

Stroke Ready: A Community Based Participatory Trial to Increase Stroke Treatment

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Summary of Changes from Previous Approved Protocol (highlighted in document):

Affected Section(s)	Summary of Revisions Made	Rationale
6.2	Add Michigan National EMS Information System	We found out that ambulance arrival data is not available from one of the hospitals. Thus, we will need to add this new secondary data source.

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1 PROTOCOL SUMMARY**1.1 SYNOPSIS**

Title:	Stroke Ready: A Community Based Participatory Trial to Increase Stroke Treatment
Grant Number:	U01MD010579
Study Description:	Stroke Ready is a health behavior theory-based, multi-level intervention, designed to increase acute stroke treatment in Flint, MI. The hospital-level intervention aims to optimize acute stroke hospital care in a safety net ED. Meanwhile, the community intervention seeks to increase acute stroke treatment (by decreasing pre-hospital delay). Stroke Ready also aims to inform future stroke preparedness interventions by exploring the relative importance of hospital optimization and community interventions.
Objectives:	To increase acute stroke treatment rates in Flint, Michigan through a two-pronged approach of hospital and community level interventions. To inform future CPBR acute stroke interventions by exploring both the relative importance of community and hospital interventions.
Endpoints:	<p>Primary Endpoint:</p> <ul style="list-style-type: none"> Acute Stroke Treatment Rates (tPA and endovascular treatment) <p>Secondary Endpoints:</p> <ul style="list-style-type: none"> Acute Stroke Treatment Rates (tPA) Number of emergency department arrivals by ambulance
Study Population:	Adults in the Flint Community
Description of Study Intervention/Experimental Manipulation:	Stroke Ready is a community based, health theory based, peer-delivered intervention delivered in a stepped wedge design to each of the four Flint community quadrants over the course of 2 years
Study Duration:	24 months
Participant Duration:	Single-session

1.2 SCHEDULE OF ACTIVITIES

Table 1: Stroke Ready Community Intervention Timeline

Quad	Time 0	Time 1	Time 2	Time 3	Time 4
1	Pre-Intervention	Workshop/Mailer Media: Radio/TV/Internet Poster/Brochure	Media: Radio/TV/Internet Poster/Brochure	Media: Radio/TV/Internet Poster/Brochure	Media: Radio/TV/Internet Poster/Brochure
2	Pre-Intervention	Media: Radio/TV/Internet	Workshop/Mailer Media: Radio/TV/Internet Poster/Brochure	Media: Radio/TV/Internet Poster/Brochure	Media: Radio/TV/Internet Poster/Brochure
3	Pre-Intervention	Media: Radio/TV/Internet	Media: Radio/TV/Internet	Workshop/Mailer Media: Radio/TV/Internet Poster/Brochure	Media: Radio/TV/Internet Poster/Brochure
4	Pre-Intervention	Media: Radio/TV/Internet	Media: Radio/TV/Internet	Media: Radio/TV/Internet	Workshop/Mailer Media: Radio/TV/Internet Poster/Brochure

2 INTRODUCTION

2.1 STUDY RATIONALE

With nearly 800,000 strokes in the US annually, stroke is a leading cause of disability.⁵ The number of US stroke survivors is projected to increase from 7 to 10 million by 2030 given the aging baby boomer generation and declining stroke mortality.⁵⁻⁸ Because most people survive their stroke, disability is the greatest challenge facing survivors and their families. About two-thirds of stroke survivors are left with disability.^{9, 10} Acute stroke treatments reduce disability but are underutilized particularly in African Americans. Acute stroke treatments reduce the relative risk of post-stroke disability by over 30%.¹¹⁻¹⁴ The two main phases of stroke care are: 1) pre-hospital— time from when the patient is in the community and a stroke occurs to their arrival to the hospital; 2) hospital— time from stroke patient's arrival to the hospital to receiving acute stroke treatment in the ED. Both of these phases are fraught with delay.

Stroke Ready is a practical and pragmatic approach to increasing acute stroke treatments, based on health behavior theory, that can be implemented in underserved minority communities. The study aims to increase acute stroke treatment rates in Flint, Michigan through a two-pronged approach of hospital and community level interventions. It also aims to inform future stroke preparedness interventions by exploring the relative importance of hospital optimization and community interventions. The result will be a rigorous, expertly crafted and conducted study that has the potential to provide an intervention that will reduce the disability and expense from stroke. This study will also create stroke preparedness public health materials that can be used in wide-spread intervention efforts to reduce stroke risk.

Our hospital-level intervention aims to optimize acute stroke hospital care in a safety net ED. This has been approved under HUM00112536. Meanwhile, the community intervention seeks to increase acute stroke treatment (by decreasing pre-hospital delay). Ultimately, by exploring the effects of the community and hospital interventions individually and together, Stroke Ready can

serve as a model for other at risk communities to increase acute stroke treatment. This application is for the community-level intervention.

Specific Aim 1: To adapt and expand our CBPR-developed, theory-based, Stroke Ready pilot community intervention and implement a hospital-based intervention to optimize acute stroke care in an urban safety-net, hospital.

Specific Aim 2: To increase acute stroke treatment rates in Flint, Michigan through a two-pronged approach of hospital and community level interventions.

Specific Aim 3: To inform future CBPR acute stroke treatment interventions by exploring both the relative importance of community and hospital interventions and the efficacy of the intervention on processes mediating the outcome.

2.2 BACKGROUND

Post-stroke disability is common, costly and projected to increase. Most of the more than 7 million stroke survivors in the US have disability. Acute stroke treatments, which include intravenous tissue plasminogen activator (tPA) and intra-arterial treatment, substantially reduce post-stroke disability but are administered to less than 5% of stroke patients. These treatments are particularly underutilized in Flint, Michigan, where the rate of acute stroke treatment is half the national rate. In fact, Flint has the lowest treatment rate of any region of its size in the entire US, which only exacerbates the existing health disparities in this predominantly African-American community. The low treatment rates of the Flint community are illustrative of racial disparities in stroke — African Americans have a higher incidence of stroke, receive acute stroke treatments less often and experience greater post-stroke disability than non-Hispanic whites. These inequities can be at least partially addressed with interventions to increase acute stroke treatment rates; but practical, cost efficient and sustainable interventions are lacking.

Acute stroke treatments are administered in the Emergency Department and are both rigidly time limited and highly time sensitive. Earlier treatment means a greater chance of stroke recovery (“Time is brain”). One of the main reasons for acute stroke treatment underutilization is pre-hospital delay — patients arrive to the hospital too late to receive the treatment. One strategy to reduce pre-hospital delay is to focus on stroke preparedness (ability to recognize acute stroke symptoms and call 911 immediately) through community behavioral interventions. Over the past 7 years, the research teams composed of researchers from the University of Michigan and community partners from Flint, increased stroke preparedness in Flint through our Stroke Ready pilot intervention (HUM00098718). In addition to pre-hospital delays, hospital delays also contribute to Flint’s low acute stroke treatment rates. When stroke patients arrive to the hospital, a multistep process occurs to determine whether the patient is eligible for acute stroke treatments and to rapidly administer the treatment. Hospitals are known to vary widely in their abilities to execute these complex treatment pathways and thus, optimal interventions to improve treatment rates should target both the community and the hospital.

Flint, the birthplace of General Motors, was once a thriving industrial city. Like many cities in the industrial Midwest, the collapse of the automobile industry has exacerbated the economic struggles of the city.¹ The majority of the population is African American (60%) and over 40% live below the poverty level. Flint is experiencing a water crisis due to high lead levels in the drinking water. It is vital to increase acute stroke treatments in Flint because: 1) Genesee County, where Flint is the largest city, has one of the highest age-adjusted stroke hospitalization

rates in Michigan²; 2) Flint has the lowest acute stroke treatment rate of any community of its size in the US³. Nationally, a mean of 4.2% stroke patients receive acute stroke treatment, but, in Flint the mean treatment rate is 2.2% and the very best regions within Flint only perform at the national average; and 3) Hurley Medical Center, the site of the implementation strategies to optimize ED acute stroke care, is well below the national average in acute stroke treatment quality measures.⁴ This study will inform future acute stroke interventions in underserved, predominately African American communities and safety-net hospitals. It will assist in determining the best use of often limited resources to increase stroke preparedness whether to community preparedness or hospital implementation.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

The Stroke Ready workshop and brief sessions are community-based education with no more than minimal risk, participants will not be consented to observe or participate in the workshops.

The potential risk is possible disclosure of confidential personal health information. We will be obtaining data from the three Flint area hospitals, which will include PHI (addresses and dates), to determine our primary and secondary outcomes.

Physical risks: We do not anticipate our intervention will induce physical risks as it is all based on educational materials.

Psychological risks: We do not anticipate our intervention will induce psychological risks as we provide positive messages. We are not collecting sensitive health information that could lead to psychological harm if disclosed to unauthorized individuals.

Financial risks: We do not anticipate any financial burden all Stroke Ready education and activities are free to the public.

Legal risk: We do not anticipate that our research protocol will include any additional legal risks.

2.3.2 KNOWN POTENTIAL BENEFITS

The goal of this project is to provide stroke preparedness education to increase acute stroke treatment rates in the community. Participants will uniformly gain access to stroke knowledge and education. It is hoped that by increasing knowledge of stroke symptoms and stroke treatments, the community will be more likely to recognize a stroke and call 911 should they see it occur in their community. This will decrease time to hospital arrival and allow us to better care for stroke patients.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

All members of the research team have been trained in research ethics, confidentiality protection, and HIPAA prior to and throughout the study period through the Program for the Education and Evaluation in Responsible Research and Scholarship (PEERRS) training

program at the University of Michigan Medical School. Any additional research personnel must also pass PEERRS certifications.

All PHI identifiable data will be stored on the secure and UMHS approved cloud storage, M-Box. The only researchers with access to the identifiable PHI in M-Box will be Drs. Skolarus, Burke, Lin and Feng. A de-identified dataset will be created from the identifiable data and the only researchers with access to this PHI link will be Drs. Skolarus, Burke, Lin and Feng. After developing de-identified datasets, these datasets will be used for analysis. For all identifiable data collected, the research team will not use them to identify a Stroke Ready workshop participant, stroke patient, or Stroke Ready video viewer.

3 OBJECTIVES AND ENDPOINTS

Table 2: Stroke Ready Program Outcome Measures			
Intervention Goal	Outcome Measure	Data Source	Data collection
Primary Outcome			
Increase acute stroke treatments	Acute stroke treatment rate (IV and EVT)	Flint Hospitals and State Inpatient Database	2010-2021
Secondary Outcomes			
Increase acute stroke treatments	Acute stroke treatment rate (IV only)	Flint Hospitals and State Inpatient Database	2010-2021
Optimize community for acute stroke	ED arrival by ambulance	Flint Hospitals	2010-2021
Tertiary/Exploratory Outcomes			
Optimize ED for acute stroke treatment	Time from hospital arrival to acute stroke treatment	Hurley hospital EMR/GWTG	About 3 years prior to project to 2021
Increase Stroke Preparedness	Time from stroke symptom onset to hospital arrival	Hurley hospital EMR/GWTG	About 3 years prior to project to 2021
Improve self-efficacy, attitude, social norms	Self-efficacy, Attitude, subjective norm	Community Surveys (STYH and FAST)	2015, 2017, 2019, 2021
Increase Stroke Preparedness	Stroke recognition, intent to call 911	Community Surveys (STYH and FAST)	2015, 2017, 2019, 2021
Provide community stroke education	Exposure to local stroke education	Community Surveys (STYH and FAST)	2019, 2021

4 STUDY DESIGN

4.1 OVERALL DESIGN

The Stroke Ready project is a quasi-experimental, health behavior theory based, hospital and community behavioral intervention designed to increase acute stroke treatments. The community intervention will be sequentially delivered to each Flint quadrant, i.e. four clusters defined by the community's geographic boundaries, until all the quadrants have crossed over from control to intervention eventually reaching the entire community (Table 1). This strategy will allow the research team to observe the effects of the community intervention separately from the hospital intervention (HUM112536) to assess the impact of each intervention level. The community intervention consists of workshops, mailers, print, radio and internet media. (Details on study components are in the *Intervention Components* section of this protocol.)

The community intervention components focus on public health education emphasizing the significance of stroke preparedness. Primary Stroke Ready components will consist of peer facilitated educational workshops, a music video adapted and expanded from the pilot (HUM98718), a mass media campaign including print materials (e.g. posters, brochure), health promotion mailers, radio/TV public health service announcements, and the Stroke Ready website and Facebook page (Table 3). The community intervention components are purely public health education, which includes stroke knowledge and stroke preparedness education, and were piloted in (HUM00098718). With regard to the music video, educational print materials, internet platforms, and mailers, there is no need to actively recruit as these interventions will be distributed and/ or implemented among the community as the others parts of the public health stroke preparedness message. We anticipate reaching about 5000 people.

Table 3: Overview of Stroke Ready Components

Intervention components	Summary of intervention	Behavioral Construct	Focus Population	Delivery
Peer-led Workshop	Discussion and interactive stations	self-efficacy, attitude, social norms, knowledge	Churches, organizations, businesses	Peer leaders
Music Video	Educational music video of stroke preparedness	self-efficacy, attitude, social norms, knowledge	Churches, organizations, businesses, events	Peer leaders, local broadcasting station, social media, website
Print media	Posters, brochures	self-efficacy, attitude, knowledge	Churches, organizations, businesses	Peer Leaders, research team, social media, website
Public Service Announcement	Educational PSA of stroke preparedness	self-efficacy, attitude, social norms, knowledge	Flint community	Radio
Website, Facebook, Instagram	Dissemination of information, education, and materials	self-efficacy, attitude, social norms, knowledge	Flint community	Internet
Mailers: magnet, brochure, information letter, action plan	Dissemination of information and education, and materials	self-efficacy, attitude, social norms, knowledge	Flint community	United States Postal Service

We have submitted the near final version of the Stroke Ready materials. Any further changes in the materials will not change the content. Additionally, graphics may be slightly altered to

enhance the professional, finished look of the product. None of the content of the materials should significantly change after IRB approval.

We reviewed the content, graphics, and music with the community to assure appropriateness of content and cultural sensitivity. No participant is forced to watch or read any of the materials. They are provided to the community for them to use as they wish.

Component 1: Peer-led workshop

Peer leaders will deliver the Stroke Ready workshop. It is expected that about 300 workshops will be delivered throughout the 6-month time period per quadrant (x 4 quadrants). The workshops vary in length from (60, 30, 15, 5 minutes), whether they are peer-led and the amount of interactive activities. For all materials and activities, if issues arise e.g., time constraints, the peer-leader may exclude some portions or alter formatting/order of certain sections in the workshop. These changes may be required in response to participant feedback or time constraints. As community organizations have moved to conducting their meetings via virtual format (eg. Zoom, BlueJeans, etc.) during the COVID-19 pandemic, workshops will be delivered via virtual format to maintain social distancing requirements. Community organizations hosting the workshop during their regularly scheduled meetings will provide the peer educator with the meeting link. All aspects of the workshops will remain the same and no data will be collected or saved from participants.

To ensure program integrity, care has been taken to ensure quality and consistency of program messaging across intervention levels and delivery materials by establishing core program components. These core components include, and are defined as follows:

1. **What is Stroke:** defines what a stroke is and what causes it.
2. **Stroke Happens in Flint:** facts about incidence and prevalence of stroke, as well as defining the consequences of stroke.
3. **Stroke Signs (FAST):** Review of signs of stroke—face drooping, arm weakness, speech difficulties, and time to call 911, as well as how to check for each sign.
4. **Stroke is treatable. TPA—the clot bluster:** visual demonstration and/or illustration showing what happens during a stroke and how TPA works to remove a blockage in the brain.
5. **Time is everything:** explanation that medicine to treat stroke can only be given in the hospital, and that earlier treatment is given, the better the chance of recovery.
6. **Stroke Ready Action Plan:** a step-by-step plan to guide a person through calling 911 if they see signs of stroke, and a reminder of the steps to follow when doing so.
7. **Stroke Ready music video or audio:** composed and performed by Flint community members and their academic partners. Include visual demonstration of signs of stroke and reinforcement of program messaging to call 911 and get to the hospital as soon as possible.

60-minute workshop: The core components of the Stroke Ready as listed above will be delivered by a peer leader. There are interactive portions which include role play, group discussions, and self-learning assessments. Each workshop will include education and behavioral/social learning strategies to which all educational materials have been geared. Participants may be given nominal gifts, such as a pens with the Stroke Ready logo.

Media format: (Pending availability of multi-media equipment per workshop location) Delivery of the intervention will be via a PowerPoint presentation with content from the workbook, audio recorded portions covering for core components, and music video.

Non-Media format: A flip chart/easel with content from the workbook will be used for delivery. Music from Stroke Ready video will be played on audio only, however peer leader will be able to facilitate participants viewing of the Stroke Ready music video on their personal smartphones, as well as directing participants to view it on the Stroke Ready website or Facebook page.

Data will not be collected.

30-minute workshop: This version of the workshop is the same as the 60-minute version except it foregoes the interactive components (i.e. the group discussion and role play).

Data will not be collected from the 30-minute workshop.

Mini workshops (brief sessions): These mini workshops, or “brief sessions” are considered a workshop adaptation and do not require delivery by a trained peer leader. This will allow for increased dissemination of the educational information in situations where holding a group session may not be feasible. It is anticipated that these sessions will be primarily delivered at events such as health fairs and “add-ons” to other community programming. There are two lengths for the mini workshops:

15-minute workshop (brief session): This version of the workshop may or may not be peer-led, and is centered around the stroke ready music video and distribution of the stroke ready brochure and action plan. Instructions for accessing the music video online will be provided for those participants not receiving music video due to unavailability of media equipment/power.

5-minute workshop (very brief session): This is a peer-leader led small group or one-on-one session with a community member. The peer leader will go over the stroke ready brochure and action plan. Instructions for accessing the music video online will be provided.

Data will not be collected from the mini workshops (brief sessions).

Component 2: Stroke Ready Music Video

The Stroke Ready music video, an integral component of the Stroke Ready community intervention, was developed during the Stroke ready pilot (HUM00098718), incorporates the National Stroke Association’s FAST stroke symptoms mnemonic (e.g. F-facial droop, A-arm weakness, S—slurred speech, T—time to call 911) into an original gospel-based music score and video. There is also a strong focus on self-efficacy with the video asking viewers to participate in demonstrating stroke signs.²⁹ There will be a full length and shorter version.

The Stroke Ready music video will be available to access on the Stroke Ready website and Facebook page and may be played during in the workshops pending media capabilities. Also, peer leaders will be asked to disseminate the Stroke Ready website address via their email, Facebook, and text messaging contacts. The link will also be placed on print materials.

Component 3: Print media – Posters and Brochures

The Stroke Ready program will include a print media campaign with posters and brochures to be dispersed by the research team per quadrant for display and distribution by local

organizations. All print materials were developed with community input and feedback through focus groups and interviews with community members (HUM00130902). The posters focus on stroke symptoms and the importance of calling 911 among other stroke preparedness messages. The brochure includes all core intervention components.

Component 4: Broadcast Media – TV and Radio public service announcements (PSAs)

An about 60-second version of the music video and audio only version will be created for use as TV and radio PSAs. There will be two additional PSAs including stroke preparedness messages the research team developed using theory based health behavior change methods and reviewed by the community PI.

Component 5: Digital Media Platforms – Website and Social Media

The Stroke Ready website will serve as a central repository for Stroke Ready information central to the Stroke Ready campaign, stroke information, and resources, Stroke Ready workshop information, printable versions of brochures and flyer-size versions of posters, links to community partner sites, and events in the Flint community. The Stroke Ready music video will be linked to the Stroke Ready website, Facebook page and Instagram. The Facebook page will be used to inform followers of upcoming workshops. The Instagram page will include photos and videos of past events as well as stroke-related infographics.

Component 6: Stroke Ready Mailers

The citywide intervention includes mailers printed and distributed throughout the city of Flint on the per quadrant schedule. The mailer may include a Stroke Ready magnet, brochure, action plan, and information letter about the Stroke Ready campaign and where to find more information or a local stroke ready event.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

Flint is naturally divided into 4 quadrants by the cross streets of Saginaw Street and 5th Avenue. The Stroke Ready community intervention will be sequentially delivered to each quadrant, eventually reaching the entire community. Quadrants will be randomly selected and then for 6 months the research team will focus on the selected quadrant of the city (Table 1). During this time the peer workshops will occur, flyers and posters distributed and workbooks made available. At the end of six months, the materials will remain in the quadrant but efforts will shift to the next quadrant. Delivery of the intervention in quadrants will: 1) allow more efficient use of resources; 2) optimize intervention efficacy by increasing the likelihood of repetitive exposure to the intervention and 3) allow for exploratory analyses to determine whether the hospital or community intervention is most important and clarify the efficacy of the overall intervention.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

Workshops will be open to the public. While our primary outcome will observe Flint-based stroke treatment rates, stroke preparedness is a global public health message applicable to most people; therefore, participants will not be excluded if they live outside the city limits. Similarly, the workshops are designed for English-speaking adults; however, non-English speaking people will not be excluded. In collaboration with community partners, Stroke Ready materials were carefully designed as to not be harmful to vulnerable populations, including women and

minorities, children, and the homeless population. The Stroke Ready workshop should not be harmful to children as it is adapted from material delivered to adults and youth in the pilot study (HUM00098718). Thus, if adults choose to bring their children, they will be accommodated in the workshops.

Inclusion of Women and Minorities: Given this is a community education intervention no one will be excluded from the community-level interventions. The Stroke Ready campaign should not be harmful to women or minorities.

Inclusion of Children: The Stroke Ready campaign should not be harmful to children as it is adapted from material delivered to youth in the pilot study (HUM00098718). Children will not be specifically recruited but they will be allowed to attend workshops if they are present.

Inclusion of Vulnerable Populations: Conscious efforts will be made to deliver the Stroke Ready intervention to vulnerable populations (e.g. homeless, cognitively impaired adults, college students, economically or educationally disadvantaged persons). Data will not be collected.

5.2 EXCLUSION CRITERIA

Given this is a community education intervention no one will be excluded from the community-level interventions. The Stroke Ready campaign should not be harmful to vulnerable populations.

5.3 STRATEGIES FOR RECRUITMENT AND RETENTION

The research team and Stroke Ready peer-leaders will work together to recruit organizations and participants for the Stroke Ready workshops through recruitment announcements, flyers, internet platforms, and word-of-mouth. Additionally, the research team or peer leaders may provide a courtesy reminder call several days before the workshop. Since Flint is naturally divided into 4 quadrants the study team will select each quadrant for implementation and then for about the next 6 months they will focus their workshop recruitment efforts and material dissemination on the selected quadrant of the city. However, given the commitment to CBPR the quadrant implementation is preferred but we would not forego a workshop in a quadrant that we are not focusing on at the time if requested. During this time the research team and community partners, including peer leaders, will work together to implement the Stroke Ready workshops and distribute educational posters and materials. At the end of about six months, the materials will remain in the quadrant and efforts will shift to the next quadrant for recruitment and workshop delivery.

To overcome challenges of recruiting racial minorities, low-income individuals, and other disadvantaged populations due to lack of transportation, childcare, inconvenient hours, etc., the research team designed the workshops such that participants can participate at their convenience. The workshops are voluntary and will be delivered by peer-leaders at locations during times that are convenient for the community (e.g. after church services, during lunch breaks). Additional factors that facilitate program recruitment and participation are: 1) the workshops, as well as all Stroke Ready materials and activities, are free and have no more than minimal risk; 2) recruitment materials and intervention components were created by the community for the community; 3) the research team has gained support of local leadership and

community members with strong ties in the Flint community; 4) children will be allowed to attend (HUM00098718).

Internet platforms will be utilized to recruit participants. Upcoming workshop events will be posted on the Stroke Ready Facebook page and website.

The research team will oversee the activities related to workshop participant recruitment to track the campaign's reach and resources, and workshop delivery processes to assess workshop fidelity.

5.4 PEER LEADERS

To build community capacity as well as to increase the uptake and relevance of the workshops in the community, peer leaders will be hired from the Flint community as much as possible for our community based intervention. We will recruit up to 16 peer leaders to start but recognize there may be turnover during the intervention or high demand for additional workshops; therefore, the research team may need to recruit additional peer leaders during the workshop delivery phase. We will pay about \$15 per hour for recruitment and delivering the workshops that include the minimum required attendees. We anticipate that some the peer leaders may be UM-Ann Arbor or UM-Flint students who prefer class credit to payment. If this were the case, we would work with the institution to facilitate credit attainment. Peer leaders will be cross-trained so that if one is unable to show up on the day of the workshop another peer leader will be able to facilitate the group. Peer leaders will be strongly encouraged to deliver workshops every week for the duration of the project.

The peer-leaders are not participants, but facilitators of the workshop. They will facilitate the workshop discussion and activities through use of a peer leader workshop facilitation guide and pre-recorded script. The research team will be available during business hours and as much as possible outside of business hours for any questions or concerns.

The peer leaders will be over the age of 18. There are no exclusions related to race/ethnicity or sex.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 FIDELITY

6.1.1 INTERVENTIONIST TRAINING AND TRACKING

The research team will conduct fidelity assessments and collect process measures to track any changes or adaptations made to a Stroke Ready workshop and Stroke Ready campaign upon implementation. Peer leaders will also be trained in and complete a self-fidelity checklist after each workshop to track and communicate field observations made during workshops, and to document any adaptations made for time constraints or settings. The Stroke Ready campaign will also collect primary, secondary and tertiary outcomes (Table 2).

Fidelity Assessment

The research team will randomly select a proportion of workshops to observe for fidelity assessments to assess whether the workshop is being conducted as intended. Other fidelity

measures the research team will collect include exposure of dose, quality of delivery, participant responsiveness, program differentiation, and intervention complexity.

Aspects of fidelity the research team will measure (See Appendix A) include:

Dose delivered – as measured by workshop duration and content delivered;

Dose received – as measured by post-intervention survey to determine exposure to all intended activities per workshop type & satisfaction;

Quality of delivery – as measured by facilitator's utilization of techniques prescribed by the program (use of facilitator's guide, use of audio/PowerPoint, appropriate facilitation of activities);

Reach – as measured by numbers served.

Barriers to participation--documented by peer leaders on the self-fidelity checklist, as well as by the research team during fidelity assessments;

Participant responsiveness – as measured by satisfaction survey to identify participant interest in activities and perceived usefulness of information;

Program differentiation – as measured through a satisfaction survey to identify which workshop components participants liked most;

Intervention complexity – as measured through tracking peer facilitator's attendance at initial training session and completion of refresher training if it has been longer than 6 months since the facilitator last delivered a workshop (which will be available as an online training module);

Context – as measured through observation field notes of aspects of environment that may influence intervention implementation or study outcomes.

Uptake of the Stroke Ready video and internet materials will be measured by counts of internet hits from internet protocol (IP) addresses of video viewers from within Flint. This will be tabulated by linking to a database that maps IP address to physical locations.

Table 4: Process Measures	
Community Intervention Process Measures	
Uptake: Music video	-Number of internet hits -Number of internet hits from within Flint
Uptake: Workshops	-Number of workshop locations -Number of workshops held (each type) -Number of workshop participants
Uptake: Print media	-Number of mailers, action plans and brochures distributed
Uptake: PSAs	-Number of plays of PSAs on radio and TV
Facebook uptake	- Number of likes on Facebook page
Instagram uptake	- Number of followers on Instagram page
Website uptake	-Number of hits to Stroke Ready website

	- Number of hits to Stroke Ready website (from within Flint via IP address)
Uptake: Workbook	-Number of materials distributed
Community Satisfaction	-Workshop survey -FASt Survey -Speak to Your Health Survey

6.2 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

The primary outcome will be measured from hospital electronic record (EMR), billing data and/or from the Get With the Guidelines (GWTG) stroke registry data. Data will be separately received from the three hospitals in Flint where patients are sent for EVT (received letters of support and UFA in progress), which together account for 95% of all stroke treatments in Flint residents. The study population will be patients with a primary diagnosis of ischemic stroke using ICD-9 codes and/ or ICD-10 codes^{33, 34}. The primary outcome will be any thrombolysis which includes both IV tPA (MS-DRG 61-63 or ICD-9 procedure code 99.10), intra-artery treatment (MS-DRG 21-23 or CPT codes 37184-6, 37201, 75896) and the combination identified by ICD-9 and ICD-10 codes.³ The research team will attempt to obtain data from 2010 to 2021 if available to account for linear trends (about 6000 ischemic stroke and 8000 total strokes and TIAs). Data will also be obtained from the de-identified publicly available Michigan State Inpatient Database for stroke rates in comparator cities.

Secondary Outcomes: The community secondary outcomes are the number of stroke patients who arrive by ambulance and IV acute stroke treatment rates. Data will be obtained from the EMR. We also request data from the State of Michigan, specifically Michigan Department of Health and Human Services, Michigan EMS Information System UFA (21-UFA04001) or GWTG data of the three hospitals in Flint.

Tertiary/exploratory outcomes: The tertiary/exploratory outcomes include onset to door time and door to needle time which will be obtained from the hospital EMR and GWTG. Survey data will also be obtained. The community survey, Speak to Your Health, is a biennial, geo-coded survey that has been designed and administered by the Flint community, Genesee County Health Department since 2003.³⁵ We added questions from the Stroke Ready pilot (HUM00098718) (including stroke attitude, self-efficacy, social norms, and written stroke preparedness vignettes) to this community survey (see Appendix B) that was administered in 2015/2017 and will continue in 2019 and possibly 2021. The research team may add stroke education exposure questions to the 2019 and 2021 STYH surveys (see section 29 of IRB application- exposure questions). These additions, along with the original questions, will assess community level change in response to the Stroke Ready program; as well as exposure to local stroke education (See Appendix B). Additionally, these same questions will be added to the Flint Area Study. This is a face to face interview of Flint residents. The survey data will be de-identified. STYH and FASt surveys are ongoing surveys in Flint. The data is de-identified and publically available.

7 STATISTICAL CONSIDERATIONS

7.1 STATISTICAL HYPOTHESES

- **Primary Endpoint(s):** The primary endpoint is change in acute stroke treatment rates (IV tPA and endovascular treatment).

- Secondary Endpoint(s): The secondary endpoints are change in acute stroke treatment rates (IV tPA) and ambulance utilization.

7.1.1 ANALYSIS OF THE PRIMARY ENDPOINT(S)

The primary analysis will be an interrupted time series comparison of acute stroke treatment rates in the three Flint hospitals. The pre-intervention period will be defined using EMR data prior to the start of the roll out of the community intervention. All patients admitted with a primary diagnosis of ischemic stroke in both the pre-intervention and intervention periods will be included in the primary analysis. Note: process measures evaluating the Stroke Ready campaign (quadrant crossover or music video view IP address) will not be linked to any obtained PHI. Logistic regression will be used to estimate the overall intervention efficacy (indicator variable) in a model predicting receipt of acute stroke treatment (binary variable). If a temporal trend exists in the pre-intervention period, we will adjust for the month since the start of the pre-period as a fixed effect while accounting for clustering at the hospital level. To maximize statistical power, both interventions (hospital-HUM00112536 and all community quadrants-this current protocol) will be parameterized with a single variable. With this approach, statistical power for the primary analysis will be more than adequate. Using hospital administrative and Medicare data, we estimate that at least 480 strokes per year will occur at the 3 Flint hospitals for a total of at least 1,440 strokes in the pre period and 1,800 in the post-period, but to be conservative we are requesting data from 2010 to 2021 about 8000 patients with a stroke. Assuming a doubling in treatment rates (pre-intervention Medicare treatment rate 2.2%),³⁷ we will have over 90% power to detect this difference considering a two-sample binomial difference in proportions. This estimate is consistent with prior simulation work based on ARIMA analyses (effect size of 1.0 (pre-intervention monthly treatment rate = 2.2%, standard deviation = 2.1, predicted post-intervention treatment rate 4.3%, auto-correlation=0.3).³⁸

7.1.2 SECONDARY ANALYSES: REGIONAL COMPARISONS AND QUADRANT-BASED ANALYSES TO ENHANCE CAUSAL INFERENCE

Secondary analyses will explore the extent that such confounding may influence the primary analysis and enhance the ability to draw causal inferences from the primary analysis. First, we will repeat the primary analysis with a concurrent control group consisting of other large Michigan metropolitan regions (regional control model) where African-Americans make up more than 25% of the population (Detroit, Saginaw, Muskegon, Benton Harbor). This analysis will control for regional effects that may lead to increased treatment rates that occur simultaneously with our intervention in Flint using data from the Michigan State Inpatient Database (SID),³⁹ which collects de-identified data on all acute care hospitalizations in the state of Michigan within a given year. Second, by delivering the intervention sequentially to geographic quadrants within Flint, we will explore whether increases in acute treatment rates parallel the geographic pattern of intervention roll out (geographic model). Specifically, each stroke patient in Flint will be geocoded to one of the four intervention quadrants using EMR data and a geocoding interface. Our primary analysis will then be repeated by modifying the intervention indicator variable to represent whether the intervention was active in the patient's geographic quadrant at the time of intervention.

7.1.3 EXPLORATORY ANALYSES: EFFICACY OF PROGRAM COMPONENTS AND TEMPORAL PATTERNS TO INFORM FUTURE INTERVENTIONS

To inform future interventions, will also perform a series of hypothesis-generating analyses to inform which elements of the program were most effective and the temporal properties of the program. Due to power concerns, our primary analysis does not consider the difference between the hospital and community effects. Thus, we will first estimate the proportion of the change in the acute stroke treatment rate attributable to the hospital-based intervention vs. the community-based intervention by repeating our geographic model including an indicator variable representing the time period of the hospital intervention as well as a community interaction term. In this way, we will be able to explore whether the Stroke Ready hospital or community based intervention was the most efficacious and whether there was synergy between the interventions. The stepped wedge design is a key innovation to this end. In typical multi-level interventions when all of the elements are rolled out nearly simultaneously, it is impossible to estimate which elements have the highest leverage, however with the stepped wedge design it is possible to gain a greater understanding of which elements are most important. Using simulation analyses, we estimate that there will be 70% power to find a doubling at the community level, 55% power to find a doubling at the hospital level and 21% power to find a doubling through a community-hospital interaction. Because this power is inadequate for a hypothesis-testing evaluation, we have specified this analysis as an exploratory analysis whose purpose is enhance our understanding of the importance of intervention elements and to inform future interventions. Second, we will determine the temporal properties of the Stroke Ready intervention by adding a linear slope term and exploring quadratic terms in our geographic model to estimate the time delay between intervention and changes in treatment rates and whether treatment rates level off or decline as the intervention persists into its latter years. Finally, a strength of our data collection approach is that we will be able to inexpensively assess the sustainability of intervention effect using Michigan SID data years after the intervention is completed without needing to perform additional data collection. Together, such analyses will determine the sustainability of the intervention and inform future interventions.

7.1.4 ANALYSIS OF THE SECONDARY AND TERTIARY ENDPOINT(S)

Changes in the proportion of patients arriving by ambulance over time will be assessed using logistic regression with an indicator variable representing the intervention period. Changes in IV tPA will be evaluated using an interrupted time series comparison of acute stroke treatment rates in the three Flint hospitals.

Changes in the time from ED presentation to acute stroke treatment and door to treatment will be explored using linear regression with a similar indicator variable representing the intervention period. Changes in outcomes measured with the community survey across intervention waves will be assessed with ordinal logistic regression (Likert-based outcomes) or chi-squared tests (binary outcomes) with indicator variables representing the survey wave. Process and satisfactory measures will be summarized with descriptive statistics, as pre-intervention values will be either unmeasurable or unintelligible, formal statistical comparisons will not be performed.

7.1.5 COST EFFECTIVENESS ANALYSIS

The research team will assess the cost effectiveness of the overall Stroke Ready Program. Cost-effectiveness will be estimated for two intervention scenarios: Stroke Ready delivery and Stroke Ready development and delivery. This will inform the value of taking the Stroke Ready Intervention, “out of the box” and delivering it in a novel context and to separately assess the cost of developing and delivering a similar intervention in a novel context.

Cost inputs to the models will be carefully recorded throughout the project. For development costs, we will use budgets from the Stroke Ready pilot to estimate the cost of developing all materials used in this proposal — music video, workbooks, workshop content and print media. Delivery costs will be tracked with each phase of the Stroke Ready program. All Stroke Ready material expenditures (e.g. print media production, website maintenance, Facebook and Instagram content marketing boost) will be tracked, and as appropriate, assigned to either the hospital or community portion of the intervention. To track personnel time for the workshops, we will maintain a spreadsheet and update it after every Stroke Ready workshop with the number of individuals involved, including participants. Each hour spent on the grant will be mapped to costs by assigning appropriate job titles and then mapping hourly wages for that title to Bureau of Labor Statistics Survey wage survey data by profession.³⁰ By summing work time costs and material costs, we will be able to estimate the total costs of the overall intervention and the hospital and community interventions separately. We will then separately estimate total quality adjusted life years (QALYs) gained by the Stroke Ready program (and separately for the hospital and community interventions) by applying the primary outcome treatment effect size to the total hospitalized population (i.e. 2.2% increase in treatment rates * 500 strokes = 11 additional patients treated) and estimated QALY gain using published stroke cost effectiveness models.^{31, 32} Estimated hospital and community effect sizes will be obtained from our secondary analysis assessing intervention component efficacy. The age distribution of patients who receive treatment via the intervention will be obtained from the overall Flint stroke population. By using repeated bootstrap samples from this population and repeatedly running the model we will estimate 95% credible intervals on the QALY gain. We will then estimate the Incremental Cost Effectiveness Ratio (ICER) by dividing estimated costs / estimated QALY gain across all scenarios.

7.1.6 SUSTAINABILITY

Project sustainability will come through several mechanisms: 1) training of peer leaders who will have knowledge of stroke warning signs and the importance of calling 911; 2) a complete community intervention package that can be administered with little to no training; 3) a well-positioned CAB to promote sustainability; and 4) optimized acute stroke care in a safety net hospital. The products of this application include a strategy to improve acute stroke treatments in safety-net hospitals and an easy to deliver Stroke Ready community intervention to allow for successful dissemination. If successful, this proposal will directly benefit the Flint community by increasing acute stroke treatment rates thereby decreasing post-stroke disability. Furthermore, it will inform future acute stroke interventions, especially in underserved, predominately African American communities.

8 DATA CONSIDERATIONS

8.1 DATA

Data and information collection from workshop participants will cease pending the approval of the IRB Amendment (Ame00084323). Previously collected satisfaction surveys and address forms (June 2018-January 2019) will be stored securely and analyzed. Pending amendment approval, there will be no data or information collected from workshop participants (no satisfaction surveys or address forms).

The only PHI identifiable data in this study will be addresses and hospital dates of stroke patients collected from the three Flint area hospital detailed below.

De-Identified

The community surveys, Speak to Your Health and the Flint Area Study, are publically available and de-identified. The Michigan State Inpatient Database (SID), which collects data on all acute care hospitalizations in the state of Michigan within a given year is also de-identified. The satisfaction survey and fidelity assessments will not include personal identifiers.

Identified

A process measure is the number of views of the Stroke Ready music video. This will be assessed by the number of internet hits from the Flint community via internet protocol (IP) addresses. The only use of this data is to assess the whether or not the video was viewed by and for the community it was intended. Additionally, basic analytics will be used to assess website visits. Data extracted will be number of views on the Stroke Ready website—total visits and visits from the Flint community via IP addresses. Exploratory analytics may include new versus returning users, frequency and engagement of site visits. We request a waiver of informed consent.

Hospital data will be obtained from the Flint area hospitals. Data may include basic demographics, treatments, date of admission and date of treatment, stroke process measures, comorbidities, and outcomes of stroke patients. This data will include identifiable information in the form of addresses, in order to map the stroke event, as well as dates. We expect some of this data to come from the EMR, billing records and Get With the Guidelines Stroke. We are working with each hospital to establish a data use agreement. We request a HIPAA authorization waiver and a waiver of informed consent.

All PHI data will be stored on the secure and UMHS approved cloud storage, M-Box. The data from the hospitals will be directly uploaded into M-Box. The only researchers with access to the identifiable PHI in M-Box will be Drs. Skolarus, Burke, Lin and Feng. A de-identified dataset will be created from the identifiable data and the only researcher with access to this PHI link will be Drs. Skolarus, Burke, Lin and Feng. After developing de-identified datasets, limited analytic datasets will be used for analysis.

For all identifiable data collected, the research team will not use them to personally identify a Stroke Ready workshop participant, stroke patient, or Stroke Ready video viewer.

8.2 DATA SAFETY AND MONITORING

Given this is a minimal risk stroke education behavioral intervention, the PI, Dr. Meurer, will monitor adverse events. Adverse events from the Stroke Ready intervention will be reported by participants.

9 PROTOCOL AMENDMENT HISTORY

The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.

Version	Date	Description of Change	Brief Rationale
2.0	12/19/2018	Re-formatted protocol, addition to study team, update secondary and tertiary/exploratory outcomes, update workshop target goals, update study design, update data collection protocol, expand scientific rationale of study, update digital media platforms and data analytics, inclusion of vulnerable population, update recruitment plan, update data and safety monitoring plan	Reformatted the original protocol (version 1.0) to a clinical trials format. Updated study team with new hires. Distinguished and updated secondary and tertiary/exploratory outcomes. Update workshop target goals. Update study design to include 15-minute brief and 5-minute very brief session, accommodating for different event settings. Update study population to include vulnerable subjects. Update recruitment plan to include Facebook page and launched Instagram page. Update on website data analytics plan. Update data collection— data (satisfaction survey and address forms) will NOT be collected from any of our workshops. Removed consent for workshops given data will not be collected. PI Meurer will be overseeing adverse events.
4.1	Clarification of delivery of peer-led workshops via virtual format.	Community organizations have moved to conducting their meetings via virtual format (eg. Zoom, BlueJeans, etc.) during the COVID-19 pandemic, thus we will be delivering stroke education workshops via virtual format to maintain social distancing requirements.	

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Appendix

Reviewer Name: _____ How many peer leaders were present? _____

Appendix**Appendix A:****Stroke Ready Fidelity Observation Form**

Peer leader name:	1 st assessment: <input type="checkbox"/> Yes <input type="checkbox"/> No
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Workshop Location:	Date:
Address:	Start Time:
	End Time:
Workshop Length: <input type="checkbox"/> 60-minute <input type="checkbox"/> 30 –minute <input type="checkbox"/> 15 –minute	Number of participants _____

<u>Logistics</u>	Yes	No	Why/Why Not?	Notes/Comments
Did the workshop start on time?				
Did the workshop end on time?				
Did all participants stay for the entire workshop?				
Did each participant receive a workbook/brochure, pen & bracelet?				
Did the workshop run the expected length of time? (i.e. did a 30 minute workshop run for 30 minutes or less?)				

Please answer the following about workshop activities.

<u>Implementation</u>	Yes	No	Why/Why Not?	Notes/Comments
Was the appropriate Presenter's Guide used by the peer leader?				
For 60-minute session:				
Were the easel and Presenter's chart set up?				

Was the audio player used to deliver workshop content?				
Were the following core components covered in the workshop?	Yes	No	Why/Why Not?	Notes/Comments
What is Stroke				
Stroke Happens				
Good News – Stroke is Treatable				
Stroke Signs				
TPA – the clot buster (illustration)				
Time is everything				
Stroke Ready Action Plan				
Music audio				
OR				
Music video				
TPA demonstration machine				
Which of the following interactive activities were included?:	Yes	No	Why/Why Not?	Notes/Comments
Why is it important to you to learn about stroke?				
Think FAST question page				
Reasons people give for not wanting to go to the hospital				
Role Play				
How many people participated in the role play? _____				
Self-assessment questions				
Check your Stroke Ready knowledge and review answers				
	Yes	No	Why/Why Not?	Notes/Comments
Did all participants sign the action plan?				
If participants were reluctant to participate in activities, did the leaders gently encourage, but NOT force their participation (even if unsuccessful)?				

Please answer the following about the peer leader(s).

<u>Facilitator/Participation</u>	Yes	No	Why/Why Not?	Notes
Did the peer leader:				
Have a professional appearance?				

Appear knowledgeable?				
Appear welcoming?				
Leave out or skip over content?				
Play audio clips in their entirety?				
Keep participants on topic?				
Encourage participant discussion after asking questions (as instructed in Presenter's guide)?				
Answer questions from participants appropriately? (i.e. Did they stick to responses provided in training?)				
Did participants:				
Appear to respond well to the peer leader?				
Appear interested in the content?				
Ask relevant questions?				
Participate in activities?				

Please answer the following about the workshop location.

<u>Setting</u>	Yes	No	Why/Why Not?	Notes
Overall, was the setting conducive to workshop delivery (i.e. participants could see/hear facilitator, easel and audio/visual clips)				
Was the workshop location easy to find?				
Was there adequate parking?				
Were there accessible electrical outlets for the TPA demonstration?				
Were there enough seats for participants?				

General notes: Please make note of any general observations not included in the notes sections above.

Appendix B:

These questions will appear in the Speak to your Health and Flint Area Survey community-level surveys.

Please circle the ONE option below for each question that BEST describes how you feel (only circle ONE)

1. Medical treatment can help someone having a stroke.				
1	2	3	4	5
<i>Strongly agree</i>	<i>Agree</i>	<i>neither agree/nor disagree</i>	<i>Disagree</i>	<i>Strongly disagree</i>

2. If I saw someone having a stroke, I would know what to do.				
1	2	3	4	5
<i>Strongly agree</i>	<i>Agree</i>	<i>neither agree/nor disagree</i>	<i>Disagree</i>	<i>Strongly disagree</i>

3. Most people would call 911 if they saw someone having a stroke.				
1	2	3	4	5
<i>Strongly agree</i>	<i>Agree</i>	<i>neither agree/nor disagree</i>	<i>Disagree</i>	<i>Strongly disagree</i>

4. Which of the following are signs of a stroke? (Check the box for all that apply)

- ☐ Sudden chest pains
- ☐ Sudden arm weakness
- ☐ Sudden nose bleed
- ☐ Sudden stomach pains
- ☐ Sudden face drooping
- ☐ Sudden trouble talking
- ☐ Sudden coughing hard

What is the first thing you would you do if you saw...

- 5. While walking to the store, your sister suddenly dropped her purse and could not pick it back up. (Please check one box)**

- ☐ Wait a couple of hours, then decide
- ☐ Call a family member or friend immediately
- ☐ Call Doctor's office immediately
- ☐ Call 911 immediately

- 6. While out to lunch, your friend is suddenly confused and unable to order from the menu. (Please check one box)**

- ☐ Wait a couple of hours, then decide
- ☐ Call a family member or friend immediately
- ☐ Call Doctor's office immediately
- ☐ Call 911 immediately

- 7. After helping to move furniture, your friend tells you his arms hurt and feel weak. (Please check one box)**

- ☐ Wait a couple of hours, then decide
- ☐ Call a family member or friend immediately
- ☐ Call Doctor's office immediately
- ☐ Call 911 immediately