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Press Release

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HAVE CHANGES IN THE USE OF ANEMIA DRUGS AFFECTED DIALYSIS PATIENTS' RISK OF STROKE AND HEART ATTACK?

Washington, DC (February 25, 2016) — A new study examines whether recent changes in the use of anemia drugs for patients on dialysis have decreased the risk of stroke and heart attack. The findings, which appear in an upcoming issue of the *Journal of the American Society of Nephrology* (JASN), indicate that these risks appear to be decreasing for all patients, and determining the role of changes to anemia drug prescriptions will require more research.

Anemia is common in patients with chronic kidney disease and almost universal in patients who undergo maintenance dialysis treatment. Erythropoiesis-stimulating agents (ESAs) that boost blood cell production are often used to correct anemia, but when clinical trials revealed that ESAs carry an increased risk of strokes and heart attacks, use of these medications declined. Their use also declined due to changes in 2011 concerning how Medicare pays for components of dialysis care. As a result, levels of hemoglobin—the component of blood that transports oxygen throughout the body—among patients receiving dialysis have decreased and the use of blood transfusions, which ESAs were intended to reduce, have increased.

To examine what effects these trends have had on the health of dialysis patients, Glenn Chertow, MD, PhD (Stanford University School of Medicine) and his colleagues conducted a study of patients in the United States who were on dialysis during the study period of January 1, 2005 through December 31, 2012. The analysis included approximately 250,000 patients receiving maintenance dialysis in each calendar year between 2005 and 2012.

The researchers found that there were marked declines in ESA use and resulting hemoglobin concentrations, and a consequent increase in transfusions in dialysis patients starting in 2010 and continuing through 2012. They also observed that there was already a decreasing trend in strokes and heart attacks, starting at least in 2005. "The reason for this trend is unknown and is seen across all Medicare beneficiaries, even those who do not receive dialysis," said Dr. Chertow. "We believe that these trends make it hard to really understand whether the changes in 2011 have resulted in fewer strokes and heart

attacks for patients receiving these medicines, and more research on this topic is needed."

Study co-authors include Jiannong Liu, PhD; Keri L. Monda, PhD; David T. Gilbertson, PhD; M. Alan Brookhart, PhD; Anne C. Beaubrun, PhD; Wolfgang C. Winkelmayer, MD, ScD; Allan Pollock, MD; Charles A. Herzog, MD; Akhtar Ashfaq, MD; Til Sturmer, MD, ScD; Kenneth J. Rothman, DrPH; Brian D. Bradbury, DSc; and Allan J. Collins, MD.

Disclosures: Several of the authors report receiving research grants from the National Institutes of Health and the Agency for Healthcare Research and Quality. Dr. Chertow serves on the Board of Directors of Satellite Healthcare, has served as a scientific advisor to Akebia, Amgen, Keryx, and Vifor, and has received research support from Amgen. Drs. Monda, Beaubrun, Pollock, and Bradbury work at Amgen and hold Amgen stock. Dr. Ashfaq worked at Amgen at the time of manuscript submission and is currently employed at AstraZeneca. Dr. Gilbertson has provided consultation to Amgen, DaVita Clinical Research, and Affymax. Drs. Gilbertson, Collins, Herzog, and Liu work at the Chronic Disease Research Group, which has received research support from Amgen. Dr. Collins has provided consultation to NxStage, Astra Zeneca, Relypsa, and Amgen. Dr. Herzog has served as a scientific consultant for Abbvie, Affymax, Amgen, BMS, Fibrogen, GSK, Keryx, Matinas Bio Pharma, Medtronic, Relypsa, ZS Pharma, and ClearView Healthcare Partners, and owns stock in Boston Scientific, Johnson & Johnson, GE, and Merck. Dr. Brookhart has received research support from Amgen and AstraZeneca, has served as a scientific advisor for Amgen, GSK, and Merck (honoraria/payment received by the institution), and has received consulting fees from RxAnte, Inc. and World Health Information Consultants. Dr. Stürmer receives salary support as Director of the Comparative Effectiveness Research (CER) Strategic Initiative, NC TraCS Institute, and as Director of the Center for Pharmacoepidemiology (current members: GSK, UCB BioSciences, Merck) and research support from pharmaceutical companies (Amgen, AstraZeneca) to the Department of Epidemiology, UNC Chapel Hill. Dr. Stürmer owns stock in Novartis, Roche, BASF, AstraZeneca, Johnson & Johnson, and Novo Nordisk. Dr. Winkelmayer reports having received honoraria for having served on scientific advisory, event adjudication, or data safety monitoring boards for Akebia, Amgen, AstraZeneca, Bayer, Medtronic, Relypsa, and Zoll. Dr. Rothman is a full-time employee of the Research Triangle Institute, an independent non-profit research organization that does work for government agencies and pharmaceutical companies.

The article, entitled "Epoetin Alfa and Outcomes in Dialysis amid Regulatory and Payment Reform," will appear online at http://jasn.asnjournals.org/ on February 25, 2016. doi: 10.1681/ASN.2015111232

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Founded in 1966, and with nearly 16,000 members, the American Society of Nephrology (ASN) leads the fight against kidney disease by educating health professionals, sharing new knowledge, advancing research, and advocating the highest quality care for patients.

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