2 target PSCs. Because both laypersons and stakeholders present equally valid yet different points of view, we will conduct focus groups and telephone interviews for these two groups separately. Given our interest in understanding race-ethnic and neighborhood barriers, we will conduct 1 AA, 1 Hispanic, and 1 non-Hispanic white focus group per target neighborhood (total 6 layperson focus groups). These will be conducted in English and Spanish and participants will receive a $50 honorarium. We will also conduct key informant telephone interviews of stakeholder/community leaders. We expect to successfully recruit 6-10 adults (age > 18 years) per layperson or stakeholders using a purposive strategy, recruiting subjects from each ethnic group in targeted neighborhoods. Since key informants will be generated from contacts with community organizations and advisory borad members' input, we plan to recruit key informants using direct communications to individuals referred or recommended by our research team, CAB, and collaborating organizational partners.

Conduct of Focus Group Interviews: The purpose of the focus group is to explore and probe barriers to calling 911 for stroke. These considerations will form the basis for developing the community intervention best suited for each race-ethnic group that will produce change in EMS use and early hospital arrival after stroke. The focus group interviews will be as consistent as possible across all groups, utilizing the same focus group moderators for each race-ethnic group between the 2 neighborhoods. Based on our preliminary data and a review of the extant literature, the study team including our Community Advisory Board members (CAB), will develop a focus group guide to explore the barriers and facilitators to 911 calls in multi-ethnic communities. This guide will include a set of probing open-ended questions to encourage focus group participants to share personal experiences. Participating community partners (such as PSCs) with history of work in the Hispanic communities and the Spanish speaking CEERIAS Study Coordinator will assist with the translation of the Spanish language focus group guide, using a combination of the back translation method and group consensus (Brislin 1970), to conduct Spanish language focus groups. The Spanish language focus group guide will be reviewed by the investigative team and Hispanic community partners to ensure appropriate literacy level and cultural equivalence. Recruitment of focus group participants will be initiated by stakeholders selected from each neighborhood. The focus groups will last approximately 1.5 hours. All participants will sign an informed consent prior to participation. The sessions will be audio recorded and transcribed into Microsoft Word documents; transcripts in Spanish will be cross-checked for accuracy. Key informant interviews will be performed one-on-one by telephone using the focus group interview guide as reference. There interviews will take 30 minutes to complete, will be performed only in English, and will be audio recorded. Verbal consent will be obtained by telephone at the start of the interview. Only those who agree to participate and provide their verbal consent will continue with the interview.

Analysis of the Focus Group Transcripts: Transcripts will be imported into NVIVO qualitative analysis software for analysis. Data will be initially coded by the lead qualitative researcher on the team using a preliminary coding scheme based on the issues of interest. Once the data are coded using preliminary codes, transcripts will be sent to the remainder of the analysis team. Team members will read and suggest additional codes and/or make amendments to the themes identified in the preliminary coding. The coded data will allow for grouping of the comments into categories using the NVIVO software features that will be incorporated into the proposed intervention (MIP-PACT to ACT FAST program) and address barriers appropriately (i.e. comments about trust, costs, family/cultural dynamics) for application into minority populations. We will also compare the discussion across race-ethnic groups and neighborhoods. We anticipate that ideas arising from the focus groups may include suggestions for changes in content, context, and delivery of the community intervention. Using an adapted Delphi approach, we will confirm our findings with a representative from each focus group in an iterative process. For these a telephone interview approach, similar that described above for key informant interviews, will be used. Only those subjects who consented to being contacted for further follow-up interviews will be recruited for this phase. Up to 6 individuals, representing each focus group, will be recruited for telephone interviews.

Once the research team, based on the Delphi method, has reached consensus, the findings will be discussed with and reviewed by recruited community stakeholder focus group members as well as the CAB. Based on messages, content, teaching styles, and learning techniques suggested in the focus groups, along with input from our stakeholders and CAB, we will develop the final adapted strategy for broad dissemination within each of the racial/ethnic communities in the 2 neighborhoods (potentially 6 total adaptations). We anticipate that based on the focus group recommendations, there will be edits to the original PACT to ACT FAST materials that will be disseminated to the community, reflecting a more culturally sensitive and specific message. Once the interventions are adapted, we will pilot the interventions with a small sample of additional stakeholders and lay community members, likely 12 individuals total, and conduct cognitive interviews with this sample to evaluate the intervention. The cognitive interview will be conducted by telephone and last approximately 30 minutes. Answers will be recorded in a Word document and password protected. Subjects will be compensated $25 for their time. Additional modifications of the intervention and messaging may be needed, based on these cognitive interviews, prior to implementation.

Specific Aim 2 (Implementation)

The protocol, evaluation forms, and consents for Aim 2 will be modified and informed by the results of Aim 1. An amendment outlining changes to the overall Aim 2 protocol will be submitted when appropriate. We present the general protocol below.

Stroke Promoters: Year two of this project will involve the implementation of the focus group derived intervention. We will identify community stroke promoters and provide them with training on strategies to improve early recognition and EMS utilization for stroke, specifically culturally-adapted solutions to current barriers and cues to aid in stroke recognition and immediate action. We anticipate that stroke promoter will come from five core community groups: hospital/clinics, public officials, public schools, faith-based organizations; and firehouses. Our implementation and recruitment of stroke promoters will be based on successful completion of focus groups.

Stroke Promoter Training: Stroke Promoters in the adapted MIP-PACT program will engage in interactive discussions with community leaders and health care professionals on strategies to enhance patient and bystander self-efficacy and increase public knowledge about stroke warning signs, treatments, and expected outcomes.

Each adapted MIP–PACT training program will include up to 15 stroke promoters (representatives from community organizations) and will be a maximum of four hours in length. Immediately preceding the training program, all attendees will receive a phone call confirming their attendance, also outlining the scope of the project and agenda for the tour (Appendix 3). Stroke promoters will be recruited concurrently at the 2 primary stroke centers in a total of 12 waves (20 Stroke Promoters trained each month or 240 total) throughout the first 6 months of year 2.

At the conclusion of the program, the participants will complete a Training Evaluation Form, sign the PACT to ACT FAST, and obtain educational materials for community dissemination that will include culturally sensitive and adapted FAST materials with information on how to restock supplies from the CEERIAS Community Navigator on a monthly basis. Each Promoter will be tasked with disseminating the educational materials to their constituents. They will be asked to present the program at least twice monthly for 6 months.

After each Promoter-led educational community event, the Stroke Promoters will also complete electronic Activity Evaluation Forms documenting the name of the event, location, numbers of persons attending, and rate the enthusiasm of the participants. Community participants who attended educational events will be asked to complete Participant Activity Evaluation Forms on paper (5 minutes), sign the PACT to ACT FAST certificate (1 minute), and the Participant Interest Form (5 minutes). These forms ask the participant to provide feedback about the presentation, the presenter, and their interest in being a Stroke Promoter and completing a telephone survey. All paper forms will be de-identified and collected by the Community Navigator and returned to Northwestern University for electronic data entry and storage.

Each Promoter will receive $732 in two installments for the training and ongoing participation in their outreach efforts. We plan to compensate those who attend the training and are engaged with the outreach efforts as outlined during the training class. If there is no level of engagement post training, they will not receive the full compensation. They will need to submit to the study coordinator a W-2 or W-9 and sign a contracted services form. Payments will be mailed based on the level of engagement after the training.

Specific Aim 3 (Comparative Effectiveness-Behavior and Action)

To compare the effectiveness of these interventions on behavior or action, we will monitor early hospital arrival and EMS use for stroke over a 60-month period at the 2 intervention hospitals using an interrupted time-series analysis. Early hospital arrival will be defined as the proportion of stroke patients arriving within 3 hours from symptom onset while EMS utilization (%) will be defined as the proportion of stroke patients arriving to the emergency department by EMS. Segmented regression analysis will be conducted to estimate whether and how much the intervention changes EMS utilization in each of the 2 target hospitals and in aggregate at both hospitals. Autoregressive error will account for correlations of the data across time points. In secondary analyses, temporal trends in early hospital arrival and EMS utilization from 2 pre-selected non-intervention Chicago hospitals (St. Elizabeth and Swedish Covenant) and from hospitals in St. Louis, a comparable Midwestern city, will be compared with the 2 intervention neighborhoods/hospitals in Chicago.

Specific Aim 3 (Comparative Effectiveness-Knowledge and Attitudes)

In addition to assessing change in action, we will conduct a survey to assess changes in knowledge, self-efficacy, and barriers to calling 911 (i.e. mechanisms for behavioral change), we will use a 2 group pre/post test design among 198 community dwelling persons from the 2 intervention

neighborhoods compared to 198 from the 2 control neighborhoods. Participants will be recruited using Participant Interest Forms completed at Promoter-led events or at already occurring stroke informational events conducted several times per year at the 2 control PSCs. Incentives ($25) will be provided to motivate individuals to participate. Control subjects will receive standard print materials regarding stroke risk factors, warning signs, and use of 911 (i.e. FAST materials). The 2 groups will be assessed at baseline and 1 year by phone interview in English or Spanish. The interviews will last approximately 30 minutes by telephone, and will not be audio recorded. Their responses will be written down in a password protected database.

Consent and evaluation tools will be submitted as an amendment to the protocol at the start of year 2 after modifications are made based on the results of Aim 1.

Sources of Data Collection Aim 1 (Focus Groups)

Research Material: The data that results from the focus group is in the form of transcripts. During analysis, quotes from the participants will be organized into a coding document. Participants will also fill out a brief demographic form prior to participation.

Access to Research Materials: Access to research materials will be limited to IRB-approved personnel. All transcripts will be kept on NU's secured internal server, with folder-level access restricted to only those on the IRB list of approved personnel. Transcripts and demographic forms will be de-identified, and participants will be referred to by a study ID only. Original transcripts with identifiers will be destroyed once de-identified versions have been created. Personal identifiers will be kept only during recruitment, and destroyed when focus groups are complete. Any paper data will be kept in locked file cabinets at the Northwestern University, accessible only to the PIs and Study Coordinator.

Sources of Data Collection for Aim 2 (Implementation)

Research Material: The data from the activity forms (participant and stroke promoter) will be collected by study personnel and transcribed into a database using REDCap for analysis and storage, an NIH-supported research data collection tool, which will be housed within NU's server and firewall.

Access to Research Materials: Access to research materials will be limited to IRB-approved personnel. All data will be stored in NU servers, available only to those with a password and login. Stored data will not contain human subject identifiers, except for Stroke Promoter ID number assigned by the Study Coordinator. Any paper evaluation forms will be kept in locked file cabinets within NU's Department of Neurology offices.

Sources of Data Collected for Aim 3 (Comparative Effectiveness-Behavior and Action)

Research Material: Hospital data will be collected using the AHA-partnered Get With The Guidelines Stroke registry, a voluntary quality improvement registry into which participating hospitals use a web-based Patient Management Tool (Quintiles Inc., Cambridge, MA) to collect stroke-specific demographic, clinical, and hospital outcome data, access decision support, and provide real-time online reporting of performance on quality of care measures. Records are de-identified and collected for quality improvement with a waiver of informed consent under the common rule. All PSCs in Chicago and in St. Louis currently use this registry for data collection.

Access to Research Materials: Access to de-identified data will be limited to IRB-approved personnel.

Sources of Data Collected for Aim 3 (Comparative Effectiveness-Knowledge and Attitudes)

Research Material: Data from this aim will be collected using an interview format and conducted by the CEERIAS Study Coordinator by phone. These will be entered directly into a data collection tool on REDCap and housed on a password-protected storage space in the NU server and within its firewalls. Follow-up interviews at 1 year will be completed by phone and entered into the same server space.

Access to Research Materials: Access to research materials will be limited to IRB-approved personnel. All data will be stored in NU servers, available only to those with a password and login. Survey data will contain only a subject ID, assigned by the Study Coordinator.

5. Study Participants

Patient Population: The proposed study will include a diverse population with respect to age, gender, race, and ethnicity. Our partnering institutions, community advisory board members, the focus groups members, and the people we want to reach will reflect this diversity. A wide range of age groups from school children to seniors and inclusive of both genders will be recruited for Aims 1 and 2. The table below summarizes the race-ethnic and overall populations in the intervention neighborhoods based on 2010 census data and characteristics of stroke patients admitted in 2013 (UC Census 2010).

Population and race-ethnic demographics of the 26 neighborhoods within 80% catchment of 2 intervention PSCs									
Total Population	Non-Hispanic White		African-American		Hispanic		Asian		
797,127	88,181 (11.1%)		493,320 (61.9%)		203,102 (25.6%)		5,281 (0.6%)		
Annual admissions, EMS use, and demographics of the stroke patients admitted to 4 PSCs in 2013									
	Total	% EMS	Mean age	% Women	White	AA	Hispanic	Asian	Other
Trinity	413	44%	68.2	60%	6%	90%	4%	0%	3%
Holy Cross	353	36%	65.4	59%	13%	75%	12%	0%	1%
St. Elizabeth	336	43%	66.3	47%	16%	25%	50%	2%	57%
Swedish	421	49%	72.4	46%	56%	6%	17%	23%	15%

Subject Characteristics: All survey participants will be children age 18 to 21 years of age and adults over 21 and will be recruited over a 12 month period in year 2 from interventional sessions held by CEERIAS Stroke Promoters in the 2 intervention communities or at standard stroke community fairs held in the 2 control communities. Interested participants will be contacted to provide informed consent. After informed consent, a CEERIAS research assistant will conduct a brief phone interview and complete the surveys. Subjects must be able to read, speak, and understand English or Spanish. Patients with cognitive deficits that prevent communication will be excluded. A research assistant will also confirm eligibility based on residence (ZIP code) of participating subjects. Instruments are listed in the table below.

6. Recruitment and Informed Consent

Focus Groups (Aim 1)

Potential layperson and patient/caregiver focus group participants will be identified by community organizations we have partnered with and local hospitals (Holy Cross and Trinity Hospitals). Potential participants will be asked if a study researcher may contact them regarding a survey about stroke symptom recognition and action. At the time of recruitment, all procedures, risks and benefits and the option to withdraw without penalty will be reviewed with each potential participant. If the individual agrees, the CEERIAS Study Coordinator will contact them by their preferred method of communication and discuss the study in detail. We will also post IRB approved fliers at community sites including clinics, hospitals, and community centers such as churches with a number that interested participants may call. Community leaders/stakeholders will be recruited directly by CEERIAS research team members. We will solicit participation in the focus groups from partnering organizations and also an established list of known local groups and organizations.

To ensure effective recruitment and participation, we will contact interested participants at least 2 weeks prior to a scheduled focus group; send confirmation letters to selected participants 1 week before the focus group describing the time and location of the group, as well as any special instructions for participants, and a copy of the informed consent document to review in advance of the focus group; and make final reminder telephone calls to every participant 1 day before the group meets.

Informed Consent: Participants will be sent a copy of the consent document in advance of the focus group, but are not required to sign or bring it to the group. Research assistants will be available by phone to answer questions in advance. At the start of each focus group, the moderator and a research assistant will distribute the consent form and describe the focus group proceedings. Participants will be reminded of their right to quit at any time without penalty or to refuse to answer any questions, and we will review their privacy rights. There will be time for questions and concerns, including available research assistants and private space for those who request discussion. Once the informed consent document has been signed by each attendee, a signed copy will be provided to the participant for their records.

Key informant telephone interview (Aim 1)
We will also conduct key informant interviews of stakeholder/community leaders. We expect to successfully recruit 6-10 adults (age > 18 years) for layperson focus groups using a purposive strategy, recruiting subjects from each ethnic group in targeted neighborhoods. Since key informants will be generated from contacts with community organizations and advisory board members' input, we plan to recruit key informants using direct communications to individuals referred or recommended by our research team, CAB, and collaborating organizational partners.

Informed consent: Identified key informants will be asked to participate one-on-one by telephone using the focus group interview guide as a reference. Consent will be obtained by telephone at the start of the interview. Only those who agree to participate will continue with the interview. The interviews will be performed only in English.

Stroke Promoter Training (Aim 2)
Stroke Promoters will be identified by community organizations, Stroke Promoter referrals, and interested participants at community events when they complete the Participant Interest Form. The CEERIAS Study Coordinator or research assistant will obtain these forms, contact interested Stroke Promoters to provide an overview of the CEERIAS study, and confirm their interest in participation in an upcoming MIP-PACT training session. At training sessions, breakfast and lunch will be served. To ensure effective recruitment and participation, we will contact interested participants at least 2 weeks prior to a scheduled training session; send confirmation letters or emails to confirmed Stroke Promoters 1 week before the training data describing the time and location, and a copy of the informed

consent document to review in advance of the MIP-PACT training session; and make final reminder telephone calls to every participant 1 day before the training session.

Community participants attending the Stroke Promoter-led activities will be asked to fill out the Participant Interest Form and Participant Activity Evaluation Form. All persons who noted an interest (very interested or somewhat interest) in learning more about the CEERIAS study will receive a follow-up telephone call from the CEERIAS Study Coordinator to discuss the CEERIAS study, answer questions and review the informed consent. Enrollment into the Stroke Promoter Program or participation in the survey will follow the flowchart as noted in Figure 5. Each consenting individual will receive a unique study ID without personal identifiers. Demographic data from the Participant Interest Form and survey forms will be entered in a REDCap database stored within Northwestern University's firewalls and will be password protected. Access will be limited to approved study personnel only.

The participant may remove their data at any time by contacting either of the co-PIs. If consent is not obtained within 6 months from the date noted on the Participant Interest form, or if the patient refuses to participate after discussion of the study details, we will assess reasons for patient refusal to provide informed consent as this information will help us anticipate obstacles that will be encountered in the future. In addition, the CEERIAS study staff will destroy the Participant Interest Form and retain no participant data.

Informed Consent: The IRB approved informed consent form will be sent to the prospective Stroke Promoter participants in advance of the training session, but they will not be required to sign it or bring it to the group. This consent form will describe the overall goals of the CEERIAS study and the types of questions that will be asked of the Stroke Promoters. Information obtained will only be used for research purposes.

The CEERIAS Study Coordinator will be available by phone to answer questions in advance. At the start of each training session, the co-PIs and/or CEERIAS Study Coordinator will distribute the consent form and describe the training session agenda. Participants will be reminded of their right to quit at any time without penalty and we will review their privacy rights. There will be time for questions and concerns, including available research assistants and private space for those who request private discussion. Once the informed consent document has been signed by each attendee, a signed copy will be provided to each participant.

Aim 3 (Comparative Effectiveness-Knowledge and Attitudes)

In year 2, community residents will be identified at hospitals, community organization sponsored stroke events (intervention and control groups), or recruited from persons indicating interest in the CEERIAS study. At non-intervention sites where educational events are being held, informed consents will be available for distribution and review to interested participants along with a copy of the Participant Interest Form to be completed at the site and returned to the contact person at each site. Incentives ($25) will be provided to motivate individuals to participate.

Informed Consent: After submitting the Participant Interest Form, the participant will receive a follow-up telephone call to obtain verbal consent for the CEERIAS Study. In giving consent, the Study Coordinator will explain the CEERIAS study and review the consent form. After all questions and concerns have been addressed and the consenting has occurred, the Study Coordinator will begin the survey immediately if convenient or schedule a time to call back. If the patient refuses to participate after discussion of the study details, we will assess reasons for patient refusal to provide informed consent as this information will help us anticipate obstacles that will be encountered in the future. The CEERIAS study staff will destroy the Participant Interest Form and retain no participant

data. In addition, if consent is not obtained within 6 months from the date noted on the Participant Interest Form the form will also be destroyed.

Risks: Risks are very minimal and may include questions that will make participants uncomfortable. There is also an unlikely risk that personal information could be revealed. All subjects will be reassured about the risk of discomfort and we have taken careful precautions to ensure that the latter does not happen.

Protection against Risk: We will try to minimize participant discomfort with any questions or discussion by reassuring patients that they can skip any questions that they do not wish to answer. If this occurs, the research task will be stopped until the subject verbalizes readiness to continue, change the topic, or terminate the session. We will reassure participants also about security systems in place to prevent personal information being divulged. This is unlikely due to security settings at NU and stringent HIPAA and ethics training of all research staff.

Potential Benefits: There is no direct benefit to participation in the focus groups or survey data collection. However, some participants may feel satisfaction from the fact that their input may influence the community interventions we plan in Aim 2 of the study and community stakeholders and Stroke Promoters may feel good about contributing in a larger mission that serves their constituents.

Alternatives: The alternative is not to participate in this study. All individuals will be reassured that this will have no bearing on the care they receive or will receive for health-related concerns or participation in future studies.

6. Statistical Analysis

Statistical Considerations and Power: Existing data of monthly onset-to-hospital arrival times and EMS utilization from January 2013 to December 2017 (five years; n=60 months) will be obtained through AHA. We will assume approximately one-third (20 months) will be post-intervention periods. The effect size will be defined as the sum of expected slope change (i.e. monthly change) over the standard deviation. Table 1 shows the study power by autocorrelation level and effect size. Assuming pre-intervention EMS use rate is 50% on average (SD: 3%; 40 months of data) and post-intervention EMS use rate is 55% on average (SD: 3%; 20 months of data; auto-correlation=0.3) and no trend change ("flat") in pre- or post-intervention periods, this 5% step-increase will be significant at 90% power at a significance level of 0.05. For a 10% step-increase (the goal) with the same assumptions, power is nearly 100%.

7. Anticipated Results and Potential Problems

Importance of the Knowledge to be Gained

The goal of this study is to develop a better understanding of individual- and community-level barriers to stroke awareness and action. The study addresses an important gap in our current ability to improve stroke outcomes. The study results will advance our knowledge of barriers to calling 911 after stroke and help develop solutions to overcome them in urban multi-ethnic communities. Subsequent adoption by other cities and non-urban populations is likely as the methodology could be replicated elsewhere and potentially for other emergency conditions like heart attack and cardiac arrest. By addressing methodological issues, a culturally specific innovative education program targeted for the minority communities can be successfully implemented. This study also can provide valuable insights on within group and between group variability in the barriers for

accessing stroke care. These may be relevant for future applications, refinement, and iterations of the intervention.

Limitations and Alternatives

Aim 1: Focus groups are time consuming and resource intensive. The outcome of the focus groups will reflect small sample sizes compared to the amount of data that quantitative surveys are able to collect. Focus groups may become influenced by one or two dominant people, which may bias the output since other respondents may feel pressure to answer questions in a similar manner to the overriding voices. If the moderator phrases the questions differently between groups they may bias the findings. In addition, focus groups are conducted in an artificial environment which could influence the responses. An alternative to the focus group would be to conduct additional in-depth interviews. If we notice diverse opinions are not shared and individuals are not heard, we could follow-up with them individually.

Aim 2: Because the MIP-PACT program will attempt to disseminate information to a broad audience in diverse settings, it may be difficult to retain control over all aspects of the dissemination process. Stroke Promoters may modify the content and format of the original program, making it difficult to evaluate the results of their efforts and avoid heterogeneity.

Aim 3: There is potential that our 2 intervention hospitals, which admitted nearly 800 stroke patients in 2013, will have a decrease in stroke admissions. However, barring this unlikely scenario, we will be able to detect a 5% change in EMS utilization with >80% power. Since data are entered by participating sites into a web-based registry without central adjudication or oversight, there remains a possibility of data entry error or incomplete data entry. Clinical data from the GWTG-Stroke registry have been found to be associated with > 95% accuracy on a recently completed national audit (Xian 2012).