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Exec Chat: Medtronic's Goodheart Talks About COVID, AI, Diversity, TAVR And More

by [Reed Miller](#)

Medtech Insight sat down with Nina Goodheart, the president of Medtronic's structural heart and aortic operating unit, to learn more about her experience with the company during the pandemic, the company's commitment to diversity and inclusion, and the future of structural heart technology.

As the market for transcatheter valve devices continues to grow, structural heart devices have become one of [Medtronic's](#) strengths.

Sales of its transcatheter valves grew 11% globally in the first quarter of fiscal 2024 (calendar May to July 2023), led by rapid adoption of Evolut FX, the fourth generation of Medtronic's successful CoreValve transcatheter aortic valve replacement (TAVR) system. (Also see "[News We're Watching: Illumina Looks At Grail Options, New AdvaMed Digital Health Division, Evolut FX Gets CE Mark](#)" - Medtech Insight, 13 Oct, 2023.)

Medtronic's structural and aortic business is a relatively new division created as part of the overall restructuring of the company initiated by CEO Geoff Martha in 2020. (Also see "[Medtronic Lays Out Plans To Achieve 5%+ Annual Growth](#)" - Medtech Insight, 15 Oct, 2020.)

Since 2021, the business has been led by Nina Goodheart, who has been with the company since 2007. She is an advocate for diversity and inclusion within Medtronic and is helping Medtronic find new ways to bring medical technology to underserved populations.

Goodheart recently talked to *Medtech Insight* about her commitment to Medtronic, where she sees the business going in the coming years, and more.

Q You have been with Medtronic for a long time. What makes Medtronic so compelling that you have turned down the chance to go anywhere else?

A Nina Goodheart: I've been in Medtronic for about 17 years. I've had a variety of roles within our cardiovascular portfolio, mostly on our growth businesses, which has been great.

When I graduated from grad school at NYU, I worked for a number of advertising agencies. I then did some consulting work, both in Big Pharma and then in medtech and became exposed to Medtronic. I think when you get to this company, it has a different feel to it.

We've got this incredible mission, about alleviating pain, restoring health, and extending life. And when you see that in action – because that's really the way we respond to the market – with the direct impact that we have on patients, it's quite incredible. And it is compelling and it's gratifying that it holds people here.

I know it's helped me and kept me here for a long time.

Q Since Geoff Martha became CEO, the company has initiated a number of structural changes to try to drive and sustain growth. How has that impacted the Structural Heart and Aortic organization at Medtronic?

A Goodheart: We made the organizational change in February of 2021, Geoff Martha had a number of things that he really wanted to accomplish and those things have been taking hold.

He wanted to simplify what was a very complicated organization of 95,000-plus people. We created operating units that are very focused on the individual businesses and getting senior leaders closer to the businesses that they run. This puts the operating units at the center of what we do at Medtronic.

The operating units are focused on growth and focused on bringing new technologies into our individual markets. All of that has gone well. We've focused on how to 'play big' and how to use the breadth and the scale of Medtronic where that's warranted.

But we also 'play small,' thinking about each of these individual businesses that bring technology into those individual markets, and make sure that we've got a strong focus on those businesses.

We're still doing some work; it's still relatively new. We're refining our operating mechanisms, etc. But the crux of what we're trying to accomplish has been very well received and is going well.

"We created operating units that are very focused on the individual businesses and getting senior leaders closer to the businesses that they run." – Nina Goodheart

Q Did this new structure help Medtronic function during the COVID-19 pandemic?

A Goodheart: COVID was hard on everything and everyone. It raised issues in every sector, ours included.

I think this specific operating model has helped, even in COVID, to get everyone closer to the businesses that we're either running or that we are a part of.

In my operating unit, we have focused a lot on communication, especially during COVID when we weren't all together. We've made sure that we've got timely, transparent communication and that we have dialogues of communication going both ways.

This ensures people understand what was happening and that they are empowered in their decision making. How do we push decision making down into the organization so the people closest to the work are making decisions about the work? That is what we've been focusing on.

Q Obviously there is so much interest in artificial intelligence right now and what it can do for business. In a large company like Medtronic, how can these new technologies help you be efficient, especially in clinical trials and R&D?

A Goodheart: I think it's clear that that AI is going to be the future of a whole lot of the work that we're going to do, especially in health care.

To your specific question, in regard to clinical trials, I think about how we use AI with EMRs, for instance, to identify patients at risk, identify physicians who are part of clinical trials, and match those up to expand those patient cohorts.

We also think about pre-procedure planning; How do we use AI to enable better imaging and better planning prior to the procedure and post-procedure, so that we start to make all of that go much more quickly and standardized in a way that benefits patients?

There's so much in front of us when it comes to AI. We are just beginning to tap into it.

Q Medtronic has been very public about its plans to improve diversity and representation in clinical trials. Women in particular have been underrepresented in cardiovascular device trials as long as there have been cardiovascular device trials. What can your business do to close that gap?

A Goodheart: You're touching on something close to my heart, because we've really been focusing on representation in a variety of areas, but particularly as it as it relates to clinical trials. (Also see "[MTI 100 2022: Big Cardio Medtechs Are Moving ESG Agenda To Center Stage](#)" - Medtech Insight, 7 Dec, 2021.)

In all areas of medicine – not just cardiology – clinical trials have been focused on enrolling men. But we create a public health issue if we ignore 50% of the population, so it's critical that we focus on ensuring that we've got the entire population enrolled in clinical trials and that we understand the differences, if there are any, between men and women in any specific area of medicine. (Also see "[National Academies Join Call For More Diversity In Trials](#)" - Medtech Insight, 20 May, 2022.)

As you may be aware, we're running a trial called the [SMART](#) trial, a head-to-head transcatheter aortic valve trial in patients with small annuli, which will primarily be women. (Also see "[Medtronic Announces Two New Trials To Expand TAVR Indications](#)" - Medtech Insight, 19 Oct, 2020.)

Women will be significantly represented in that clinical trial. And then we'll be able to see the impact of technologies on women with valve disease. We'll be presenting the results of that trial this spring and we're all really excited to see what that shows.

Q In structural heart trials, is the size of the valves, etc, the main difference between men and women or are there other key differences that you want to account for?

A Goodheart: That's what we're going to learn. We're going to see if there are differences. There are all kinds of hypotheses that there might be, but there've been no clinical trials to be able to show whether or not that's true. And so that's why we're so excited about this. We're going to learn a lot about differences and how we might treat patients differently.

"We're just scratching the surface. There is an enormous opportunity to bring these technologies to more patients." – Nina Goodheart

Q TAVR has been an enormously successful technology for everyone involved. [The latest evidence shows](#) that it is durable and therefore a suitable alternative for surgery in even low-risk patients. So are there any other “frontiers” for improvement in TAVR? How can it get even better?

A Goodheart: There are still many opportunities. If we think about structural heart in general – not just TAVR, which is very successful in treating patients with valve disease – it is still underpenetrated.

There are still a large number of patients around the world who have aortic stenosis and who still don't have the opportunity for TAVR. So we think about access – women, underserved and underrepresented communities, Hispanics, African Americans, etc.

We know that the penetration of TAVR in those communities is significantly lower than the population at large. That's an enormous opportunity for TAVR. How do we bring this technology to new areas around the world?

We just recently launched the Medtronic TAVR technology in China, for example, but there are still a lot of places around the world where we haven't yet launched this technology. There's still a lot of geographic expansion needed, but we are still pursuing new indication expansions.

TAVR is indicated for severe, symptomatic aortic stenosis, there's also moderate and asymptomatic aortic stenosis. There are all kinds of areas still to be penetrated with TAVR.. And there are lots of additional opportunities, both in mitral replacement and

mitral repair and tricuspid repair.

When I think about the structural heart space, we're just scratching the surface. There is an enormous opportunity to bring these technologies to more patients.

"We have amazing teams at Medtronic, and I'm proud of the work they've done across all four of our valve programs to bring these life changing technologies to market." – Nina Goodheart

Q What more can be done to bring therapies like TAVR to more centers, especially in underserved areas?

A Goodheart: Of course, we have to we have to follow all the Centers for Medicare and Medicaid Services' (CMS) coverage requirements. (Also see "[Manufacturers Support CMS' New TAVR National Coverage Decision](#)" - Medtech Insight, 24 Jun, 2019.)

But there are a lot of areas where there's not a TAVR center but there is a surgical program, so there is the opportunity to put in a TAVR center, especially in underrepresented communities.

We're doing pilot programs, especially in the southeast part of the United States in a couple of key areas, looking at where there is very low penetration of TAVR and a high, underserved population, and looking to see how we engage more physicians in those areas in clinical trials.

How do we create more shared decision-making tools so that patients have a better understanding of the opportunities? And how do we bring those things together so that we can have a higher penetration into some of those underserved communities?

And, to be a structural heart program, you have to have programs in all four heart

valves. We just recently launched a transcatheter pulmonary valve called Harmony for pediatric and adult patients. (Also see "[Two-Year Results Support Medtronic's Harmony Transcatheter Pulmonary Valve System](#)" - Medtech Insight, 14 Jun, 2023.)

That has been phenomenally successful. It is amazing to be able to treat these young patients. Now they have the opportunity for a great, healthy life. And because these technologies have been so successful in children and young people, there are now adults living with congenital heart disease that will have ongoing treatment needs. We recently introduced this technology in the U.S. and Japan with more launches coming to help patients around the world.

We have amazing teams at Medtronic, and I'm proud of the work they've done across all four of our valve programs to bring these life changing technologies to market.