Acute Stroke Therapy at Crossroads, Researchers Write

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(Medical Xpress) -- Acute stroke therapy is at a crossroads, a University of Cincinnati (UC) researcher writes in a national medical journal, with clinical practice increasingly using approaches that have not been proven clinically effective while conduct of clinical trials to provide critical data is impeded.

Joseph Broderick, MD, Albert Barnes Voorheis Chair of Neurology at the UC College of Medicine, co-authored the commentary in *JAMA: the* Journal of the American Medical Association, with Philip Meyers, MD, an associate professor of radiology and neurological surgery at Columbia University in New York. It appears in the Nov. 9 issue of *JAMA*.

Broderick is the principal investigator for the Interventional Management of Stroke (IMS III) trial, begun in 2005, which compares a combined intravenous (IV) and intra-arterial (IA) treatment approach to restoring blood flow to the brain after an acute ischemic stroke to intravenous treatment with tPA alone. UC recently received $12.7 over four years from the National Institutes of Health (NIH) to continue coordinating the trial. Meyers is external interventional safety monitor for the IMS III trial.

In the commentary, the authors note that endovascular technology designed to reopen occluded blood vessels has expanded in the past 10 years. But while the U.S. Food and Drug Administration (FDA) has cleared various devices for use to remove blood clots in acute stroke, the authors point out that they were not approved as clinically effective

treatments.

The commentary accompanies an article detailing the results of the Carotid Occlusion Surgery Study (COSS), which tested the hypothesis that bypass surgery, added to the best medical therapy, reduces subsequent stroke in patients with thickening and blockage of the internal carotid artery and insufficient blood flow to the brain. The trial was terminated early for futility, with the surgery failing to provide an overall benefit on two-year stroke recurrence.

The COSS trial was one of several studies, the authors write, in which "the device or medication accomplished its biologic purpose … but clinical efficacy was not proven in Phase III trials."

The authors also point out that reimbursements set by the Centers for Medicare and Medicaid Services (CMS) have an impact on acute stroke care.

"Reimbursement for devices and procedures that lack evidence for clinical efficacy greatly increases their use by physicians and hospitals as well as the cost of health care in the U.S.," the authors write.

The authors also note that reimbursements affect enrollment into randomized clinical trials, citing recent trials: one in which enrollment was facilitated and the trial reached a relatively rapid conclusion because CMS chose to reimburse only within the setting of the clinical trial, and others in which the CMS did not similarly restrict reimbursement and U.S. enrollment has lagged behind sites in Canada, Australia and Europe.

The authors make several recommendations, including:

• "Clinical science and reimbursement for delivery of clinical stroke care must be balanced and aligned."

• "Stroke physicians and interventionalists must recognize the current lack of evidence for clinical efficacy of endovascular therapy and enroll patients in randomized trials."

• "The review process of (the) FDA and CMS must be harmonized and should require higher standards of evidence for clinical efficacy prior to clearance or approval of devices for stroke and subsequent reimbursement."

• "Long-term and ongoing reimbursement should be predicated on evidence for equivalent or superior clinical efficacy, and cost effectiveness should be an important consideration for clinically equivalent therapies."

Provided by University of Cincinnati