Implementation of New Practice in the Treatment of Acute Ischemic Stroke

Eileen Gallagher

Drexel University

College of Nursing and Health Professions
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of Tables</td>
<td>3</td>
</tr>
<tr>
<td>List of Figures</td>
<td>4</td>
</tr>
<tr>
<td>Abstract</td>
<td>5</td>
</tr>
<tr>
<td>Introduction</td>
<td>6</td>
</tr>
<tr>
<td>Problem Statement</td>
<td>7</td>
</tr>
<tr>
<td>Aims and Objectives</td>
<td>8</td>
</tr>
<tr>
<td>Review of Literature</td>
<td>10</td>
</tr>
<tr>
<td>Theoretical Framework</td>
<td>20</td>
</tr>
<tr>
<td>Methods</td>
<td>21</td>
</tr>
<tr>
<td>Project Design</td>
<td>22</td>
</tr>
<tr>
<td>Setting</td>
<td>23</td>
</tr>
<tr>
<td>Evaluation</td>
<td>24</td>
</tr>
<tr>
<td>Human Subjects Protection</td>
<td>26</td>
</tr>
<tr>
<td>Timeline</td>
<td>26</td>
</tr>
<tr>
<td>Strengths and Limitations</td>
<td>26</td>
</tr>
<tr>
<td>References</td>
<td>29</td>
</tr>
<tr>
<td>Table 1. Timeline</td>
<td>33</td>
</tr>
<tr>
<td>Table 2. Table of Evidence</td>
<td>34</td>
</tr>
<tr>
<td>Figure 1. SWOT Analysis</td>
<td>42</td>
</tr>
<tr>
<td>Figure 2. Current In-House Stroke Algorithm</td>
<td>43</td>
</tr>
<tr>
<td>Figure 3. Revised In-House Stroke Algorithm</td>
<td>44</td>
</tr>
<tr>
<td>Figure 4. Gantt Chart</td>
<td>45</td>
</tr>
</tbody>
</table>
### List of Tables

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Timeline for Quality Improvement Project</td>
<td>33</td>
</tr>
<tr>
<td>2. Table of Evidence</td>
<td>34</td>
</tr>
</tbody>
</table>
## List of Figures

### Figures

<table>
<thead>
<tr>
<th></th>
<th>Figures</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SWOT Analysis</td>
<td>41</td>
</tr>
<tr>
<td>2</td>
<td>In-House Acute Stroke Algorithm</td>
<td>42</td>
</tr>
<tr>
<td>3</td>
<td>Revised In-House Acute Stroke Algorithm</td>
<td>43</td>
</tr>
<tr>
<td>4</td>
<td>Gantt Chart</td>
<td>45</td>
</tr>
</tbody>
</table>
Abstract

**Background:** New guidelines in the treatment of acute ischemic stroke include timely recognition of stroke symptoms and evaluation for rapid treatment of stroke with IV t-PA administration and endovascular intervention.

**Methods:** The DNP student/project coordinator led a collaborative effort to integrate the updated AHA/ASA ischemic stroke guideline through revision of the current in-house stroke algorithm; facilitation of the implementation plan; and evaluation of the implementation plan.

**Evaluation:** The DNP student/project coordinator suggested an evaluation of the practice change through monthly discussion of algorithm fall-outs at the Stroke Committee meetings at the hospital.

**Significance and Implications:** Implementation of this project introduced a practice change in the clinical setting for patients who experience an in-hospital stroke. Early consideration for treatment with endovascular intervention may allow for an increase in the number of patients who are eligible to receive ischemic stroke intervention, and may lead to an improvement in stroke treatment response time.

**Keywords:** Mechanical thrombolysis, stroke, endovascular intervention, thrombectomy
Implementation of New Practice in the Treatment of Acute Ischemic Stroke

Introduction

Stroke is a devastating event caused by a lack of blood flow to the brain resulting from a vascular rupture or occlusion of a cerebral vessel. Close to 800,000 strokes occur each year in the United States and it is currently the fourth leading cause of death. Approximately 4% to 17% of reported strokes occur in patients who are hospitalized for other illnesses (Cumbler, Zaemisch, Graves, Brega, & Jones, 2011). Recent literature suggests that patients who experience a stroke while hospitalized for other diagnoses are not afforded the same level of care and adherence to the recommended stroke core measures as those who arrive through the emergency medical system (Cumbler et al., 2013).

Due to the variability in stroke diagnosis and treatment, there is a need for quality improvement initiatives aimed to decrease variability within the in-hospital stroke alert process (Cumbler et al., 2011). Doing so may result in significant improvements in the functional outcome of patient who experiences a stroke while hospitalized (Cumbler et al., 2011). To improve upon the time of stroke recognition to computed tomography (CT) scan, and stroke alert to intervention, it is necessary to develop a standardized clinical process, or algorithm for frontline responders to follow for all incidents of suspected stroke (Cumbler et al., 2011).

Although those who suffer an in-hospital stroke have an opportunity to receive the standard treatment of available care, the process may be complicated by the patient’s comorbidities and a delay in the recognition of stroke symptoms (Moradiya & Levine, 2013). In addition to the increased risk of stroke under-recognition, patients experiencing in-hospital stroke have a higher incidence of medical and surgical co-morbidities that may influence eligibility to
IMPLEMENTING NEW PRACTICE IN STROKE CARE

receive intravenous tissue plasminogen activator (IV t-PA), making it vital to offer the option of endovascular intervention early in the process of stroke management (Cumbler et al., 2011).

A recent study by Cumbler et al. (2014) demonstrated an opportunity to improve in-hospital adherence to the established core measures for stroke. Cumbler et al. (2014) performed a retrospective cohort study utilizing data from a national database to evaluate the quality of care for the in-hospital stroke population. The results from 1280 sites for in-hospital stroke patients (N=21,349) demonstrated a need for quality improvement efforts for this population (Cumbler et al., 2014). In particular, patients who experienced an in-hospital stroke had a higher level of presenting deficits (P<0.0001), received IV t-PA at a lower rate and at a delayed time (P<0.0001), and were left with greater disabilities at discharge (P<0.001). The standard of care in the treatment of acute stroke must be employed at both the in-hospital and emergency department settings (Cumbler et al., 2014).

The 2013 American Heart Association/American Stroke Association (AHA/ASA) Guideline recommend sole use of mechanical thrombectomy for ischemic stroke treatment for patients who are ineligible to receive IV t-PA (Stetka & Lutsep, 2013). The 2015 AHA/ASA stroke guideline amended this recommendation by including the need to consider both endovascular intervention and IV t-PA simultaneously for the treatment of acute ischemic stroke as the new standard of care (Powers et al., 2015).

Problem Statement

The American Heart Association/American Stroke Association (AHA/ASA) published a focused guideline in 2015 updating the 2013 recommendations (Powers et al., 2015). The updated 2015 ischemic stroke guideline resulted in a paradigm shift in the treatment of acute ischemic stroke, including the recommendation to consider endovascular intervention early in the
stroke treatment plan. The revised guideline advises to avoid waiting for the patient’s response to intravenous tissue plasminogen activator (IV t-PA) before considering endovascular intervention, and to consider endovascular intervention even if IV t-PA is contraindicated. The third recommendation for healthcare systems was to design and implement processes that result in rapid assessment and treatment of the acute ischemic stroke population (Powers et al., 2015).

As a result of the updated guideline, a clinical practice gap in the treatment of acute ischemic stroke was identified in the DNP student/project coordinator’s hospital system. The current in-patient stroke algorithm addresses sole administration of IV t-PA (Figure 1), but did not advocate for the concurrent assessment of both administration of IV t-pa and endovascular intervention eligibility.

**Aims and Objectives**

The aim of this project was to introduce and incorporate recommendations from the 2015 AHA/ASA acute ischemic stroke guideline into clinical practice for treatment of in-house acute ischemic stroke through the development and implementation of a revised hospital-wide stroke algorithm. Objectives included a collaborative assessment of the current in-house stroke alert algorithm. The hospital’s initial in-house algorithm did not reflect the latest recommendations, including endovascular treatment consideration with concurrent administration of IV t-Pa.

Revision of this in-house stroke algorithm was achieved through a collaborative approach involving the DNP student/project coordinator and key stakeholders from the neuroscience department at the institution. The second project objective was to shepherd the revised algorithm through the hospital’s approval process. To accomplish this objective, the revised in-house algorithm was presented for approval to the stroke committee by the DNP student/project coordinator and the chief of neurology. Upon approval, the chief of neurology presented the
revised algorithm to the Pharmacy and Therapeutics (P&T) committee, and then to the Medical Executive committee. The third objective was to incorporate the recommended changes into clinical practice by using project planning techniques and program evaluation strategies to ensure successful integration of the new algorithm into institutional stroke care processes.

To accomplish these objectives, the doctoral student/project coordinator incorporated recommendations for successful practice guideline implementation outlined by Shiffman, Michel, Essaihi, and Thornquist (2004), including:

- Selecting specific recommendations that were used to revise the in-house stroke algorithm. Selected recommendations involved the early pursuit of endovascular intervention for ischemic stroke treatment.
- Operationalized guideline recommendations through the revision of the current in-house stroke algorithm in collaboration with key members of the neuroscience inter-professional team members.
- Presented recommended revisions to the algorithm to the chief of neurology for approval through the established health system committee structure.
- Guided the implementation planning process for the revised algorithm with the endorsement of the stroke committee
- Consulted with the stroke committee to perform a SWOT analysis to plan for implementation of quality improvement project.
- Used established project management strategies to outline steps and timeline for implementation.
- Selected strategies to assure attendance at inter-professional meetings arranged to present the revised algorithm to all clinical disciplines, allowing time for discussion and questions.
• Evaluated effectiveness of the implementation process by ongoing review of the process at the monthly stroke committee meetings.

In summary, the goal of this project was to incorporate changes to the current stroke algorithm to assure compliance with the 2015 AHA/ASA ischemic stroke guideline.

**Review of Literature**

The role of endovascular intervention in the treatment of acute ischemic stroke has been the topic of debate and discussion for the past 10 to 20 years. Until recently, randomized clinical trials have not demonstrated efficacy of endovascular therapy. A review of the literature was conducted using the key words *endovascular intervention AND stroke; mechanical thrombolysis AND ischemic stroke; in-hospital stroke AND process maps; in-hospital onset stroke AND clinical practice guidelines; in-hospital stroke algorithm; stroke care pathways; code stroke; AHA scientific statements; ischemic stroke management*.

The Cochrane Database of Systematic Reviews was the first database explored. Since Cochrane “is a collection of databases containing a variety of high-quality, independent evidence informing healthcare decision-making” (Craig & Smyth, 2012, p. 67), this search was conducted to yield evidence showing the benefit of endovascular intervention as standard treatment for ischemic stroke. The database was further explored by the topic of *neurology*, and further narrowed to the topic heading of *stroke*. The search included the terms of stroke treatment; organization of stroke services; and stroke management. Techniques used to eliminate irrelevant retrievals in this database included avoiding systematic reviews or trials that did not specifically address recommendations for in-hospital stroke management, endovascular interventions, stroke patient management, care pathways or stroke response algorithms. All references addressing pre-hospital or hospital presentation of stroke were eliminated from review.
PubMed was explored using the Clinical Queries option to secure articles that were evidence-based. The initial search was similar to the search conducted in Cochrane, but also included the use of Boolean operators of AND and OR to refine the search linking the terms of tissue plasminogen activator OR endovascular intervention AND stroke. To further refine this search, parenthesis were placed around both (tissue plasminogen activator OR endovascular intervention) to enhance the search. The term endovascular intervention was replaced with mechanical thrombectomy to seek additional evidence. Attention to the medical subject heading (MeSH) terms produced were monitored and used for additional database searches.

Key words including stroke management, in-patient stroke treatment, activation system, code stroke, and stroke algorithm were also added to the search strategy. The search was narrowed by adding the filters of age, language, and publication date. The filters included the population of adults greater than the age of eighteen, the English language, and a publication date of the last five years.

The literature search consistently employed the subject terms of stroke management, tissue plasminogen activator, endovascular intervention, stroke guidelines, and clinical pathways or algorithms. Additional searches in clinical queries included the terms code stroke; stroke symptoms AND hospitalized patient were conducted.

The third database explored was CINAHL, utilizing subject terms of stroke management, tissue plasminogen activator, and endovascular intervention. To refine these terms into a manageable search, Boolean operators were added for the search.

The American Association of Neuroscience Nursing (AANN) website was explored to assess for updated clinical practice guidelines for the care of the ischemic stroke patient. These guidelines were reviewed for any recommendations specifically for the incorporation of the
updated AHA/ASA ischemic stroke guidelines. The AHA/ASA website was also examined for updated resources related to stroke recognition, stroke statistics, educational resources available to improve stroke care, as well as review of guidelines and protocols developed pertaining to stroke care and treatment.

Quality clinical guidelines were reviewed by accessing websites such as the US Agency for Healthcare Research and Quality’s (AHRQ) National Guideline Clearinghouse (Craig & Smyth, 2012). Turning Research into Practice (TRIP) was also investigated to search best practices for implementation of new guidelines by an interdisciplinary healthcare team along with a more narrowed search of the newest available guidelines for stroke recognition, care and acute management.

The literature search yielded multiple meta-analyses, primary studies, and two systematic reviews. In an effort to secure the best available literature available, a search was conducted in the Cochrane, PubMed, CINAHL, and McMaster Federated ACCESSS databases using both keywords of endovascular intervention AND stroke; and mechanical thrombectomy AND stroke. The MeSH terms used for both the Cochrane database and PubMed included mechanical thrombolysis, stents, stroke, and thrombectomy.

Search of the Cochrane database using keywords mechanical thrombolysis yielded one relevant review from the Database of Abstracts of Review and Effects. This review yielded a systematic review of thirteen articles evaluating the use of mechanical thrombectomy for acute ischemic stroke treatment (Koh, Lee, Ryu, & Kim, 2012). In addition to the systematic review, the search provided one randomized control study.

PubMed was searched using keywords mechanical thrombolysis AND stroke. Filters of clinical trials, five year, and humans were applied to this search, yielding forty nine references
for review. Of the forty-nine, five studies were included for further review based on the design and population. The five studies reviewed included subjects experiencing an acute ischemic stroke, and offered both medical intervention and endovascular intervention, when eligible, as part of the treatment design. Studies declined for review included those that offered either medical management or endovascular intervention, not evaluation for both treatment options. A review of the CINAHL database failed to produce additional studies to be included in this paper. To assess for missed citations, the McMaster Federated ACCESSSS database was explored yielding two additional randomized controlled studies and two meta-reviews of literature.

One systematic review analyzed studies (N = 13) in which patients were treated with mechanical thrombectomy using a retrievable stent, after intravenous tissue plasminogen activator (t-PA) was deemed ineligible or if it failed to open the occluded cerebral vessel (Koh, Lee, Ryu, & Kim, 2012). This review identified outcomes including an 89.7% recanalization rate with complications of the procedure resulting in symptomatic hemorrhage of 6.8%, and an 11.1% mortality rate. Additionally, functional outcome improvement for this group was 47.3% (Koh et al., 2012). Although this systematic review failed to show clinically significant improvement in the functional outcome in patients experiencing an acute ischemic stroke, this review did show a benefit in the use of a retrievable stent for mechanical thrombectomy over the only two approved devices at that time, the Mechanical Embolus Removal in Cerebral Ischemia (MERCI) retriever, and the Penumbra aspiration system (Koh et al., 2012).

In 2015, the American Heart Association/American Stroke Association (AHA/ASA) published a focused update on the recommendations for endovascular treatment in the setting of acute ischemic stroke (Powers et al., 2015). Updated guidelines were developed following the recently published findings from eight randomized controlled studies, five of which employed
the use of new generation stent retrievers for mechanical thrombolysis plus intravenous t-PA or administration of intravenous t-PA alone (Powers et al., 2015).

The first three trials included in the analysis used first-generation mechanical embolectomy devices and failed to show a benefit of treating ischemic stroke with mechanical thrombolysis over intravenous t-PA administration (Powers et al., 2015). The SYNTHESIS trial (Ciccone et al., 2013), enrolled patients (N=181) to receive either intravenous t-PA or endovascular therapy. The primary outcome was a 90 day modified Rankin score (mRs) of 0 or 1, indicating the patient was alive without functional disability. The results of this trial showed a mRS of 0-1 in 30.4% of the endovascular group, and 34.8% in the intravenous t-PA group, with an odds ratio 0.71; 95% CI, 0.44-1.14; P= 0.16 (Ciccone et al., 2013). The authors concluded there is no additional benefit to endovascular intervention therapy for the treatment of ischemic stroke over the current standard treatment of intravenous t-PA (Ciccone et al., 2013).

Based upon the findings of five recent trials employing the use of new generation stent retrievals for mechanical thrombectomy, the acute ischemic stroke guidelines were updated and a focused 2015 guideline was published (Powers et al., 2015). Randomized controlled trials (RCTs) included in the review conducted by the AMA/AHA included the Mr. Clean, ESCAPE, SWIFT PRIME, REVASCAT and EXTEND-IA trials. Guidelines now recommend that patients who are eligible for intravenous t-pa should receive it without delay, while endovascular treatment is also being considered; patients should receive endovascular therapy with the use of a stent retrieval device only; and observing a patient’s response to intravenous t-PA before pursuing endovascular therapy is not recommended and should not be delayed if the patient is deemed eligible for this procedure (Powers et al., 2015).
Bush et al. (2015) conducted a meta-analysis of the five RCTs listed above. The five trials enrolled patients (N=1,287) and randomly assigned subjects to either endovascular therapy and intravenous t-PA or intravenous t-PA alone. Patients who were randomized to the endovascular intervention groups achieved a 2.22 greater odds of improved functional outcomes, measured using the mRS, compared to patients randomized to the intravenous t-PA control group. This represented a 95% CI, 1.66 to 2.97; P<0.001 (Bush et al., 2016). The use of endovascular therapy was not associated with an increase in the rate of mortality, or symptomatic intracerebral hemorrhage. The meta-analysis summarized findings identifying improved functional outcomes for participants receiving endovascular interventions compared to administration of intravenous t-PA alone (Bush et al., 2016). The positive effects of endovascular therapy is found in all categories including age, gender, level of neurological severity upon presentation, or the use of intravenous t-PA (Bush et al., 2016).

A second meta-analysis reviewed twenty-one studies and patients (N=4,473). Analysis led to the conclusion that endovascular intervention for stroke treatment improves the functional outcomes for stroke patients at 90 days (Tan, Wang, Ji, Tan, & Tan, 2016). The authors acknowledged that although intravenous t-PA is beneficial in the treatment of stroke, there is a need to consider endovascular therapeutic options in the treatment of ischemic stroke (Tan et al., 2016). After review of the above discussed studies, the student saw a shift in support favoring endovascular intervention from neurological experts following the results of the most recent randomized controlled studies which will now be discussed (Tan et al., 2016).

The Mr. Clean trial was a randomized controlled trial that randomly selected and enrolled patients (N=500) into either the intravenous t-PA control group or the intervention group which received endovascular intervention and intravenous t-PA group for treatment of ischemic stroke.
Patients in the intervention group received endovascular intervention within six hours of stroke symptom onset. Stent retrieval devices, which are the newest generation devices, were used for all interventions (Berkhemer et al., 2015). The study resulted with the primary outcome of increased functional outcome by 13.5 percentage point improvement in the intervention group; lack of increase in mortality, or increase in rate of intracerebral hemorrhage in the intervention group (Berkhemer et al., 2015).

The ESCAPE trial, also a randomized controlled trial, equally and randomly assigned subjects (N=316) into either the control group (intravenous t-PA), or intervention group (endovascular intervention and intravenous t-PA) equally. This trial differed from the Mr. Clean trial by providing endovascular intervention up to twelve hours from onset of neurological symptoms (Goyal et al., 2015). This trial was stopped early due to efficacy in established outcomes of functional independence scores. Outcomes for this trial were similar to those of the Mr. Clean trial; functional independence scores (mRs at 90 days); rate of mortality; incidence of intracerebral hemorrhage (Goyal et al., 2015). This trial replicated and reinforced the findings of those found in the Mr. Clean trial, and further identified the value of endovascular treatment for patients experiencing an ischemic stroke (Goyal et al., 2015).

The SWIFT PRIME trial was a randomized controlled trial that followed the similar design as both the Mr. Clean and the ESCAPE trials. Patients were randomized within six hours to either the control or intervention group. The endovascular procedure was performed using a stent retrieval device. This trial was stopped early due to efficacy. The primary outcome was a measure of disability at 90 days (mRS). Secondary outcome was mortality rate, functional independence at 90 days, and change in neurological deficits at twenty-seven hours (Saver et al.,...
Patients in the intervention group experienced a significant improvement in the functional independence score resulting in the early stoppage of the trial (Saver et al., 2015).

The REVASCAT trial was the third trial to be discontinued early as a result of demonstrated efficacy on the outcome of benefit and safety with the use of thrombectomy for the treatment of acute ischemic stroke (Jovin et al., 2015). This was a randomized controlled trial assigning patients to either the control group (intravenous t-PA only) or the intervention group (endovascular intervention and intravenous t-PA) for treatment of ischemic stroke (Jovin et al., 2015). Study findings included a functional independence increase of 15.5 percentage points in the endovascular group. This demonstrated that 6.5 patients would need to be treated to prevent one death or significant disability. As a result of these early positive findings as well as similar results from concurrent studies, enrollments were terminated to avoid ethical concerns related to assigning subjects to the control group known to have inferior outcomes (Jovin et al., 2015).

The EXTEND-IA is a randomized controlled study designed with the control group (intravenous t-PA) and intervention group (endovascular intervention and intravenous t-PA). The endovascular intervention was initiated within six hours of stroke symptom recognition (Campbell et al., 2015). The trial enrollment was stopped upon release of the Mr. Clean study which reported significant improvement in functional outcomes in the intervention group receiving endovascular intervention. This enrollment was terminated to avoid the ethical dilemma associated with enrollment of patients into the control group which could result in inferior functional independence or other complications (Campbell et al., 2015).

The five trials have multiple similarities contributing to the development of a robust body of evidence highlighting the benefits of endovascular intervention as an early treatment option for patients who are experiencing an ischemic stroke. The trials were designed to incorporate the
use of the newest generation of stent retrieval devices disregarding the earlier devices from previous studies that may have impacted outcomes. As well as demonstrating the improvements made to the retrieval devices used to perform these procedures, the studies incorporated the use of advanced imaging to refine the selection criteria to identify appropriate candidates for endovascular intervention (Berkheimer et al., 2015; Campbell et al., 2015; Goyal et al., 2015; Jovin et al., 2015; Saver et al., 2015).

The studies differed in the eligibility criteria when assessing time from symptom onset to intervention. Mr. Clean, SWIFT PRIME, used the timeline of six hours from stroke symptom onset, REVASCAT used the timeline of eight hours, ESCAPE used twelve hours for the timeline, and EXTEND-IA did not use time as a variable, but used size of completed infarction based upon imaging results for eligibility criteria (Berkheimer et al., 2015; Campbell et al., 2015; Goyal et al., 2015; Jovin et al., 2015; Saver et al., 2015).

The use of computed tomography perfusion scans (CT perfusion) has become increasingly important in patient selection for endovascular intervention and has contributed to improving patient safety in the performance of these procedures. Increasing use of CT perfusion has reduced the risks associated with these procedures by improving the patient selection process (Goyal et al., 2015; Jovin et al., 2015; Saver et al., 2015).

The five trials included subjects from diverse backgrounds and from multiple countries, ages, ethnic backgrounds, and medical histories. Although a diverse group, designs for the studies remained similar with randomization to the control or intervention group, use of improved stent retrieval devices, administration of intravenous t-PA to eligible patients, and use of CT perfusion to promote safety and efficacy throughout the trials. The treatment effect of endovascular interventions demonstrated a need to offer this treatment for eligible patients
experiencing an acute ischemic stroke. The primary outcome demonstrated a positive treatment effect when endovascular intervention is performed and included an analysis of the number needed to treat to improve the outcomes of one patient.

Primary outcomes across the five trials were similar, all evaluating the level of functional independence at 90 days (mRs), rate of mortality, and complications of symptomatic intracerebral hemorrhage (Berkheimer et al., 2015; Campbell et al., 2015; Goyal et al., 2015; Jovin et al., 2015; Saver et al., 2015). In all studies, statistical significance was found in the improvement of functional independence for those in the intervention groups; there was an absence of statistical significance in increase of mortality rates or intracerebral hemorrhages in the intervention group (Berkheimer et al., 2015; Campbell et al., 2015; Goyal et al., 2015; Jovin et al., 2015; Saver et al., 2015).

Four of the five studies reviewed were terminated early due to efficacy reached and it was determined to be ethically unacceptable to continue enrolling patients into the control arm of the trial and deny the offer of endovascular intervention if they met the eligibility criteria (Campbell et al., 2015; Goyal et al., 2015; Jovin et al., 2015; Saver et al., 2015). Although the studies were stopped prior to the complete enrollment of the predetermined number of participants, the sample size and the data generated from the studies were powerful and reinforced the findings of the pivotal Mr. Clean study.

The studies effectively addressed the questions surrounding the role of endovascular intervention in the treatment of acute stroke. The five randomized, controlled studies had similar designs including the control and intervention group assignments, use of imaging in the analysis, and statistical analysis of both primary and secondary outcomes.
IMPLEMENTING NEW PRACTICE IN STROKE CARE

Based upon the findings of the randomized controlled studies, systematic review, and meta-analysis, it was reasonable to consider a review of the current stroke response algorithms to assure the incorporation of this new evidence. To accomplish this, an evaluation of current processes, algorithms, as well as the development of treatment criteria may aid in rapidly identifying patients who would be eligible to receive this time sensitive treatment. The 2015 AHA/ASA update of the acute ischemic stroke guidelines resulted, in part, from a review of recent randomized clinical trials, including those discussed in this literature review within this paper (Powers et al., 2015).

Theoretical Framework

To implement this program improvement project, an evidence-based practice (EBP) model was utilized to assist with the steps of assessment, implementation, and evaluation of the implementation process. Evidence-based practice models assist the leader to avoid “failure in completion of implementation of projects, help to facilitate establishment and evaluation of outcomes, and improvement in utilization of available resources” (Schaffer, Sandau, & Diedrick, 2012, p. 1199).

The doctoral student/project coordinator referred to the framework of the Advancing Research and Clinical practice through close Collaboration (ARCC) model. This project involved a practice change at a system level, making this model an appropriate framework to guide, as it can be utilized to help health care systems employ and sustain evidence-based practice change. Implementation of this practice change proved to be a complicated process occurring within a healthcare system wrought with complexity. Although evidence to support endovascular intervention for the treatment of ischemic stroke has been well established, implementing this practice change throughout the hospital setting, evaluating the implementation
IMPLEMENTING NEW PRACTICE IN STROKE CARE

process, and creating a sustainable change throughout the hospital benefited from employing concepts identified in the ARCC model.

The ARCC Model was developed in 1999 at a major medical center for the purpose of improving patient outcomes and quality measures through translation of evidence into clinical practice (Melnyk, 2012). The ARCC model is structured to focus on “organizational use, assessing both organizational strengths and barriers to change; identifies EBP mentors; assesses organizational culture; implements evidence; evaluates outcomes” (Schaffer et al., 2012, p. 1201). It is based on the assumptions that “there are both barriers and champions of EBP within the health care system; that barriers must be removed, and champions must be mentored; clinicians must believe in the value of the EBP change that is to be implemented; mentors for EBP change must be developed and are necessary for the health care system to sustain the proposed change” (Melnyk, 2012, p. 132).

Methods

To implement this project, the project coordinator met with key stakeholders including the chair of the neurology department, the stroke program manager, neurologists, advanced practice nurses, nursing educators from the neuroscience department, and the vice-president of neuroscience, to translate the 2015 AHA/ASA stroke guideline into a revised in-house stroke algorithm that is tailored to the hospital system. The DNP student/project coordinator, in collaboration with the stroke manager, presented the suggested changes resulting from this collaboration to the stroke committee, which is chaired by the Chief of Neurology. Following acceptance of the revised algorithm, the Chair of Neurology presented these changes to the Pharmacy and Therapeutics (P&T) committee, and then to the Medical executive committee.
Once changes to the algorithm progressed through the hospital’s committee approval structure, the DNP student/project coordinator led a multidisciplinary team to begin the steps for implementation of the program improvement project. To assure successful implementation of this project, the project coordinator engaged the multidisciplinary team in a review of the current stroke algorithm, presented the suggested changes to the algorithm, and performed a *Strengths, Weaknesses, Opportunities and Threats* (SWOT) analysis prior to development of the implementation plan (Figure 1). Evaluation of the program’s success is conducted by the stroke committee, led by the chair of neurology and the stroke manager at the monthly stroke working group meeting.

**Project Design**

A SWOT analysis specific to updating the algorithm and revising associated processes and care practices was conducted with key team members of the stroke and neurology department by the DNP student/project coordinator. This was a helpful step early in the process as it helped to inform project planning processes. A SWOT analysis allows the team to help focus on areas where it is strongest and allows the team to identify where key opportunities exist (Pearce, 2007).

Following completion of the SWOT analysis, the DNP student developed and maintained a Gantt chart to identify and assign tasks with timelines for expected completion. This tool assisted the DNP student/project coordinator with delegation of tasks and clarification of roles for all team members. Utilization of this tool aided in the assessment and identification of barriers to the project’s successful implementation. The Gantt chart was initially developed close to 100 years ago, and although revisions have occurred, it has proven to be effective and resilient when applied to overall project management. This chart is known as a valuable tool
when used to navigate complicated projects due to the focus on tasks and timing (Geraldi & Lechter, 2012).

The Gantt chart was utilized to highlight the start and completion dates of the tasks, as well as to provide the team with a visual depiction of the relationships between the tasks assigned. The chart was also used to show the project’s status of proposed meetings throughout the project timeline. Tasks with months of completion are represented on the chart. (Figure 3).

Initial planning meetings included the clinical leadership throughout the hospital system to obtain a broad assessment of all potential barriers as well as potential champions of the project. Once the Gantt chart was developed, the process of implementation was initiated, with the DNP student/project coordinator monitoring progress. Revisions occurred as needed based upon monitoring of progress, reporting of any unforeseen obstacles, re-evaluation of process, and receipt of ongoing feedback to clinical and administrative leadership.

Setting

The setting for this project was the main campus of hospital, located at Philadelphia, Pennsylvania. The hospital a 937 bed tertiary acute care facility with five locations in the greater Philadelphia area that provides care to a diverse population and wide range of clinical specialties including trauma, neurosurgery, orthopedic, and oncology to name a few. This project included the main campus, as well as the specialty hospital for neuroscience. This facility is a Joint Commission Certified Comprehensive Stroke Center, and is a regionally recognized neuroscience center that provides primary stroke care services to over 28 community hospitals in the surrounding communities. It is ranked 24th in the country in Neurology and Neurosurgery with a score of 65.6% (U.S. News and World Report, 2015).
**Evaluation**

Completion of the project was based upon revision of the in-house stroke algorithm, approval of the algorithm, and hospital wide implementation of new algorithm. To perform ongoing evaluation, the stroke manager reviews all in-house stroke cases at monthly stroke working group meetings to assess the effectiveness of the current process.

Revision of the current stroke algorithm was initially met with resistance from the hospital’s rapid response team (RRT). This was a critical issue requiring the assistance from the chair of neurology to achieve resolution. The leadership of the RRT initially opposed the involvement of this team for the activation of a stroke alert notification citing a strain on available resources this process demands. This allocation of resources was discussed by the neuroscience clinical leadership in collaboration with the administration of the hospital. It was decided the RRT would respond to stroke alert activation in non-critical areas only and remain with the patient and the neurologist until disposition. In the event a stroke alert occurred in a critical care area, the critical care staff nurse would remain with the patient, along with the neurologist, throughout the initiation of the stroke alert until patient disposition.

Due to the variation in practice between the critical care and non-critical care units, the Advanced Practice Nurse (APN) group was provided with a focused power-point education highlighting the revision of the stroke algorithm specific to the earlier consideration of endovascular intervention. Additionally, education was developed and provided to address the unit specific patient emergency escalation process, as well as a review of the acute signs and symptoms of ischemic stroke. Educational implementation included the offer of both the stroke manager and the DNP student/project coordinator to meet with the staff in the monthly shared governance meetings to provide the education. The APN group preferred to accept the
IMPLEMENTING NEW PRACTICE IN STROKE CARE

responsibility to provide the staff with the education focusing on these three components, and will be involved in ongoing evaluation of stroke treatment outcomes on their units at ongoing APN meetings. It was further suggested to enhance the communication by empowering the stroke manager to provide ongoing updates on case studies and summaries of patient outcomes to the individual units.

Revision to the algorithm was also met with feedback from the neuroscience educational department. They believed the algorithm should have been terminated with the decision to administer IV tPA, perform endovascular intervention, or perform both. The group felt the additional steps of the algorithm were redundant and unnecessary. The stroke committee reviewed the algorithm and decided that although this may appear to be redundant in the specialty hospital for neuroscience, it was a necessary step in the algorithm for a non-neurological, medical-surgical unit. The chair of neurology decided to keep the algorithm as presented, and continue with the proposed education.

Although the opportunity to test this algorithm was not possible for this project, processes were developed to provide ongoing analysis of outcomes for all in-house stroke alerts. The stroke working group, co-chaired by the chief of neurology and the stroke manager, added a standing agenda item for a monthly review of all in-house strokes. Metrics that will be evaluated include the patient’s last known well time to activation of the stroke alert system, time from last known well to decision to administer IV tPa if appropriate, and time to last known well to arrival at endovascular unit for intervention as appropriate. This is a significant shift in practice as it is the first time these outcomes will be traced for an in-house stroke patient. Additional outcomes that will be captured are the rate of patients who are eligible and receive endovascular
intervention for stroke, and the time from recognition of stroke to vessel access. This data will be collected and analyzed by the neurology department and reported to the stroke working group.

With the ongoing monitoring of the above stated metrics, it is possible to continue the development of additional process improvement practices and procedures that will continue to improve the care offered to the in-house stroke patient population, with the goal to positively impact the long term outcomes of this vulnerable population.

**Human Subjects Protection**

Application for initial Investigational Review Board (IRB) approval of this project from the health system was followed by subsequent review by Drexel University’s IRB. Both IRBs determined that the project satisfied requirements as a quality improvement project was granted exempt status.

**Timeline**

The timeline for the entire project was approximately ten weeks and commenced upon approval of the project coordinator’s committee chair as well as IRB approval (Table 1).

**Strengths and Limitations**

The success of this program improvement project was determined by the acceptance of the in-house stroke algorithm by the multidisciplinary stroke committee and the implementation of the project throughout the hospital. A strength of this project was the translation and application of new evidence into the clinical practice setting. The goal of a revised stroke algorithm was to increase awareness of the revised stroke guideline and to offer an increased opportunity for hospitalized patients to be evaluated for endovascular intervention in the initial treatment phase of an acute ischemic stroke. A second strength was the development of a new process to review
all in-hospital strokes at the monthly stroke working group meeting. The goal of this review is to identify process improvement opportunities in an effort to improve stroke care delivery.

A limitation of this project was that although the revised algorithm supports the latest evidence in stroke treatment, the possibility of failure to recognize the patient’s stroke symptoms in a timely manner still exists. This potential failure to recognize an acute stroke would impact the rate of endovascular intervention offered to patients experiencing an ischemic stroke. Although the revised algorithm also addresses the signs and symptoms of stroke, recognition of subtle stroke symptoms rely upon the clinical staff’s recognition of the patient’s change in neurological status.

A second potential limitation of the project may be the individual or unit based nonadherence to the revised algorithm. Although education was provided at the unit level by the APN group highlighting the need to escalate an emergency response with a neurological change, if the algorithm was not followed, neurology experts would not be called to the patient’s bedside. This failure to activate the stroke alert algorithm would result in a delay in stroke care for the patient experiencing an acute ischemic stroke.

**Significance and Implications**

There is potential for future areas of study with this project both within this health system as well as within the surrounding Neuroscience Network. With this revision of the algorithm, patients are being offered the opportunity to receive the best options for acute ischemic stroke care, and it will be important to study the impact of this practice change on overall patient outcomes, particularly the modified Rankin scores and mortality rates. Future studies may include an assessment of stroke response time, and adherence to the updated stroke algorithm, rates of endovascular intervention, and functional outcomes of patients who are treated with
endovascular intervention comparing these data to the same outcomes prior to revision of the algorithm.

Implications of this project include the potential to replicate this program improvement process with future initiatives within the health system as new evidence is presented. Opportunities were presented resulting with the establishment of a process that engaged a multidisciplinary team focused on the revision of stroke algorithm to improve stroke care throughout the hospital. This process may be transferable to multiple healthcare initiatives throughout the healthcare system, potentially impacting care delivery and patient outcomes. This project was pivotal in the identification of committee structure, process, and navigation techniques to spearhead the practice change through a complex structure.

Finally, future implications include the potential translation of this practice change throughout the hospital system’s neuroscience network of primary stroke centers. Clinical leaders of primary stroke centers can utilize this algorithm as an opportunity to identify early triggers or stroke characteristics to escalate the transfer of a patient to a comprehensive stroke center with the capabilities to perform endovascular stroke intervention.
REFERENCES


## Tables

Table 1. Timeline for Project Improvement Project

<table>
<thead>
<tr>
<th>Task</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assessment of organizational culture and readiness for EBP implementation</td>
<td>1. October 2016</td>
</tr>
<tr>
<td>2. Conduct a SWOT analysis with multidisciplinary neuroscience team members</td>
<td>2. October, November 2016</td>
</tr>
<tr>
<td>3. Meet with key neuroscience interdisciplinary team to perform revision to current in-house stroke algorithm</td>
<td>3. October 2016</td>
</tr>
<tr>
<td>4. Develop Gant Chart for Project development and implementation</td>
<td>4. September 2016</td>
</tr>
<tr>
<td>7. Meet with APN group to discuss Implementation of Educational Plan at Unit level.</td>
<td>5. November, December 2016</td>
</tr>
<tr>
<td>9. Stroke Manager will review all in-house stroke alert cases at monthly Stroke Committee Meetings</td>
<td>7. December 2016 / January 2017</td>
</tr>
<tr>
<td>Author/ Date</td>
<td>Purpose</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------</td>
</tr>
</tbody>
</table>
| Cumbler et al. (2011)| Purpose: Discover if non-adherence to stroke core measures result in delay in treatment for the in-patient stroke population in comparison to the patient community onset stroke | Design: Cohort Study. Retrospective review of database  
Inclusion Criteria: Hospitals who participate in the Get With The Guidelines(GWTG) Stroke quality measure database and reported at least 1 stroke from both groups studied  
Exclusion Criteria: Age younger than 18 years or hemorrhagic stroke.  
Sample Characteristics/Setting: The consortium of 35 statewide hospitals- years study included (2005-2009). In-hospital stroke (n=116); out-of-hospital strokes (n 4,946) were compared. Cohort mean age 71.5, 46% male, 77.8% were white.  
Outcome Concept: Primary outcome is adherence to 9 or 10 GWTG quality measures. Secondary Outcome include adherence to GWTG measures and time from symptom recognition by staff to brain imaging  
Measures/Instrument: Stroke Core Measures reported to national database Get with the Guidelines. Analysis via SAS statistical software.  
Interventions: Compare whether patients who have a stroke while hospitalized receive the same standard of care as those patients who arrive to the hospital from the community diagnosed with Stroke | Results/Findings: High variability in the percentage of in-hospital strokes reported suggests a possibility of under-recognition or under-reporting of in-hospital strokes by some hospitals. In-hospital stroke patients were more likely to have CAD (p=0.02), have a higher NIHSS (p=0.01), had a longer time from symptom recognition to brain imaging. Adherence to the GWTG quality measures of Stroke Education and assessment of rehabilitation needs was better for the in-hospital stroke population. Thrombolytic therapy administration rates for eligible patients were similar for both groups (p=0.54), although in-hospital strokes had a higher rate of contraindications to IV tPA and therefore lower number of patients eligible. | Conclusions: Strokes with onset during hospitalization are under-recognized. In-hospital strokes have time to brain imaging two times that of those who experience a community onset stroke. Additionally, those that experience an in-hospital stroke have more contraindications to receiving tPA.  
Limitations: The variability in reporting stroke from various hospitals may suggest under-reporting, or under-recognition of stroke symptoms. If only a percentage of the total number of in-hospital strokes are reported, this may lead to over estimating compliance to the quality measures and possibly bias by only reporting strokes that are being closely followed. | Level IV |
<table>
<thead>
<tr>
<th>Author/Date</th>
<th>Purpose/Theoretical Framework</th>
<th>Methodology</th>
<th>Results</th>
<th>Limitations/Conclusions</th>
<th>Level of Evidence</th>
</tr>
</thead>
</table>
| Ciccone et al (2013) | **Purpose:** Discover whether endovascular treatment, with or without intraarterial t-PA is more effective than treatment with IV t-PA alone | **Design:** Randomized controlled study.  
**Inclusion Criteria:** Patients aged 18 to 80 with acute ischemic stroke; clearly defined time of symptom onset 4.5 hours for IV t-PA and up to 6 hours for endovascular therapy.  
**Characteristics/Setting:** Multicenter, open-treatment clinical trial with a blinded end point. Patients were randomized into the control group (n=181) of receiving IV t-PA only and the intervention group received endovascular therapy only (n=181).  
**Outcome Concept:** Primary outcome was survival with a functional independence measure as a modified Rankin score of 0 to 2 at three months.  
**Measures/Instrument:** The study was designed to determine whether there was an absolute difference of 15 percentage points between the proportions of patients with a mRS between the control and intervention groups.  
**Interventions:** Control group was offered medical intervention (IV t-PA) only for treatment of ischemic stroke; intervention group was offered endovascular intervention only | **Results/Findings:** Results of improved functional outcome at 3 months between the two groups was not statistically significant. Odds ratio adjusted for age sex, stroke severity, and atrial fibrillation, 0.71: 95% CI, 0.44 to 1.14; P=0.16. Intracranial hemorrhage was equal among the two groups. | **Limitations:** Imaging to detect large vessel occlusion was not performed as a condition for inclusion into the trial-limiting the ability to verify the patient had a large cerebral vessel occlusion prior to treatment; Stent retrieval devices were used infrequently during this trial, which may have provided greater benefit if used widely throughout the trial.  
**Conclusions:** Trial did not show endovascular therapy was superior to medical management as evidenced by improved functional outcomes at 90 days. | Level 1 |
<table>
<thead>
<tr>
<th>Author/Date</th>
<th>Purpose</th>
<th>Methodology</th>
<th>Results</th>
<th>Limitations/Conclusions</th>
<th>Level of Evidence</th>
</tr>
</thead>
</table>
| Berkhemer et al. (2015) | Purpose: Discover whether intraarterial treatment plus IV t-PA would be more effective than IV t-PA alone for patient with a proximal occlusion in the anterior cerebral circulation. | Design: Randomized controlled study  
**Inclusion Criteria:**  
Patients aged 18 or older with a proximal arterial occlusion in the anterior cerebral circulation; confirmed by imaging; treatable within 6 hours after stroke symptom onset.  
**Characteristics/Setting:**  
The study enrolled 500 patients from 16 medical centers in the Netherlands. Mean age was 65; 233 patients were assigned to the intervention group (IV t-PA + intervention)/267 assigned to the control group (IV t-PA only). Demographics similar for both groups. NIHSS 17 for Intervention group/18 for Control group. Risk factors for stroke and aspects scores of pre-randomization treatment were evenly distributed between the two treatment groups  
**Outcome Concept:**  
Primary outcome was rate of functional independence (modified Rankin score 0 to 2). Secondary outcome was rate of mortality or symptomatic intracerebral hemorrhage.  
**Measures/Instrument:** | Results/Findings:  
The authors calculated a needed sample of 500 patients to yield a power of 82% at a significance level of 0.05 to achieve an increase of 10 percentage points of a modified Rankin score of 0 to 3 in the intervention group compared to the control group. The absolute difference in percentage points was 13.5 with a 95% CI 5.9 to 21.2.  
**Conclusions:**  
Patients with proximal cerebral occlusions in the anterior circulation can experience improved functional outcomes if intraarterial treatment is initiated within 6 hours of stroke symptom onset  
**Limitations:**  
Randomization was unbalanced with 34 more assigned to the control group; the rate of reperfusion was low compared to other similar studies; 9% of patients in the intervention group had an embolization of a second vessel due to additional clot formation; a lower proportion of patients in the control group | Level I |
The study was designed to determine whether there was an absolute difference of 15 percentage points between the proportions of patients with a mRS between the control and intervention groups. **Interventions:** Control group was offered medical intervention (IV t-PA) only for treatment of ischemic stroke; intervention group was offered endovascular intervention only.

### Table

<table>
<thead>
<tr>
<th>Author/Date</th>
<th>Purpose/Theoretical Framework</th>
<th>Methodology</th>
<th>Results</th>
<th>Limitations/Conclusions</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campbell et al. (2015).</td>
<td><strong>Purpose:</strong> The purpose of this trial tested whether more advanced imaging, recently developed stent retrieval devices, and earlier endovascular intervention positively impacts patient outcomes.</td>
<td><strong>Design:</strong> Randomized Controlled study. <strong>Inclusion Criteria:</strong> Adult patients age 18 or older experiencing an ischemic stroke who were eligible to receive intravenous alteplase within 4.5 hours; had an anterior circulation stroke; occlusion of the internal carotid artery; or the first or second segment of the middle cerebral artery; had salvageable brain tissue demonstrated by CT perfusion. <strong>Characteristics/Setting</strong> Seventy patients underwent randomization (n=35 in control group, n=35 in the intervention group. Ten study centers (Australia and New Zealand). Average age 68-70; equal number of male/female between groups; NIHSS in intervention group was 17 vs. 13 in the control group. <strong>Outcome Concept:</strong> Primary outcome was reperfusion of occluded vessel, and early neurologic improvement, identified as an 8 point improvement of ischemic territory that was reperfused was greater in the intervention group vs. the control group (median, 100% vs. 37%, P=0.001). The improvement in functional outcome was greater in the intervention group vs. the control group (71% vs 40%, P= 0.01). Endovascular group had greater early neurological recovery at 3 days. Intervention group/Control group = 80%/37%; (P&lt;0.002) Endovascular group had improved functional outcome (mRs at 0-2 at 90 days due to the broad inclusion criteria; although the outcome assessment was blinded, the patients were aware of what group they were in which may have influenced their opinions on how well they were doing functionally at 90 days.</td>
<td><strong>Conclusions:</strong> Patients with anterior circulation strokes in a proximal vessel with salvageable brain tissue have improved reperfusion, early neurologic recovery and improved functional outcomes with the use of stent retrieval devices and IV t-PA, than those that receive IV t-PA alone. <strong>Limitations:</strong> Due to the small sample size, the ability to perform subgroup analyses was unavailable. Early termination of the trial may result in the...</td>
<td>Level I</td>
<td></td>
</tr>
</tbody>
</table>
the NIHSS, or a score of 0-1 at 3 days post event. Secondary outcomes included the NIHSS at 90 days; death for any reason; and symptomatic intracranial hemorrhage. **Measures/Instrument:** The trial was stopped early due to efficacy at 70 patients. The percentage of ischemic territory that was reperfused was greater in the intervention group vs the control group (median, 100% vs. 37%, \(P=0.001\)). The improvement in functional outcome was greater in the intervention group vs. the control group (71% vs 40%, \(P=0.01\)). **Interventions:** Endovascular intervention with stent retrieval devices + IV t-PA in the intervention group vs. IV t-PA alone in the control group.

<table>
<thead>
<tr>
<th>Author/ Date</th>
<th>Purpose/Theoretical Framework</th>
<th>Methodology</th>
<th>Results</th>
<th>Limitations/ Conclusions</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goyal et al. (2015)</td>
<td>For patients with an anterior proximal cerebral occlusion stroke, up to 60 to 80 percent of these patients may die within 90 days</td>
<td><strong>Design:</strong> prospective, randomized, open-label, controlled trial with blinded outcome evaluation; PROBE design. Randomization was</td>
<td><strong>Results:</strong> The 90 day mRS in the intervention group was 2, and 4 in the control group; (53.0%)</td>
<td><strong>Limitations:</strong> The investigators failed to keep a log of how many patients were</td>
<td>Level I</td>
</tr>
</tbody>
</table>

**Findings:** The study was stopped early due to efficacy. Reperfusion rate in the endovascular group was statistically significant determining the need to offer this treatment to all patients meeting the inclusion criteria.

90 days) odds ratio, 2.0; 95% CI, 1.2 to 3.8; \(P=0.006\)

Potential to overestimate the effect size
after stroke or will not regain functional independence despite treatment with intravenous t-PA. Treatment with endovascular/mechanical thrombectomy in addition to intravenous t-PA administration may improve these outcomes.  

achieved through an internet-based procedure aimed to achieve balance in the groups related to age, sex, baseline neurological deficit, location of cerebral occlusion, and baseline Alberta Stroke Program Early Computed Tomography Score (ASPECTS).

**Inclusion Criteria:** Adults with no upper-age limit; disabling stroke who were functioning independently prior to this event; enrollment up to 12 hours after onset of stroke symptoms. Patients with a large core infarct, or poor collateral circulation as demonstrated by CT angiography were excluded.

**Characteristic/Setting:** Worldwide trial/22 centers with 316 participants. Of the 312, the intervention group (n=165), control group (n=150). Demographics of intervention/control groups were similar. Risk factors for stroke and aspects scores of pre-randomization treatment were evenly distributed between the two treatment groups.

**Outcome Concept:** The primary outcome measured was the modified Rankin score at 90 days resulted with a common odds ratio, 2.6; 95% confidence interval 1.7 to 3.8; P<0.001. Intervention group associated with a decreased mortality (10.4% intervention vs. 19.0% control groups. P=0.04. Symptomatic ICH occurred in 3.6% intervention vs. 2.7% control group (P=0.75.

**Measures/Instrument Intervention:** Intervention group underwent rapid endovascular treatment/cerebral angiogram was performed/retrievable stents were the preferred device used for procedures/IV t-PA if met criteria.

ineligible for inclusion in the trial. A high percentage of the endovascular group was treated at centers with efficient workflow and imaging processes, allowing for rapid intervention. Since this efficiency does not exist in all facilities, the generalizability of these results may be limited.
control group received the current standard medical care (administration of IV t-PA).

<table>
<thead>
<tr>
<th>Author/Date</th>
<th>Purpose/Theoretical Framework</th>
<th>Methodology</th>
<th>Results</th>
<th>Limitations/Conclusions</th>
<th>Level of Evidence</th>
</tr>
</thead>
</table>
| Saver et al. (2015) | The authors questioned whether treatment with mechanical thrombectomy with the use of a stent retriever in addition to intravenous t-PA improve cerebral reperfusion and improve long-term functional outcomes in the acute ischemic stroke population | Design: Randomized Controlled trial  
Inclusion Criteria: All patients included had an acute ischemic stroke with moderate to severe neurologic deficits; had a proximal vessel occlusion verified by imaging; received IV t-PA; and were eligible to undergo endovascular intervention within 6 hours of symptom onset  
Characteristics/Setting: Participants were randomly assigned to either the intervention group (IV t-PA plus stent retriever group) or the control group (IV t-PA group only) via an interactive web based system. Patients were assigned in equal number (1:1) to one of two treatment arms: 1) IV t-PA and Solitaire FR or 2) IV t-PA only. The groups were similar in age, sex, race, NIHSS, admin of iv t-PA at outside hospital, median time from symptom onset to iv t-PA, and ASPECT value. The number of treatments and controls will be balanced within investigational sites and by baseline NIHSS severity (≤ 17 versus >17), age, and occlusion location within site.  
Outcome Concept: Primary outcome measured was mean mRS at 90 days. Secondary outcome was the mortality rate at 90 days, | Results: The primary outcome was a shift in the distribution of global disability scores on the modified Rankin scale at 90 days. Result P<0.001. This result was lower than established threshold of P<0.01to stop the study (Saver et al., 2015). The number needed to treat for one additional patient to have less disability was 2.6. The secondary outcome looked at the proportion of functional independence of the intervention group at 90 days. The intervention group had a difference of 25 percentage points with a 95% CI, 11 to 38; risk ratio of 1.70 with a 95% CI, 1.23 to 2.33; P<0.001. The number needed to treat to obtain one more patient who would be functionally independent (modified Rankin score of 0-2) was | Limitations: Generalizability may be limited due to the homogeneous patient population. The study also allowed for continuous quality-improvement program to occur to improve efficiency with the endovascular workflow process. The centers involved in the trial were all tertiary care facilities with established stroke centers with experienced neuro-interventional capabilities.  
Conclusions: Patients with large anterior circulation strokes can benefit from treatment with IV t-Pa and endovascular intervention with a stent retrieval device within 6 hours of stroke symptom onset | Level I |
and the change in the NIHSS at 27 hours following randomization

**Measure/Instrument:**
Disability rate at 90 days as measured by the mRs; inter-group differences in 90 day mortality; inter-group difference in rate of intracranial hemorrhage

**Intervention:**
Endovascular intervention with stent retrieval devices within 6 hours of symptom onset + IV t-PA in the intervention group vs. IV t-PA alone in the control group.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th>4.0.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Implementing New Practice in Stroke Care

#### Strengths
- Identifies members of its leadership team
- Neuro Resident coverage 24/7
- Endovascular team on call 24/7
- Capable to perform neurovascular procedures advocated for with algorithm change 24/7
- Current Stroke Program Manager
- Dedicated Neuroscience Hospital
- Dedicated Rapid Response Team
- Auto-Acceptance for all Stroke patients
- APNs coverage in majority of clinical areas
- Neuroscience Education team
- Clinical Administration for Neuroscience
- Evidence of specific stroke performance measurement and review by the stroke team
- System-wide clinical sub-committee team meetings with review of performance measure

#### Weakness
- Rapid Response Team administration does not support teams involvement in Acute Ischemic Stroke algorithm
- Neurology Resident responds to Stroke Alerts without support from other clinical disciplines
- Current fragmentation of program leadership and resources impedes ongoing strategic planning and implementation
- Variation in activation of patient emergency response from unit to unit
- Lack of formalized structure to evaluate stroke response time and patient outcomes
- Reporting structure follows discipline, not service line
- Metrics for time sensitive advanced stroke intervention not captured
- Lack of formalized PDSA process for Stroke metrics
- Current Stroke Working group meeting without consistent medical leadership

#### Opportunities
- Introduce the updated algorithm to stroke centers in the hospital's Neuroscience network
- Collaborate with hospital's Neuroscience coordinators to partner with facilities within the neuroscience network to implement the newest guidelines into practice
- Engage Stat in the process improvement efforts to decrease time to treatment for Acute Ischemic stroke from the Main building to neuro specialty hospital
- Increase communication from the hospital’s transfer center to the INR suite
- Increase professional collaboration through a multidisciplinary effort to decrease the time from recognition of stroke symptoms to treatment in the INR suite.

#### Threats
- Use of Jeff Stat for surrounding hospitals may impact the availability of immediate transport
- Fragmented Med-Surg Stroke Alert activation system
- Lack of involvement from RRT during immediate stroke response may delay care
- Limited resources at bedside at onset of stroke
- Lack of streamlined transfer from Main Building to INR at Neuroscience building
- Multiple transfers from outside facilities to INR suite may delay patient care/patient remains on non-neuro unit

---

**Figure 1. SWOT Analysis**
IMPLEMENTING NEW PRACTICE IN STROKE CARE

IN-HOUSE ACUTE STROKE ALGORITHM

**Stroke Symptoms**
- **F**- FACE DROOPING: Does one side of the face droop or is it numb?
- **A**- ARM WEAKNESS: Is one arm weak or numb?
- **S**- SPEECH DIFFICULTY: Is speech slurred: Is the person unable to speak or hard to understand?
- **T**- TIME TO CALL RAPID RESPONSE TEAM: If someone shows any of these symptoms, check the time so you’ll know when the first symptoms appeared.

**CALL RAPID RESPONSE TEAM**
Operator=Overhead Page
Gibbon: 5-6074
JHN: 3-9999

**PRIMARY RN:** Establish time of onset of symptoms or Last Known Well-time (LKW). Obtain blood glucose.

**CALL STROKE ALERT**
Gibbon: 5-6095
JHN: 3-9999
Advise: “Stroke Alert” & “Room Number”
EITHER Stroke tPA ≤ 4.5 hrs
OR Stroke Endovasc; LKW=4.5-12 hours

**STAT NON-CONTRAST CT SCAN HEAD**
Confirm IV/Line access
CBC, PLT Count, BMP, PT/PTT/EKG
Make patient STRICT NPO (including PO medications)

**CT Scan without evidence of hemorrhage**
Patient meets Inclusion/Exclusion Criteria for IV tPA
- **YES**
  - Initiate Acute Ischemic Stroke IV tPA Algorithm (GOAL: Event to tPA < 45 minutes)
- **NO**
  - **CTA/CT Perfusion**
  - Admit ICU?
  - Stroke Workup?

**CT Scan with evidence of hemorrhage**
(Intracerebral Hemorrhage) (Subarachnoid Hemorrhage)

**Consult Neurosurgery**
Gibbon: (877) 656-5402
JHN: (877) 656-5403

**Initiate Hemorrhagic Stroke Algorithm (ICH or SAH)**

Figure 2. Current In-House Acute Stroke Algorithm
IMPLEMENTING NEW PRACTICE IN STROKE CARE

**Stroke Symptoms (Acute and Sudden Onset)**
- B- Balance: dizzy/coordination/vertigo
- E- Eye: Visual changes/diplopia/loss of vision
- F- FACE DROOPING: Does one side of the face droop or is it numb?
- A- ARM WEAKNESS: Is one arm weak or numb?
- S- SPEECH DIFFICULTY: Is Speech slurred: Is the person unable to speak or hard to understand?
- T- TIME TO CALL RAPID RESPONSE TEAM/Stroke Alert: If someone shows any of these symptoms, check the time so you’ll know when the first symptoms appeared.

If patient shows any of the above symptoms Activate Rapid Response Team/Stroke Alert
(THE ACTIVATION PROCESS IS UNIT SPECIFIC)
**R/O Stroke Mimics**
**EMERGENCY NUMBERS**
Gibbon: 5-6074 JHN: 3-9999

---

**Stroke Alert Called**

Neurology Resident/Primary RN Respond
STAT NON-CONTRAST CT SCAN HEAD
Confirm IV/Line access (Secure line above the wrist)
CBC, PLT Count, BMP, PT/PTT/EKG

---

CT Scan without Evidence of Hemorrhage
Consider IV tPA and/or Endovascular Intervention

- Patient meets Criteria for IV tPA and Endovascular Intervention
  - Yes: Initiate AIS IV tPA Algorithm and Activate INR response team
  - No: Consider IV tPA or Endovas Interv. only; Complete stroke work-up

- Patient meets Criteria for IV tPA only
  - Yes: Initiate AIS IV tPA Algorithm
  - No: Complete stroke work-up

- Patient meets Criteria for Endovascular Intervention Only
  - Yes: Activate INR response team
  - No: Complete stroke work-up/Consider IV tPA only

---

CT Scan with evidence of hemorrhage
(Intracerebral Hemorrhage)
(Subarachnoid Hemorrhage)

- Consult Neurosurgery:
  - Gibbon: (215) 554-4172
  - JHN: (215) 554-4605

- Initiate Hemorrhagic Stroke Algorithm (ICH or SAH)

---

**Figure 3. Revised In-House Acute Stroke Algorithm**
<table>
<thead>
<tr>
<th>Task Item</th>
<th>Start</th>
<th>End</th>
<th>Lead</th>
<th>Status</th>
<th>Month/Year</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Administrative Liaison</td>
<td>Sept 2016</td>
<td>Sept 2016</td>
<td>EG</td>
<td>Received approval letter to implement DNP project at hospital</td>
<td>Sept 2016</td>
<td>VP of Clinical Services Chair of Stroke Program</td>
</tr>
<tr>
<td>Revision of Current Acute Ischemic Stroke Algorithm</td>
<td>October 2016</td>
<td>October 2016</td>
<td>EG</td>
<td>Completed</td>
<td>October 2016</td>
<td>Collaboration with the Stroke Committee and Chair of hospital Stroke Program to propose revisions to current In-house Acute Ischemic Stroke</td>
</tr>
<tr>
<td>SWOT Analysis</td>
<td>October 2016</td>
<td>October 2016</td>
<td>EG</td>
<td>Completed</td>
<td>October 2016</td>
<td>Partnered with the Stroke Manager/Neurologist lead/Neuro APN/Neuro Education team to develop a SWOT analysis</td>
</tr>
<tr>
<td>Present final Revised Algorithm to Stroke Committee for Approval</td>
<td>October 2016</td>
<td>October 2016</td>
<td>CP</td>
<td>Completed</td>
<td>November 2016</td>
<td>Physician champion chairs meeting and will present changes to algorithm to the hospital Stroke Committee meeting for approval</td>
</tr>
</tbody>
</table>
| Present Revisions to Key Leadership Committees/Teams                     | October 2016| December 2016| EG/RD/CP | Completed | November and December 2016 | Presented changes to the In-House Acute Ischemic Stroke Algorithm to Key Stakeholders  
  - Neuro Working Group  
  - Rapid Response Team  
  - Hospital APN Committee |
<table>
<thead>
<tr>
<th>System Approval of Algorithm</th>
<th>October 2016</th>
<th>November 2016</th>
<th>CP</th>
<th>Completed</th>
<th>November 2016</th>
<th>Physician presented revised algorithm to approval committees</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Presented and approved by P&amp;T committee</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Presented and approved by MEC</td>
</tr>
<tr>
<td>Presentation of Revised Algorithm to Hospital Neurology Residents</td>
<td>November 2016</td>
<td>November 2016</td>
<td>CP</td>
<td>Completed</td>
<td>November 2016</td>
<td>Overview of algorithm revisions presented to Neurology Medicine Department</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Chief Neuro Resident presented algorithm changes to neurology group at Monthly Grand Round meeting</td>
</tr>
<tr>
<td>Implementation of Educational Plan</td>
<td>November 2016</td>
<td>January 2017</td>
<td>EG/RD</td>
<td>Completed</td>
<td>January 2017</td>
<td>Met with the APN group to discuss overview of algorithm revisions</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Provided education to the APN group</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Provided power-point slides to guide APN group for ongoing education to staff at unit level</td>
</tr>
<tr>
<td>Evaluation of Practice change/revised algorithm status</td>
<td>November 2016</td>
<td>Ongoing</td>
<td>RD/CP</td>
<td>Completed</td>
<td></td>
<td>Standing agenda item added to Stroke committee monthly meeting</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Review of all in-house stroke alerts</td>
</tr>
</tbody>
</table>

Figure 4: Gantt chart