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New Study Finds Chronic Kidney Disease Remains Largely Undiagnosed in Nearly Half of Patients with Type 2 Diabetes and Chronic Kidney Disease

Worldwide, 160 million people with type 2 diabetes (T2D) are at risk for developing chronic kidney disease (CKD)[1]

Study underscores the need for increased education focused on diagnosing and treating patients with T2D and CKD

TITUSVILLE, NJ, May 10, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results of a new, retrospective, observational study showing 49 percent of patients with type 2 diabetes (T2D) and lab-confirmed chronic kidney disease (CKD) did not have a CKD diagnosis from their doctor in a claims database. The 123,000-patient study, titled *Prevalence and Factors Associated with Undiagnosed Chronic Kidney Disease in Diabetes Mellitus*, was presented this week at the National Kidney Foundation (NKF) 2019 Spring Clinical Meetings in Boston, Mass.

CKD is a progressive condition that occurs when damaged kidneys cannot properly filter blood, often leading to kidney failure or even death.[2] This worldwide health crisis affects 10 percent of the world population[3] and is the fifth fastest-growing cause of death around the world.[4] Type 2 diabetes is the leading cause of CKD and there have been no new medicines to treat or prevent CKD in more than 17 years.[5-7]

"About one in three people with T2D have CKD,[8] so it's important to look for it in its early stages," said lead study investigator George Bakris[i], M.D., professor of medicine and director, Comprehensive Hypertension Center, University of Chicago. "We found that nearly half of the patients we studied with T2D and CKD had no CKD diagnosis even when their labs confirmed the presence of CKD. While the undiagnosed CKD rate declined over time, there is still a clear and urgent need for education and detection of this serious and potentially life-threatening complication."

***Click to Tweet**: New study finds chronic #kidneydisease remains largely undiagnosed in nearly half of patients with #type2diabetes and #CKD #NKFClinicals https://ctt.ec/Qg_cT+*

Researchers also found:

- Patients in stage G3a and G3b CKD, defined as having an estimated glomerular filtration rate (eGFR) of <45-59 mL/min/1.73 m^2 and <30-44 mL/min/1.73 m^2, respectively, were the most undiagnosed. Specifically, 57.1 percent of patients with mild to moderate loss of kidney function (stage G3a CKD) and 29.9 percent with moderate to severe loss of kidney function (stage G3b CKD) had no record of CKD diagnosis. Of those with severe loss of kidney function (stage G4 CKD) and kidney failure (stage G5 CKD), 10.8 percent and 4.2 percent, respectively, had no record of CKD diagnosis.
- People between 55 and 69 years old, women, and those who reside in the Northeast and North Central regions of the U.S. were more likely to be undiagnosed with CKD.
    - Women had 41 percent higher odds of being undiagnosed compared to men (52.8 percent vs. 44.3 percent).

    - Relative to patients who were 70-74 years old, those who were 55-64 and 65-69 years old had 36 percent and 13 percent higher odds of being undiagnosed, respectively, while those who were 75-79 and 80-84 years old had 10 percent and 17 percent lower odds, respectively.
    - Relative to patients in the South, those living in the Northeast and North Central regions had 97 percent and 22 percent higher odds of being undiagnosed, respectively, while patients in the West had 42 percent lower odds.
- Patients who visited a nephrologist, had complications related to T2D, or had specific cardiovascular comorbidities had lower rates of undiagnosed CKD.
    - The undiagnosed rate was 6.5 percent among patients who visited a nephrologist.
    - The undiagnosed rate was below 50 percent among patients with T2D complications, including neuropathy (38.6 percent) and retinopathy (41.6 percent), as well as those with specific cardiovascular comorbidities, including hypertension (47.9 percent), peripheral vascular disease (37.1 percent) and congestive heart failure (38.7 percent).
    - The availability of ACR (albumin-to-creatinine ratio), a urine test to assess kidney function, was a factor independently related to lower odds of undiagnosed CKD.
- The undiagnosed CKD rate declined over time, from 56.3 percent in 2011 to 40.3 percent in 2017.

"With the prevalence of T2D continuing to rise globally, CKD has become one of the most serious health challenges we face today," said Paul Burton, M.D., Ph.D., FACC, Vice President, Medical Affairs, Internal Medicine, Janssen Scientific Affairs, LLC. "While there is no cure for CKD, recent research has shown it may be possible to prevent or delay its progression. Janssen remains committed to tackling this challenge, and we believe the work we're doing has the potential to transform the lives of millions of people living with T2D and CKD."

About the Study

Researchers examined claims data and lab results from the Optum Clinformatics database from January 2010 through September 2017. Adult patients less than 85 years old with confirmed T2D and at least two lab tests (on or after the first T2D diagnosis) indicating impaired kidney function were enrolled in the study. Impaired kidney function was confirmed by two serum creatinine (SCr) measurements resulting in eGFR of <60 mL/min/1.73 m^2. Patients with type 1 diabetes, pregnancy-related diagnosis, gestational diabetes, steroid-induced diabetes, acute kidney injury, polycystic ovary syndrome, renal transplant or those on dialysis were excluded from the study.

Investigators examined medical claims from 12 months prior to the first eGFR<60 mL/min/1.73 m^2 to one month after the second for CKD-related diagnosis. Diagnosed CKD was identified by ICD-9/10 codes entered during the study period. Undiagnosed CKD was defined as the absence of any of the following: CKD, T2D with kidney complication, diabetes with renal manifestation, hypertensive CKD or disorders from impaired renal function. Baseline characteristics also were measured during the 12-month period preceding the first eGFR <60 mL/min/1.73 m^2.

About Janssen Cardiovascular & Metabolism

In Cardiovascular & Metabolism (CVM), we take on the most pervasive diseases that burden hundreds of millions of people and healthcare systems around the world. As part of this long-standing commitment and propelled by our successes in treating type 2 diabetes (T2D) and thrombosis, we advance highly differentiated therapies that prevent and treat life-threatening cardiovascular, metabolic and retinal diseases. Uncovering new therapies that can improve the quality of life for this large segment of the population is an important endeavor – one which Janssen CVM will continue to lead in the years to come. Our mission is global, local and personal. Together, we can reshape the future of cardiovascular, metabolic and retinal disease prevention and treatment. Please visit www.janssen.com/cardiovascular-and-metabolism.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal. Janssen Pharmaceuticals, Inc., and Janssen Scientific Affairs, LLC, are two of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding Janssen research in type 2 diabetes. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Scientific Affairs, LLC, any of the other Janssen Pharmaceutical companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of

these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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[i] *Dr. George Bakris worked directly with Janssen Pharmaceuticals, Inc. and was compensated for his work on this study.*