AI-Powered EchoSolv Clinical Trial Identifies 72% More Patients with Severe Aortic Stenosis and Reduces Gender Bias

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FOR IMMEDIATE RELEASE

Sydney, Australia – A groundbreaking clinical trial conducted at St Vincent's Hospital Melbourne and St Vincent's Hospital Sydney has revealed significant advancements in the diagnosis of severe aortic stenosis, a life-threatening cardiac condition. The study, funded by Edwards Lifesciences (NYSE:EW), utilized EchoSolv, an innovative AI-powered diagnostic-decision support software developed by Echo IQ. EchoSolv demonstrated exceptional capabilities, identifying 72% more patients with severe aortic stenosis compared to conventional human diagnosis methods. Furthermore, it successfully removed unconscious gender bias in diagnosis, ensuring more accurate and equitable healthcare for all patients.

In the study, researchers analyzed 9,189 patient echocardiograms, which were reviewed by cardiology teams at both hospitals. Initially, routine clinical care diagnosed 218 individuals (2.4% of the study group) with guideline-defined severe aortic stenosis. However, when EchoSolv was applied to the same group, it identified a staggering 376 individuals (4.1% of the study group) with severe aortic stenosis as per guidelines. This implies that EchoSolv accurately identified an additional 72% of patients with severe aortic stenosis who had not been diagnosed by routine clinical practice alone.

The study also brought to light the presence of unconscious gender bias in conventional diagnosis. Women were 66% less likely to receive accurate diagnoses of severe aortic stenosis compared to men when relying on human-only assessments. EchoSolv, on the other hand, proved to be unbiased and impartial in identifying patients, regardless of their gender. Moreover, even when women were identified with severe aortic stenosis, they were 50% less likely to receive intervention compared to men. EchoSolv's unbiased identification of disease emphasizes the need for equitable healthcare practices.

St Vincent's director of Heart Lung Program and Cardiology, Professor Michael Feneley stated, "With the general aging of the population leading to an increasing prevalence of aortic stenosis, it is encouraging to see how artificial intelligence could be used to improve the identification of disease and increase the opportunities to treat patients in a timely manner."

Additionally, EchoSolv's unique ability to categorize patients into low-risk and significant-risk groups (94% and 1.9% of the study population, respectively) has the potential to streamline healthcare resource allocation. This feature enables healthcare facilities to prioritize patients who require immediate review and consideration for treatment.

Echo IQ's Chief Medical Advisor, Professor David Playford said EchoSolv was the first decision-support platform in the world to show improved detection of severe aortic stenosis compared with current clinical practice. "We expect the automatic highlighting of patients with significant aortic stenosis risk using EchoSolv will assist doctors in decision-making for aortic valve intervention and follow-up in a consistent, systematic and efficient manner," he said.

"Our goal is to support improved diagnosis free of unconscious bias and irrespective of age, gender, background or socioeconomic status ... these findings are a significant step towards our goal of assisting doctors in finding the right patients, every time, for the right intervention for heart valve disease."

Severe aortic stenosis is a critical condition that restricts blood flow from the heart to the aorta, resulting in life-threatening consequences if left untreated. The success of the EchoSolv clinical trial paves the way for a new era of AI-powered diagnostics, bringing precision and impartiality to cardiac disease identification.

About Echo IQ and EchoSolv:

Echo IQ is a leading innovator in AI-powered healthcare solutions, committed to revolutionizing the identification of cardiovascular diseases. EchoSolv is their proprietary diagnostic-decision support software, empowering healthcare professionals to make accurate and unbiased assessments in cardiac disease identification.

About Edwards Lifesciences:

Edwards Lifesciences is a global leader in patient-focused medical innovations for structural heart disease and critical care monitoring. As a leading sponsor of this clinical trial, Edwards Lifesciences is dedicated to advancing medical technology for better patient outcomes.

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About Professor Geoff Strange

Geoff Strange; Professor in the School of Medicine at the University of Notre Dame in Fremantle, Western Australia and a Fellow of the Cardiac Society of Australia and New Zealand. Geoff a member of the cardiology team at Royal Prince Alfred Hospital in Sydney, he is also the current and founding CEO of the Pulmonary Hypertension Society of Australia and New Zealand (PHSANZ) for which he is also Chief Investigator of the PHSANZ Pulmonary Hypertension Registry (>21 centres across ANZ). Geoff is Director and Chief Investigator of the National Echo Database of Australia and New Zealand (NEDA) – the largest echocardiographic database in the world.

Geoff's research interests include Pulmonary Hypertension, Congenital Heart Disease and Echocardiography. Geoff has established the Congenial Heart Alliance of Australia and New Zealand, a research entity spanning fifteen centres across the region (initiating 27 M in funding for the National Action Plan on childhood heart disease form The Hon Minister Hunt).

Geoff has over 60 peer reviewed publications and scientific abstracts, including various books and book chapters. He is a reviewer of the Journals Pulmonary Circulation and Heart, Lung and Circulation.

Alongside his academic career and achievements Geoff has eighteen years of senior leadership experience operating at Vice President level in big pharma, bio-tech start-ups and device manufacturers. Geoff specializes in taking scientific and clinical data / concepts, through to commercial success. Geoff is the Director and owner of Mozaic Solutions, a consulting company set up to meet industry needs from strategic medical marketing, marketing, medical writing, scientific protocol development and trial implementation, advisory and KOL management.



What's new?

- A significant clinical trial has shown that AI can uncover 72% more patients with severe aortic stenosis than human diagnosis alone. This AI is a clinical decision-support tool designed to be used to compliment human diagnosis.
- Women were 66% less likely to have been accurately diagnosed than men. This AI does not take into account gender, removing bias.
- Where patients had been under-identified using human interpretation alone, there was a low rate of valve intervention. Patients who do not receive valve intervention face a high risk of mortality.

Additional information:

- Severe aortic stenosis is a structural heart disease that generally affects an aging population. Its symptoms—breathlessness, fatigue, heart palpitations—are common and often dismissed as simply "aging." Once a patient reaches the severe stage, they have a <u>50% chance of dying in two</u> years—and an <u>11% of dying within six months</u>. The only interventions are <u>TAVR</u> and <u>SAVR</u>, but they are highly effective at extending healthy years <u>a decade or more</u>.
- Severe aortic stenosis is known to be <u>underdiagnosed and undertreated</u>. This study corroborates this, as it showed that an additional 376 patients meeting the guideline criteria for severe aortic stenosis than cardiologists found unaided.
- The underdiagnosis of aortic stenosis is understood to correlate with various biases. Others have found <u>racial disparities</u>, whereas this study showed that women were 66% less likely than men to receive accurate diagnoses.
- Severe aortic stenosis can be notoriously difficult to diagnose, particularly in cases of <u>low-flow</u> <u>low-gradient</u> and <u>concomitant mitral regurgitation</u>, potentially leading to the underestimation of aortic stenosis severity.
- This trial complements an earlier study completed at <u>Harvard Medical School's Beth Israel</u> <u>Deaconess Medical Center</u>.
- The team behind EchoSolv, Echo IQ, was able to accomplish this by leveraging their exclusive license to the world's largest database of echocardiograms linked to mortality, <u>NEDA</u>. Whereas other technologies have relied simply on checking a few measurements, this AI takes into account the complex hemodynamic interrelationships of the whole heart and the outcomes of that phenotype. When the cardiac care team needs to gauge the risk of intervention and more precisely manage the care pathway, this risk becomes critical.
- The EchoSolv technology is "locked," meaning that the artificial intelligence is fully trained. The platform is commercially available in the US and Australia as a clinical decision-support tool,

automatically flagging cases of guideline severity. Both aortic stenosis and mitral regurgitation are available, with additional structural heart diseases rolling out through 2023.

Additional quotes:

- "The results from the St Vincent's trial show that there's immense potential for "collaborative intelligence"—AI as a tool for cardiologists. What we're seeing is that every piece of this job is tough. It's tough for sonographers to consistently take accurate measurements on each and every patient. It's tough for cardiologists to manage increasing demand on their time and energy. And then it can be tough to make the call if or when to intervene. In the real world, complex cases and unconscious biases—cases of patients who are outliers from the clinical norm—can slip through the cracks. Unfortunately, this is a disease without patience. Patients will pass away if they don't receive the care they need, made all the more tragic by that the technology to find them and to add years of quality life is here, ready today. That's the good news: cardiac care teams are doing incredibly challenging, tough work already—and now they have a powerful new tool in their toolkit." --Don Fowler, US President, Echo IQ
- "It's a challenge to find time to fit in patients. Some referrals are inappropriate, but some are urgent. What I find valuable about this technology, which this trial has highlighted, is that the severe cases can be automatically brought to the top of my visibility. To make my job really count, I need to see the people where I can make the biggest difference. In reality, these are the patients that, if left untreated, are likely to have a bad outcome. Knowing who is at a high risk of mortality is immensely valuable." –Practicing cardiologist
- "We found that a significant proportion of individuals (particularly women) being investigated within a high-quality tertiary referral setting are potentially being overlooked for appropriate management of guideline defined, severe AS. This study revealed the strong potential for an AI system to appropriately flag these individuals for further care evaluation." –Geoff Strange, Professor at the University of Notre Dame Australia and Chief Strategy Officer of Echo IQ