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Medtronic begins multicenter study to address health disparities in structural heart disease care

Collaboration with health technology company Tempus seeks to identify causes for undertreatment of minority patients with heart valve disease who may benefit from minimally invasive therapies

Medtronic plc, a global leader in healthcare technology, today announced it began a randomized study sponsored by Tempus, a technology company leading the adoption of AI to advance precision medicine and patient care. The Addressing undertreatment and health Equity in aortic stenosis and mitral regurgitation using an integrated eHR platform (ALERT) study will address the undertreatment of severe aortic stenosis or moderate to severe or severe mitral regurgitation, while also evaluating the racial, ethnic, gender, and geographic disparities associated with guideline recommended treatments such as transcatheter aortic valve replacement (TAVR), a minimally invasive therapy.

“Through our collaboration with Tempus, we are able to use artificial intelligence to equip heart teams with a more efficient way to identify patients with symptomatic severe aortic stenosis,” said Nina Goodheart, senior vice president and president of the Structural Heart & Aortic business, which is part of the Cardiovascular Portfolio at Medtronic. “Ultimately, our goal is to provide a pathway to patients who are currently underserved, so they are one step closer to heart valve clinic care and access to lifesaving TAVR treatment.”

Symptomatic severe aortic stenosis is a common, yet severe form of heart valve disease that impacts approximately 250,000 people annually in the United States and remains undertreated according to AHA/ACC Guidelines criteria. Patients with symptomatic severe aortic stenosis may suffer from chest pain, shortness of breath, fatigue, and dizziness – and if left untreated, it can lead to heart failure. Mitral regurgitation (MR), another prevalent cardiac valvular condition, presents a similar set of challenges in regard to underdiagnosis and undertreatment.

The study will utilize the Tempus Next platform to identify severe aortic stenosis or moderate to severe mitral regurgitation patients who meet guideline indicated therapy criteria, but do not have a treatment plan in place. The study will evaluate the impact of electronic health record notifications generated by Tempus Next on treatment with valve therapies such as TAVR and clinical visits with heart valve centers. Tempus Next provides a suite of software including a cloud-based, automated patient identification and care pathway management for cardiovascular disease based on practice guidelines, as well as a patient communication and data collection/analysis platform.

Data suggest white patients represent the majority (91%) of all TAVR procedures. Conversely, patients who are Black, Hispanic, Asian, or part of other racial groups are not being treated with TAVR at the same rates as white patients. Existing evidence suggests that this minimally invasive option could result in less time in the hospital and a quicker recovery compared to open heart surgery.

“Undertreatment of symptomatic severe aortic stenosis can be devastating for patients’ recovery and potentially fatal within two years if intervention does not happen. The goal of this study is to move towards better solutions for more equitable and timely care and eliminate barriers to treatment,” said Wayne Batchelor, M.D., director of Interventional Heart Program, Inova Health System, Fairfax, Va. and Steering Committee Chair of the ALERT study.

“We are excited to be one of the first sites activated in this critically important study. We look forward to working to address health disparities to bring more equitable and timely care to patients with valvular heart disease in our community. I am encouraged by the potential impact of this initiative as additional sites are activated around the country,” said Brian R. Lindman, MD, MSCI, medical director, Structural Heart and Valve Center and Associate Professor of Medicine at Vanderbilt University Medical Center.

The study is funded by Medtronic.

About Tempus

Tempus is a technology company advancing precision medicine through the practical application of artificial intelligence in healthcare. With one of the world’s largest libraries of clinical and molecular data, and an operating system to make that data accessible and useful, Tempus provides AI-enabled precision medicine solutions to physicians to deliver personalized patient care and in parallel facilitates discovery, development and delivery of optimal therapeutics. The goal is for each patient to benefit from the treatment of others who came before by providing physicians with tools that learn as the company gathers more data. For more information, visit tempus.com.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission – to alleviate pain, restore health, and extend life – unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow Medtronic on [LinkedIn](#).

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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