CRYPTOGENIC STROKE

Advancing Awareness and Addressing Gaps to Improve Patient Outcomes:

A PUBLIC HEALTH CONFERENCE REPORT
“The ability to discern the causes of 
cryptogenic strokes has profound implications 
for secondary prevention of stroke and 
improving patient outcomes. With the 
Cryptogenic Stroke Public Health Conference, 
we are coming together as a healthcare 
community to increase our knowledge about 
cryptogenic stroke and improve treatment.”

Mary Ann Bauman, M.D.,
Chair of the American Stroke Association 
Advisory Committee
EXECUTIVE SUMMARY

PUBLIC HEALTH CONFERENCE SCOPE AND PURPOSE

The American Heart Association/American Stroke Association (AHA/ASA) is a global leader in the stroke field and has a long history of discovering, disseminating and applying scientific knowledge. Because of the impact of cryptogenic stroke in the United States, the AHA/ASA has embarked on the Cryptogenic Stroke Initiative, a two-year effort to increase awareness in the medical and public health community with a primary focus on supporting the clinical community with knowledge to better diagnose and treat cryptogenic stroke, facilitate appropriate research and identify effective interventions.

Addressing the gaps in knowledge of cryptogenic stroke and uncertainty of healthcare professionals in diagnosing and treating patients, the AHA/ASA convened the Cryptogenic Stroke Public Health Conference in Washington, D.C., in October 2015. Experts from 50 leading U.S. healthcare and public health organizations discussed possibilities for a coordinated, systematic approach to diagnose and manage cryptogenic stroke patients.

The conference format included panel presentations by subject matter experts in identification and diagnosis, barriers to care, patient management and systems of care of cryptogenic stroke. Presenters addressed these issues from clinical and public health perspectives, followed by participant discussions that informed how to address gaps and needs.
The AHA/ASA convened the Cryptogenic Stroke Public Health Conference to make cryptogenic stroke a national health priority by enhancing knowledge of diagnostic clinical pathways — and supporting the AHA/ASA’s goal to reduce stroke deaths by 20 percent by 2020. Key conference activities included:

1. Identifying guideline-based medical treatments to prevent recurrent strokes.
2. Defining potential stroke-related health disparities and determining the impact in subpopulations.
3. Determining actionable strategies to prevent second strokes, leading to improved patient outcomes.
CONFERENCE RECOMMENDATIONS

These discussions informed the development of gaps to address to affect impact. Call-to-action recommendations from the conference included:

- Raising awareness of cryptogenic stroke with healthcare professionals and consumers.

- Increasing professional education to ensure proper and thorough evaluation of all strokes.

- Improving transitions of care and communication along the continuum of care.

- Standardizing follow-up diagnostic procedures for cryptogenic stroke patients.
BACKGROUND: ABOUT 800,000 NEW OR RECURRENT STROKES OCCUR EVERY YEAR IN THE UNITED STATES, making it the fifth leading cause of death and leading cause of serious long-term disability for Americans.¹ Most stroke patients experience some residual impairment at six months post-event, and the aftermath of a stroke is associated with numerous adverse effects, including hemiparesis, cognitive deficits, and depressive symptoms.

A STROKE can drastically and negatively affect a person’s quality of life by causing speech and visual impairments, and weeks of therapy and months of treatment are often required to reach maximal recovery.² Stroke patients are also at increased risk of a recurrent stroke. Studies have shown that the risk of recurrence at two years post-stroke ranges from 14 percent to 25 percent.³ Risk factors for stroke include hypertension, tobacco use, cardiac disease, diabetes, and personal or family history of stroke.⁴ Ninety percent of the attributable risk of stroke can be explained by 10 risk factors, and 80 percent of this risk is attributable to five key risk factors: hypertension, abdominal fat, inactivity, hyperlipidemia and diet.⁵ Patients with atrial fibrillation (AF) are also five times more likely to experience ischemic stroke than those without AF.⁶ There are two major types of stroke with different frequencies, mechanisms and implications. Hemorrhagic strokes occur when a blood vessel in the brain ruptures and account for about 13 percent of strokes. Ischemic strokes account for 87 percent of strokes, and occur when a blood vessel is obstructed, depleting the brain of its blood supply. Of all ischemic strokes, 25 percent to 30 percent are classified as “cryptogenic,” which means that no definite clinical cause has been identified. Cryptogenic strokes are also referred to as stroke of unknown origin, a cause or source of stroke of unexplained origin.

Cryptogenic strokes are diagnosed by a process of elimination of known causes, and are defined by the TOAST criteria (Trial of Org 10172 in Acute Stroke Treatment) as a brain infarct not attributed to a definite source of large-vessel atherosclerosis, cardioembolism or small-vessel disease, in the presence of (1) extensive cardiac, vascular, hematologic and serologic evaluation; (2) incomplete evaluation; or (3) evidence of more than one competing cause.⁷ Cryptogenic stroke patients don’t have mechanism-targeted treatments like patients with AF or symptomatic carotid stenosis, causing it to be more difficult to prevent recurrent events.

Due to the high rate of recurrence, secondary prevention is critical for patients who have suffered from a stroke. Treatment for secondary prevention of stroke is dependent on the stroke subtype: anticoagulants are prescribed for patients with definite cardioembolic etiology due to AF and antiplatelet therapy is prescribed for patients with noncardioembolic strokes.⁸ Therefore, it is essential to identify the etiology of a stroke to prescribe the most appropriate treatment.

Healthcare Provider Awareness Around Cryptogenic Stroke

In a recent AHA/ASA survey of more than 650 neurologists, cardiologists, hospitalists, primary care physicians and stroke coordinators, half considered themselves inadequately equipped with information about cryptogenic stroke. Furthermore, 51 percent to 70 percent of the physicians polled, depending on their specialty, admitted uncertainty in how to best approach finding the underlying causes of strokes. This presents an opportunity to inform and better clarify existing science and guidelines for cryptogenic stroke, ensuring that a thorough evaluation occurs for every patient, tailored to the clinical scenario, so that few strokes remain cryptogenic.

**Other key findings include:**

- Fifty-eight percent to 72 percent of healthcare professionals (HCPs) use the term “cryptogenic stroke” with each other, yet only 12 percent to 18 percent share this diagnosis with patients.

- A notable segment of HCPs are uninformed about cryptogenic stroke (three in 10 neurologists and cardiologists feel only somewhat or not informed) and feel less than confident that treatment will prevent another stroke (nearly six in 10 neurologists and cardiologists feel only somewhat or not confident).

- Stroke neurologists are more likely than general neurologists to consider additional causes outside of Afib (cardiac/paradoxical embolism; atrial septal aneurysm).

- Atrial fibrillation is well understood by HCPs to be a leading cause of stroke, and nine in 10 think it’s important to look for AF. However, many find challenges in detecting AF. Lack of consensus about optimal therapy is a barrier to agreement regarding use of anticoagulants and other preventive treatments (27 percent to 48 percent of HCPs agree).

The high incidence of cryptogenic stroke in combination with low provider awareness of the potential causes of cryptogenic stroke and lack of confidence in prescribed treatment creates an opportunity for healthcare provider education around the need to conduct a full evaluation for patients.

**Stroke as a Public Health Issue**

A two-way interaction exists between stroke clinical organizations and the public health community on stroke treatment and management. Strokes are preventable and treatable; public awareness is an essential component of effectively reducing the burden of stroke. Public health and medical care communities can use population health to raise awareness and change the interaction between stroke and public health issues. Population-based interventions to prevent stroke (primary prevention) include initiatives to increase physical activity, improve nutrition, control blood pressure, reduce salt intake and decrease tobacco use. To best address the gaps in making cryptogenic stroke a public health issue, it is important to understand the landscape of stroke education and systems initiatives.

**Acute Stroke Evaluation**

According to the Acute Ischemic Stroke Guidelines, stroke etiology can often be assessed based on a patient's symptoms, medical history, physical examination, blood tests, diagnostic testing and imaging studies. A typical initial evaluation to identify the etiology of a stroke would include non-invasive imaging of the brain, blood vessels and heart. Examples of these imaging studies include brain computed tomography (CT) and/or magnetic resonance imaging (MRI), carotid ultrasound, electrocardiogram (EKG)/cardiac telemetry, transthoracic echocardiography, and routine blood tests. Depending on patient factors and the results of the initial evaluation, additional imaging tests such as computed tomography angiogram (CTA), carotid angiography and magnetic resonance angiogram (MRA) as well as transesophageal echocardiography (TEE) and Holter monitoring or additional prolonged cardiac rhythm monitoring may

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also be performed. Potential etiologies of cryptogenic stroke that may be identified only with these or other targeted tests include, but are not limited to, occult paroxysmal AF, patent foramen ovale, inherited thrombophilias, aortic arch atheroma or other occult blood vessel atheroma [intracranial vessel disease], or a combination of several of these mechanisms. Once the cause of an unexplained stroke is identified, the stroke is no longer considered cryptogenic. In many cases, a definitive cause cannot be ascertained, but one or more causes of varying degrees of likelihood may be considered or identified.

Despite the availability of a diverse array of diagnostic tests, ~30 percent of ischemic strokes are considered cryptogenic. Some of these strokes are placed in the “cryptogenic” category due to limited evaluation by physicians or limitations in diagnostic detection. The current approach to stroke management involves initiating treatment as soon as possible, and thus physicians may begin therapy before sufficient evaluation can determine a likely etiology. Physicians are also constantly required to balance the costs of diagnostic tests with the utility that can be derived from correctly identifying the etiological cause of the stroke. Concerns surrounding costs and overuse of diagnostic procedures, therefore, can also impact whether an etiology is identified. Physicians also balance in their decision-making approach for full diagnostic testing against the likelihood of finding a treatable cause and financial implications of the testing to find a cause. Finding the stroke etiology could help improve stroke outcomes in these populations, specifically for patients diagnosed with treatable conditions, like atrial fibrillation and hypercoagulable disorder.

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Research and Funding

Stroke treatment guidelines and standards are informed by well-designed scientific studies that guide new concepts for managing cryptogenic stroke. The National Institutes of Health (NIH)/NINDS and AHA/ASA lead stroke research efforts. The AHA/ASA has invested more funds to stroke research than any organization (except the federal government), garnering more than 4,400 stroke-related research grants since 2001. Furthermore, the NIH has a current investment of $300 million for clinical research and innovative basic science investigations in stroke. The NIH-funded StrokeNet is a national network of 25 regional centers and more than 200 hospitals that conduct clinical trials to advance acute stroke treatment, prevention, recovery and rehabilitation. The NINDS supports a full spectrum of research to investigate stroke diagnosis, treatment and biomarkers, as well as translational research to put discoveries into practice. Research findings suggest that a molecular biology approach may yield new diagnostic tests that practitioners can use to identify the cause of cryptogenic stroke. For example, proof of concept studies are being conducted to evaluate ribonucleic acid (RNA) expression profiles. This identification could then lead to specific treatments for patients to intervene to lower their personal risk of subsequent events. However, the cryptogenic stroke research portfolio at the NIH is small, with fewer than 10 active grants, thereby presenting a key area of research opportunity.

Research in stroke is underfunded, considering its impact nationally. Stroke is the fifth highest cause of death, with the prevalence expected to increase by 20.5 percent by 2030. Total direct stroke-related costs are expected to triple. Yet, NIH invests a highly disproportionate 1 percent of its budget on stroke research. This funding level is not commensurate with scientific opportunities, the number of people affected, or the physical and economic toll exacted upon our nation. Increased investment in stroke research can help inform the cryptogenic stroke landscape and advancement of stroke treatment.

Disparities in Stroke

Differences in stroke incidence and outcomes exist among races, socioeconomics and gender. These disparities are often access-related and present the same obstacles for cryptogenic stroke diagnosis and care as with other types of stroke. Disparities in stroke care for African-American and Hispanic populations may in part be due to differences in access to care, including challenges with paying for prescription drugs, managing medical care and lacking access to health insurance. Compared with Caucasians, African-Americans are two times more likely to have a first stroke and die from a stroke.

Hispanics and Latinos also face elevated risks of stroke, because of their higher incidence of hypertension and hyperlipidemia. Culture, language, belief of fatalism around stroke, socio-economic status and attitudes about risk factor management affect compliance, treatment and outcomes among Hispanics. Clinicians must consider these cultural factors, language barriers and access issues to improve their communication and approach to treatment.

The incidence of cryptogenic stroke is also higher among African-Americans and Hispanics than whites. In the Northern Manhattan Stroke Study (NOMASS).
incidence rates of all ischemic stroke subtypes, including cryptogenic stroke, were higher in African-Americans and Hispanics than in Caucasians.\textsuperscript{21} In the Greater Cincinnati/Northern Kentucky Stroke Study (GCNKSS), African-Americans had twice the annual incidence rate of cryptogenic stroke as Caucasians (125 versus 65 per 100,000 persons). Yet, this result was not confounded by differential diagnostic patterns among African-American versus Caucasian patients.\textsuperscript{22} In San Diego, the prevalence of cryptogenic stroke increased nearly 46 percent among Mexican-American patients.\textsuperscript{23} Again, this statistic was not explained by differences in diagnostic testing.\textsuperscript{24}

With respect to sex differences in stroke epidemiology, lifetime risk for stroke and the one-year stroke mortality rate are significantly higher for women than for men.\textsuperscript{25} Rates of death from stroke in women are twice that of breast cancer.\textsuperscript{26} Again, standardizing treatment and evaluation could improve diagnosis and help reduce these disparities.

**Patient Management and Secondary Prevention of Stroke**

Epidemiologic, basic and applied science can be used to alter the landscape for cryptogenic stroke patients. Medical societies play an important role in developing and disseminating clinical guidelines and in working with other organizations to address cryptogenic stroke. Opportunities exist to elevate cryptogenic stroke awareness and education through organizational key meetings, including providing offerings such as Continuing Medical Education courses, scientific publications in journals and education through member/society communication channels. Organizations working together can increase adoption of guidelines. Collaboration similar to how the American Academy of Neurology works with the AHA/ASA to develop guidelines for stroke treatment and management could expedite implementation.

*The Guidelines for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack*\textsuperscript{28} are a template for clinicians to manage stroke patients. As some AHA guidelines in stroke management

have “C-grade” levels of clinical evidence, there is an opportunity for more clinical research to advance knowledge in diagnostic and treatment approaches for cryptogenic stroke patients.

Enhancing Systems of Care

Although stroke evaluation guidelines exist, adherence and diagnostic uniformity among practitioners is suboptimal. Consequently, patient care depends on the healthcare setting. Variations in treatment may also be caused by health disparities, access issues and inconsistencies in stroke work-up by healthcare providers. To overcome these differences, it’s important to standardize quality improvement processes and promote adherence to guidelines for a basic stroke evaluation. In the stroke community, The Joint Commission, Centers for Disease Control and Prevention (CDC) and AHA/ASA are leaders in quality improvement and stroke systems of care — from which much can be learned.

System of care refers to optimizing the stroke treatment process from stroke identification, to EMS protocols, to inpatient stroke care (Emergency Department and in hospital), to hospital improvement processes, patient education, discharge processes and post-stroke recovery. The Million Hearts Program, supported by the CDC and Centers for Medicare and Medicaid Services, which has a goal to prevent 1 million heart attacks and strokes by 2017, is a public health campaign with best practices for cryptogenic stroke. Developing a strong call to action and a measurable goal has been highly successful for the Million Hearts Program. It progressed via a national initiative that resonates with the public, assesses measurable metrics tied to incentives and leverages partnerships by using quality dashboards to measure, track care and drive quality improvement over time.

The Joint Commission’s (JJC) mission is to partner with healthcare organizations to improve quality and safety outcomes. It monitors whether healthcare organizations are following appropriate standards and continues to expand to include patient-reported outcomes to improve quality of care for Acute Stroke Ready facilities, Primary Stroke Centers (PSC) and Comprehensive Stroke Centers (CSC). These certified stroke centers serve as a backbone for implementing new management strategies and leading along with TJC best practices in managing patients.

A standardized process should be guideline- and protocol-driven, informed by clinical expertise and applied to the appropriate populations. Two AHA/ASA programs that focus on improving quality improvement are Get With the Guidelines-Stroke (GWTG-Stroke) and Guideline Advantage. These programs help us leverage outcomes-based reporting through a robust registry. The GWTG-Stroke Program has driven quality improvement through its award program in more than 1,800 participating hospitals, improving time to treatment and excellence in stroke care. The Guideline Advantage, a collaboration with the AHA/ASA, American Diabetes Association and American Cancer Society, is based on guideline-recommended care for primary care providers in the outpatient setting. These programs monitor data, reward healthcare provider practices for best practice care/outcomes and thus lead to better practice outcomes. Because they incorporate the framework of evidenced-based guidelines, the programs are disseminating and ensuring implementation of practice guidelines in hospitals and the practice setting.

While quality improvement programs like GWTG-Stroke and Guideline Advantage can help improve transition from one setting to another through registry reporting, communication among health providers can be improved. Primary Care Physicians may often not be involved with their patients’ hospital care and may not even know that the patient was hospitalized. Discharge summaries are typically brief and primary care physicians often don’t receive them in a timely manner. A neurohospitalist is a physician and/or provider who cares for a hospitalized patient with, or at risk for, neurological disorders and disease. This is an evolving and growing group of medical professionals focused on managing acute neurological illness. The neurohospitalist model could serve as an approach to facilitate coordination of multidisciplinary care through standardized processes.
SUMMARY OF DISCUSSIONS

The AHA/ASA convened representatives of more than 50 of the nation’s leading medical and public health organizations to identify gaps in the care of cryptogenic stroke and to recommend strategies to alleviate the public health burden. Participants at the Cryptogenic Stroke Public Health Conference discussed evidence-based diagnostic approaches, treatment and secondary prevention, along with actionable strategies and tactics to improve patient outcomes.

Over the last 30 years, research has informed clinical practice in the care of stroke. Methods of evaluation and treatment that were once cutting edge, such as MRI scanning and interventional radiology, have become broadly accepted as a standard of care. Despite this progress, stroke continues to be a major public health issue as a cause of long-term morbidity and mortality. In a significant proportion of patients with ischemic stroke (~30 percent), an etiology is not identified because standard evaluation is not done.27 Since treatment varies by stroke etiology, identifying a cause of any cryptogenic stroke offers the promise of reducing the risk of recurrent stroke and improving outcomes.

Addressing the full continuum of care for cryptogenic stroke patients provides an opportunity to improve outcomes. Improved diagnostics are being investigated to identify the specific cause of a patient’s stroke to correctly prescribe therapy. Consensus is needed regarding what should be a full evaluation post-cryptogenic stroke using a standardized approach. Education for patients and providers can be addressed so that the results of care innovation are available. Recommendations should consider the public health perspective so that racial, ethnic and sex disparities can be minimized.

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GAPS AREAS TO ADDRESS

Participants of the Cryptogenic Stroke Public Health Conference created an agenda to make cryptogenic stroke a public health priority. The group identified actions that individuals and organizations can take to advance understanding and treatment of cryptogenic stroke.

Raise awareness of cryptogenic stroke among consumers and healthcare professionals.

- Enlist support of medical and public health organizations to adopt cryptogenic stroke as a focused priority.
- Conduct public awareness campaigns to elevate terminology awareness of cryptogenic stroke and survivor knowledge on steps in preventing a second stroke.
- Develop culturally relevant and health-literate education tools for patients and caregivers.

Increase professional education on cryptogenic stroke.

- Educate neurologists, cardiologists, hospitalists, primary care physicians and nurses on secondary prevention of stroke to ensure existing diagnostic and treatment guidelines are put into practice.

Improve transitions of care and communication along the continuum of care.

- Explore digital solutions for transition of care, continuity of care and follow-up.

Standardize follow-up procedures for patients with unexplained stroke.

- Use hospital registries to measure rate of diagnosis and treatment.
- Develop hospital protocols in support of current AHA/ASA Guidelines for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack.
- Ask accreditation bodies and organizations that can influence quality improvement standardization to ensure that healthcare providers and institutions implement clinical practice guidelines for secondary prevention of stroke.
- Define the evidence gaps on secondary prevention (reducing recurrent strokes) that require further clinical research.

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CRYPTOGENIC STROKE PUBLIC HEALTH CONFERENCE

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American Academy of Neurology
American Association of Heart Failure Nurses
American Association of Neuroscience Nurses
American College of Emergency Physicians
American College of Physicians
American Foundation for Women’s Health
American Public Health Association
American Society of Echocardiography
Biotelemetry
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Hispanic Health Council
Medstar Southern Maryland
Million Hearts
National Association of County and City Health Officials
National Black Nurses Association
National Institute of Neurological Disorders and Stroke
National Quality Forum
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Neurohospitalist Society
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The Joint Commission
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University of Virginia
University of Washington Medical Center
University of Wisconsin School of Medicine and Public Health
WomenHeart
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