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Exec Chat: Abbott Wants to Identify Heart Failure Patients Earlier

by Reed Miller

Abbott executives Philip B. Adamson and Robert Kormos talked to *Medtech Insight* about how the company is trying to slow the progression of heart failure and reduce heart failure hospitalizations.

<u>Abbott</u> is trying to address heart failure before the patient reaches the hospital.

Since it acquired <u>*St. Jude Medical*</u> in 2017, Abbott has been one of the leading providers of devices that manages advanced heart failure, including cardiac resynchronization (CRT) devices and the HeartMate line of left-ventricular assist devices (LVAD).

But heart failure is a progressive disease, so treating it before the patient needs a hospitalization would dramatically improve many people's quality of life.

So Abbott is trying to reach potential heart failure patients "further upstream."

For example, the company introduced the CardioMEMS HF System, an implantable monitor for patients who had been hospitalized for heart failure in 2014. Last year, the US Food and Drug Administration expanded CardioMEMS' indication to include patients with Class II heart failure and those who undergo a blood test showing elevated biomarkers of worsening heart failure who had not yet been hospitalized. (Also see "*Abbott Hopes To Prevent Heart Failure Hospitalizations With New CardioMEMS HF Labeling*" - Medtech Insight, 22 Feb, 2022.)

The effort to expand the reach of its heart failure division is part of Abbott's overall ambition to serve three billion people by 2030.

To reach that target, Abbott needs to find ways to connect to people who currently have little or no support from the health care system, according to two of the physicians leading Abbott's



heart failure division.

Philip B. Adamson, the divisional vice president for global medical affairs and chief medical officer in Abbott's heart failure business and Robert Kormos, the divisional vice president for global medical affairs in Abbott's heart failure business, talked to *Medtech Insight* about the deficiencies in how heart failure is currently addressed by the health care system and what Abbott is doing to improve outcomes for these patients.

[Editor's note: This conversation was edited for clarity and length.]

Q *Medtech Insight*: How can Abbott get more people connected to the right resources to prevent the progression of heart failure, long before they need to be hospitalized?

 A Philip Adamson: We really need to understand how that transition occurs. With CardioMEMS, we performed a trial purposely looking at patients who had not already had a hospitalization but had mild elevation of a biomarker suggesting that they had congestion which would put them at risk for hospitalization.

Now we're moving further back on the spectrum [as defined by] the New York Heart Association classification, but that is subjective and what we discovered was that people who have less symptoms are not always less sick. And we're really recognizing that as a sort of a continuum through the spectrum of disease states and that patients may be able to accommodate symptoms from their left ventricle failing, but by the time that right ventricle fails, they can't accommodate those symptoms and they are identified as advanced heart failure symptoms.

We have purposely built the evidence base to focus on individuals that have not had that catastrophic event of a hospitalization to now understand that 85% of these patients have significant secondary hypertension. Their lung circulation is going to kill the right ventricle if we don't deal with it.

We've made these discoveries in the last two years. And I think that now our job is to

bring that disease awareness, shifting from making all the decisions based on symptoms and trying to objectify the underlying disease process.

"Now our job is to bring that disease awareness, shifting from making all the decisions based on symptoms and trying to objectify the underlying disease process." – Philip Adamson:

Q How can Abbott help people who have not had a lot of contact with the health care system or, at least, do not have a regular cardiologist?

A Adamson: We have discovered that often it's not the cardiologists, but the nurse practitioners that actually manage that patient. And so we have recognized the importance of nurse practitioners in logistical management and how independently they make decisions. We really are now focusing on inclusion in that segment.

Half the people with heart failure have preserved ejection fraction heart failure so they may not touch base with a cardiologist. But instead, they kind of 'float' into primary care doctors' offices through the hospital and they kind of cycle through that process.

We're really trying to focus on which group of providers we will have the most impact on and get these folks into the system. That's led us to broaden our scope.

But so many of the kinds of people who are typically underrepresented in, for example, clinical trials, don't see anybody. And that's what makes us want to be improving the access to health care in general, but also in clinical trials.

Q Are there enough heart failure specialists and what role do they play in



preventing heart failure?

A Adamson: There are about 1,000 heart failure-certified cardiologists in our country and this is really the only country in the world that has this kind of certification.

But they focus really on the advanced treatment, whether that be a left-ventricular assist device or transplant. For 98% of people walking around with heart failure, they may 'touch' the cardiology interventional cardiologist, a surgeon or a general cardiologist, but many of them are really cared for by internists or primary care physicians/family physicians.

We believe there's a lot of folks out there that could benefit from monitoring and even advanced therapies that are just being relegated to palliative care and hospice.

This is a quest. First, where are the patients and who's taking care of them? And then, where can we go from here? The advanced heart failure specialty is very small.

"We have found that physician education in treating advanced heart failure patients is critical." – Robert Kormos

A Robert Kormos: We have found that physician education in treating advanced heart failure patients is critical.

For example, the HeartMate 3 [left ventricular assist device] can reliably add years to one's life, but only if it's been offered to all populations, and that only begins when physicians know about it. And reaching these patients early is critical to survival.

Heart failure has a five-year survival of about 25%, which is so much worse than most cancers, including those that are subject to widespread campaigns to encourage screening. For example, the five-year survival for breast cancer is 73%, for prostate

its 58% [colon– 43%, rectum – 43%, lung – 10%, etc]. By making an impact in heart failure mortality, we can make a huge impact in saving lives.

Q Just to clarify for a broad audience, can you back up and explain how somebody could have heart failure and not be aware of it?

A Adamson: Most of the time, these are people who have other conditions like obesity, high blood pressure, arthritis, or hyperlipidemia. They look at the spectrum of the things that they swallow pills for, such as fatigue or short breath, and they say, 'Well, you know what to expect?'

The fatigue and shortness of breath worsens to the point that they acutely decompensated and then require intravenous medications in the confines of a hospital - that is a defining moment that really declares them as having heart failure.

But we don't want that to happen. We want to start earlier, because that first hospitalization has a big, big impact on their survival. And so we're really trying to bring that awareness before the hospitalization. But many times, that's the first point when people say, 'Oh my gosh, I must have something else.'

The other group of people coming in have coronary artery disease or acute myocardial infarction that's associated with their disease and then they are discovered to have damage to their left ventricle.

But frankly, it is very difficult sometimes for people who have lots of things wrong with them to say, 'This must be heart failure.'

Q To get back to your earlier point about improving diversity in clinical trials,
Abbott has invested a lot in improving access to clinical trials. In heart failure in particular, why are so many clinical trials disproportionately enrolling

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mainly white men and not enrolling enough members of some of these other groups that have high prevalence of heart failure?

A damson: There are large geographic disparities in early deaths from treatable diseases. For example, life expectancy drops eight years from one side of 9th St in Louisville to the other. There you're still seeing the impact of redlining and segregation.

They haven't had access to hospitals and health care providers. As long as we expect the patients to go to the health system, it's not going to happen. It is going to create this kind of health inequity. We've studied this a lot to try to understand where it starts, and what we've discovered is that it is seriously multifactorial. It requires input from the patient and requires education, from the patient all the way to the regulators.

[For example] regulators will sometimes accept clinical trials in white men, even if the disease mostly affects Black females. And so the responsibility falls on a lot of different players here.

What we've discovered is that when we go where the patients are underrepresented, we start the process by bringing them into the innovation that is associated with the clinical trial. Because when an innovation is approved by the FDA, the first people to use that device will be the people that were involved in clinical trials.

For example, if you do a clinical trial in research centers that only serve affluent, white males, the population that uses that technology is always going to be underrepresented by certain populations. And that will impact how innovation is going to be used. If we can control the enrollment in clinical trials then certainly we can keep tabs on that.

We believe that there there's a great opportunity to make progress here, just simply by where we choose to do our trials. And if we can build research centers in areas that serve underserved populations, we're doing that. And then we can ensure that our trials really represent the disease state and the population that has the disease.

Then we'll see the first iterations come out of decreasing this health equity issue. But it is complex. It is multifactorial. We have identified sites that are excellent research centers and do all the components of a research trial very well. But when you look at where those places are, they're typically places that serve affluent people. And they're not located where those that are typically underrepresented are.

We have now reached out to communities of color. We have identified areas that have high patient populations that are interested in research and then built infrastructure for them to do research. The person that's telling them about the trial, recruiting them, and taking them through the trial, will also look like them and understand the culture and the values that sometimes stand in the way of being involved in clinical trials. Those are things that we've seen have immediate effects. (Also see "*Minute Insight: Abbott Sponsors New Physician Training Program To Diversity Clinical Trial Leadership*" - Medtech Insight, 11 May, 2022.)

For example, we ran a trial of CardioMEMS called <u>CHAMPION</u> and 25% of the population involved were women. So for the next two trials we simply said, 'Look, we need to make sure that we enroll adequate numbers of women in the trials.'

And because we had that on our minds and because we actually thought about it, it worked. We didn't have to do anything crazy like restricting enrollment for men. We thought about the beginning, recruiting sites and places that were where the patients are, and they can then profit from the research.

Q Did you learn anything important about health inequality during the COVID-19 pandemic?

A Adamson: Very often, the Black Native American, and Hispanic Americans who died
from COVID were those who didn't have access. They weren't close enough to the

hospital or they didn't have a bus to take them to the hospital.

For example, in Louisville where we have collaborators, there is an area where a hospital has not been built in 170 years. It's just rebuilding now. That's the kind of disparity of access that really became apparent during COVID.

One of the advantages of CardioMEMS is that it allows remote management monitoring for nearly anywhere. So patients who can't get on the bus and get to the hospital or to the office can now be managed with very high robust management. It essentially makes distance irrelevant.

CardioMEMS lets doctors see remotely what, eight years ago, they were only able to see in the intensive care unit.

That kind of sophisticated management from a remote perspective became very clearly the way to do things at the height of COVID. And now that is the trend.

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A Kormos: Educating the physicians managing these communities is crucial.

Thousands of people with advanced heart failure die every year because they do not receive a heart pump, largely because their physicians are not aware of the option or its full benefits.

There are too many patients who aren't provided the opportunity to be evaluated for a heart pump, such as those with obesity, diabetes, certain cancers, and blood types

or those from underserved communities across the United States.

Abbott's heart failure business has a dedicated staffer leading a special populations initiative including key external leaders to better reach minority communities and women. The goal is to provide tailored messaging to the public including physicians who focus on the populations that are represented in their communities.

Q What are some important future advances that you expect will have a big impact on heart failure?

A Adamson: In 10 years, we'll be using appropriate multisensorial arrays that will bring data together, probably in the cloud, and using some level of advanced analytics in an informative way and bring the patient into the mix.

I think the biggest person in the workforce we've neglected – being paternalistic doctors – is the patient. We tell them what to do. We don't ever ask, 'How we can help?'

We don't live and breathe it into the solution. I think this information screen is going to now turn into an ability for the patient to be directly involved in their care and utilize that information and the data about themselves and motivate them to be responsive to their status. And I always make the differentiation between data and information.

We can get a lot of data together, but we have to make that data stream available so that people can act on it and not necessarily focus on the doctors or the nurses being the ones acting. There are capabilities and opportunities for the patients to take action.

If there's any disease that could strip someone's life away, it's heart failure. It makes it hard to do what you normally would or eat what you would normally eat. You can't go anywhere if you can't breathe, you can't use stairs. It takes everything away and strips it down into pill boxes that you have to take every six hours. It's abysmal.

If we're able now to take that information and put it back into the patient hands so that they get freedom and give them a locus of control, then their involvement and adherence to those therapies, all of a sudden, will skyrocket. We've seen that in preliminary experimental work, and we're now focusing on bringing the patient in as the as the prime player here.

Q What messages about heart failure would you like to get to the general population?

A Adamson: The heart failure physicians are focused on people who already know that they have a diagnosis of heart failure. As the innovations build, physicians seem not to be incorporating them into clinical interventions as rapidly as we'd expect them to.

Patients are much more aware, and they are much more interested in becoming aware, of what's available out there.

It's our duty to make sure that they get the right information. I'll never forget having a patient come in with a long list of stuff that they printed off the Internet and they wanted to just go on for hours about it but only one percent had any kind of meaning at all.

We really have to be very clear and ensure that the education that we take directly to the consumer has to be very focused and appropriate. We have to bring the patient into that education scheme. They have to know their disease, because if they don't know that they have, for example, an opportunity to get a left ventricular assist device, when it's appropriate, then they will die.

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If we're able to bring that kind of information to them in the right way – that's the key element; is it the 'right way' – then that will help them to make their decisions.