Intensive education at clinics about multidisciplinary care improved likelihood that adults with type 2 diabetes and cardiovascular disease were receiving guideline-directed medicines, according to real-world study

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- *The findings, from the COORDINATE-Diabetes trial, demonstrate the benefit of clinic-level educational interventions, including a focus on coordinating care between cardiology and diabetes care providers*

- *Results were presented at the Joint American College of Cardiology/*Journal of the American Medical Association *Late-Breaking Clinical Trials Session 2023 and simultaneously published in* Journal of the American Medical Association

RIDGEFIELD, Conn. and INDIANAPOLIS, March 6, 2023 /PRNewswire/ -- Providing clinics with a coordinated, multifaceted intervention, with assessment of barriers, care pathways and feedback, improved the likelihood that adults with type 2 diabetes and cardiovascular disease were receiving guideline-directed medical therapy after one year versus usual care. The results, from COORDINATE-Diabetes (COOrdinating CaRDIology CliNics RAndomized Trial of Interventions to Improve OutcomEs), were presented today at the Joint American College of Cardiology/*Journal of the American Medical Association* Late-Breaking Clinical Trials Session 2023 and simultaneously published in *Journal of the American Medical Association.* COORDINATE-Diabetes is led by the Duke Clinical Research Institute (DCRI) and funded by Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY).

COORDINATE-Diabetes included 43 cardiology clinics across the U.S. These clinics were randomized to a usual care or intervention arm. In the usual care arm, clinics were provided with the current practice guidelines, including recommendations outlined by the American College of Cardiology (ACC), American Heart Association (AHA) and American Diabetes Association (ADA). The intervention arm comprised multiple components, including: assessment of barriers to prescribing recommended therapies and pathways to address these barriers; coordination of care among physicians; clinician education; auditing and feedback of metrics; and patient-facing educational materials.

"The use of a multidisciplinary care approach to optimize care and outcomes for people with type 2 diabetes and cardiovascular disease is critical given the public health impact of these diseases," said Christopher Granger, M.D., professor of medicine in the Division of Cardiology at Duke University and lead researcher for COORDINATE-Diabetes. "We have shown, with the highest level of evidence through randomization, that patients will get better care when they are treated by a dedicated team of doctors and specialists, with assessment of barriers, tools to address barriers, care pathways and feedback, with education of both providers and patients. COORDINATE-Diabetes shows how collaboration among providers can help achieve better care*."*

The primary endpoint of COORDINATE-Diabetes was the proportion of participants prescribed all three of the following guideline-directed therapies after 6 to 12 months: a high-intensity statin, an angiotensin-converting-enzyme inhibitor (ACE inhibitor) or angiotensin receptor blocker (ARB) and an anti-hyperglycemic agent with proven cardiovascular benefits such as an SGLT2 inhibitor or a GLP-1 receptor agonist. The findings showed that participants in the intervention arm were significantly more likely to be prescribed all three guideline-directed therapies versus the usual care arm (37.9% vs. 14.5%, respectively) at 6 to 12 months.

"Beyond clinical trials, it is essential that we understand how to optimize care for people with type 2 diabetes and cardiovascular disease in a real-world clinical setting," said Mohamed Eid, M.D., M.P.H., M.H.A., vice president, Clinical Development & Medical Affairs, Cardio-Renal-Metabolism & Respiratory Medicine, Boehringer Ingelheim Pharmaceuticals, Inc. "These findings show that, when healthcare providers work closely together, their combined efforts lead to improved chances of adopting guideline-directed medications that are proven to reduce cardiovascular risk, including SGLT2 inhibitors."

"Though the advantages of multidisciplinary care are intuitively known, few real-world studies have evaluated the effects of clinic-based provider education on patients receiving guideline-directed therapy," said Jeff Emmick, M.D., Ph.D., vice president, Product Development, Lilly. "Given the mounting burden of cardiovascular disease linked to type 2 diabetes, it is important that cardiology and diabetes care providers work together to implement integrated care strategies for this vulnerable population."

Participants in the intervention arm were also significantly more likely to be prescribed two or more guideline-directed therapies at 6 to 12 months versus the usual care arm (79.0% vs. 55.4%, respectively). Changes in surrogate measures such as blood pressure, LDL cholesterol and A1c were not significantly different at last follow up. Risk of the composite endpoint of death or hospitalization for a cardiovascular event trended toward improvement but was not significantly different between arms at one year.

About COORDINATE-Diabetes
COORDINATE-Diabetes (COOrdinating CaRDIology CliNics Randomized Trial of Interventions to Improve OutcomEs), led by Duke Clinical Research Institute and funded by Boehringer Ingelheim and Lilly, was designed to optimize care for people with type 2 diabetes and cardiovascular disease through evaluation of a multidisciplinary approach at cardiology clinics across the U.S. The trial included 43 cardiology clinics randomized to a usual care arm that provided basic education around clinical treatment guidelines or an intervention arm that focused on assessing local barriers to providing evidence-based therapies, developing care pathways to overcome these barriers, coordinating care among clinicians, providing clinician-facing education and patient-facing educational materials, and implementing audit and feedback to improve care. The care teams at the intervention sites were encouraged to communicate with patients' primary care physicians to facilitate a well-rounded, multidisciplinary approach to patient care.

The trial measured the impact of the intervention on use of guideline-recommended therapies in adults with type 2 diabetes and established cardiovascular disease after up to one year. The primary endpoint was the proportion of participants prescribed all three of the following guideline-directed therapies after 6 to 12 months: a high-intensity statin, an ACE inhibitor or ARB and an anti-hyperglycemic agent with proven cardiovascular benefits such as an SGLT2 inhibitor or a GLP-1 receptor agonist (or metformin if A1c was below 7%).

Prioritizing Cardio-Renal-Metabolic Care
Through research and educational initiatives, Boehringer Ingelheim and Lilly are driven to redefine care for people with cardio-renal-metabolic conditions, a group of interconnected disorders that affect more than one billion people worldwide and are a leading cause of death.

The cardiovascular, renal (kidney) and metabolic systems are closely intertwined and share many of the same disease-related pathways. Dysfunction in one system may accelerate the onset of dysfunction in others, resulting in the progression of comorbid diseases such as type 2 diabetes, heart failure and chronic kidney disease. Conversely, improving the health of one system can lead to positive effects across the others and can help reduce the risk for further complications.

Understanding their interconnected nature, we are working to advance treatments that can protect the organs of the cardio-renal-metabolic systems. It is only through a holistic approach to care that we can truly transform outcomes and restore the harmony between these critical systems.

Boehringer Ingelheim and Eli Lilly and Company
In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an Alliance that centers on compounds representing several of the largest diabetes treatment classes. Depending on geographies, the companies either co-promote or separately promote the respective molecules each contributing to the Alliance. The Alliance leverages the strengths of two of the world's leading pharmaceutical companies to focus on patient needs. By joining forces, the companies demonstrate their commitment, not only to the care of people with diabetes, but also to investigating the potential to address areas of unmet medical need.

About Boehringer Ingelheim
Boehringer Ingelheim is working on breakthrough therapies that improve the lives of humans and animals. As a leading research-driven biopharmaceutical company, the company creates value through innovation in areas of high unmet medical need. Founded in 1885 and family-owned ever since, Boehringer Ingelheim takes a long-term perspective. Around 52,000 employees serve more than 130 markets in the three business areas, Human Pharma, Animal Health, and Biopharmaceutical Contract Manufacturing. Learn more at www.boehringer-ingelheim.com/us.

About Lilly
Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 47 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/newsroom or follow us on Facebook, Instagram and LinkedIn.

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