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ROBERT KOWAL: Good afternoon, good evening, or good morning, depending on where you are. On behalf of Medtronic's MCS group, welcome to our webinar entitled LVAD Patient Management in an Era of COVID-19. My name is Rob Kowal. I'm Chief Medical Officer of Medtronic's Cardiac Rhythm and Heart Failure Group, and I'm joined today by three distinguished and outstanding guests who are active in the field.

With me today are Erin Davis, who is the Program Manager of Cardiothoracic Transplant at the University of Utah's Transplant Center. In addition, we have Liviu Klein, who's Director of MCS and Heart Failure Device Program and an active clinical researcher at UCSF, and Greg Macaluso who is Fellowship Director for Advanced Heart Failure at the University of Illinois at Chicago, part of the Advocate Christ system, and also active in clinical research. Welcome to all three of you.

GREGORY MACALUSO: Thank you, Rob.

ROBERT KOWAL: Sure, so just a couple of housekeeping things. During the program today, if you have questions, please click at the bottom to submit a question, and we'll do our best to get that in. In addition, the program is going to be recorded. And so if you have to step away, or if you have a colleague who you like to see it, that will be-- you'll get an email shortly when that's posted online for viewing. So without delay, I'd like to get started, and we're going to turn it over to you, Erin, to start with the discussion about shared care models.

ERIN DAVIS: Thank you so much for the time and the opportunity to share something that I'm extremely passionate about, and that is getting access to patients to advance therapies and LVADs in the model of shared care. And it's something we've been familiar with Utah for many, many years, at least 15 that I'm aware of. One of the things that makes us unique in this area is where we're located, and I'll share a little bit about that.

But what's so timely about this presentation and this ability to share this is COVID-19 has really thrown wrenches into everyone's care and how they follow these complex patients in the community. And I feel very passionate, as do my copresenters today, on how shared care can help us manage these patients, whether it's because of a pandemic, or where the patient's located, or programmatic issues that might be specific to your area. So things that we share today, I really hope that those in the community can take back and utilize in their own ways, and to help improve their own patients and their own programs.

So again, something that makes us unique is where Utah is located. And so we had-- we saw a problem with this map. As you can see, these are all the destination therapy, CMS-approved therapy centers in the United States. And the problem we saw was, we were one of two in an interstate region that offered LVAD therapies and advanced therapies to these patients. So just because you might not understand the west, it doesn't mean there aren't patients living in Idaho, Montana, Wyoming, Nevada, in these places that do not have centers for these patients. So we thought, what can we do to improve access to these patients and make sure they have the same opportunities as someone that lives in a more urban setting?

So shared care, we've been doing it for 15 years. Many centers look at it differently, but basically, it's collaboration between the referring provider, and the community setting, whether that's a primary care provider or a cardiologist, and the implanting center experts. And we define it as, you are one of our referring providers. We want to give you continuing education. We want to give you access to the experts that understand all that therapy and additional heart failure therapies.

We are very keen that this is a customizable partnership. And in this paper that we're going to present to you today that we published, we talk about levels of shared care. These levels we categorized in one, two, and three, but ultimately, these are tailorable to whatever the patient needs and whatever the provider and the local community needs.

And lastly, the most critical part of this shared care is consistent and open communication. And this has been an interesting-- as I've talked to coordinators from across the world, we found that communication with these patients during COVID has been an interesting challenge. And for us to-- whether you're new to shared care or somebody that's done it a long time, the most important piece was consistent and open communication, you and the patient-- that may be through remote monitoring. That may be through just telehealth and phone calls-- and you and the referring provider, to help keep the patient safe in their community.

So the paper we're going to talk about today that we finally got published was "Impact of Shared Care in Remote Areas for Patients with LVADs." Everyone has done shared care to an extent and you'll meet a few other providers today that have utilized it. But no one really proved, does it work? Is it better than-- is it as good or better than being at the implanting center? Is it worse? Are your outcomes worse? Are your adverse events worse?

So we felt like it was very important to publish our data showing we actually can do this safely, effectively, and basically how we did it, so we can share it with others. So how we did this-- we have a very large population. We have-- 70% of our advanced heart failure therapy patients come from outside of Utah. We have 10 actively referring states into us.

And so we have this population that is coming in, and needed help, and wanted to go back to their local areas. They don't want to live in Salt Lake City, although it's very beautiful in Utah. They didn't want to leave their farms, their home communities, where they've lived forever and ever. And so how can we help them get back to their community safely?

Well, we set up shared care partnerships. We initially started this very small. We started doing patient takebacks to the local community, visiting with the providers. The coordinator would go. Sometimes, industry would come and help us. Sometimes, the physician would join us. And we taught the local providers how to care for them.

We separated this in our paper into three levels. Level one, basic, basic, basic-- here's what we know that patient is, here's how you draw their blood, and if you need anything, give us a call, and send it back to us for everything. That's what we call level one shared care. The provider wasn't very interested or didn't have the time to manage the patient, and it wasn't as engaging.

Level two was everything provided in level one, plus, we allowed the local provider-- we taught them-- how would you anticoagulate this patient because of LVAD? What makes them special? Why do we need to bridge them more urgently than maybe just an AFib patient?

We talked about advanced antibiotic therapy for their drive lines. We did some basic echo training. Here's how you give an echo on a pump-- on a patient with a pump when there's artifact, and what views look better than others. We talked about basic LVAD and troubleshooting. So this is power, this is flow, this is PI, these are watts, and those numbers, waveforms. We would teach them how to look at alarms, basically, understand the drive line. And then again, they would feel more comfortable then, to then stabilize the patient if the patient had problems, maybe actually treat the patient for simple things-- fluid overload, maybe a little diuresis-- in their local community and then send us all the complications. So that's level two.

Level three, we did a lot of everything that level one and two did, including advanced troubleshooting. Now, we're actually going into their hospitals and training their ICUs, and the floors, and their clinics to keep the patient, if they feel comfortable and ready to. In this level, it really does take usually a cardiologist that is trained in heart failure, are very, very comfortable with these LVAD patients, participates regularly with us in grand rounds or other opportunities and offerings that we have, definite, good communication. But in this level, we've been able to allow the hospitals there to admit our patients, treat our patients, as long as they're comfortable. And they only come back to us if they're in big trouble.

So with that being said, I know we're going to have a lot of discussion about what our outcomes were with this. But I'm going to turn it over to Dr. Macaluso and let him talk about how this applies, not only to a rural setting like in Utah, but maybe to some more urban setting in Chicago.

ROBERT

So Erin, I'm going to jump in here real quick before Greg starts because that's a great introduction. You've laid

KOWAL:

out these nice three layers of-- or levels. How have you managed trying to move people between the levels? And how has that been accepted?

ERIN DAVIS:

So that's a really good question and something that actually came up when we were publishing this paper. Some providers, once you give them a little taste of this, and you demystify the LVAD, so it's not as scary, and they feel more comfortable managing these patients. Some providers crave, saying, "Hey, tell me more. Let me help more." And patients become more comfortable in the community.

This usually happens when there's more than one patient in a community, when we start to build up a referral base, and the patients are going back. But we will, again, tailor this to what they need. If they say, "Yeah, I really want to see the patients in clinic and do everything I can, getting the LVAD interrogation and everything that goes along with that. And I don't really want to touch them in the hospital setting." So we'll tailor it that way.

So we allow them to move from level one to level two, level two to level three, depending on their comfort level, and their communication with us, and their willingness to be educated. My ultimate goal with this is that LVAD should not be scary. Patients should be able to live in our communities. I mean, there's a dialysis center in every community. Why can there not be an LVADs touch base center in every community?

ROBERT

Great. So Greg, yeah, so Erin said this was initiated originally because they were not around other centers.

KOWAL:

You're in a large metropolitan center. There are other competing centers. Can you describe why you took a model like this and put it in, and how-- the uniqueness of where you are versus her played into that?

GREGORY
MACALUSO:

No, absolutely, and I appreciate-- I'm going to share my screen here, so we can actually kind of-- I could talk through that while I actually give you some idea of what we modeled to do. A lot of this really started from-- and I'd like to, again, thank everybody for being in-- taking time out of their day today to do that. And I hope everybody's staying safe.

But ideally, what we did as a group, we wanted to find out, could we establish shared care sites amongst sort of a privademic model within a large hospital system, as well as across referring bases and where our surgical colleagues had worked at different hospitals, as well as private cardiologists. And when all things started, we had one big implant center in Oak Lawn, which was in the southern aspect of Chicago. And all of these crosses kind of represent hospitals within our system.

But relationships didn't initially exist based on that. We had to start to establish relationships. Cardiologists who wanted to work with us or advanced practice nurses really started up in the north shore. Now, in Chicago, this is about a 25-mile distance, as opposed to a 40-mile distance. But in any sort of traffic, that could be upwards of two hours of travel time for a patient one way.

And so what we really wanted to do was say, could we partner, and do we have administrative buy in to have an implant center that would do these implants? And then, could we get people in the community-- much like Erin said-- where we could see these people in their own backyards. And we needed to kind of identify people that wanted to help see these people, both administrative support, and then build a shared care team which included cardiologists, nurse practitioners, and nurses that could see these folks.

And as this really blossomed over time, starting out in some of the sites, we saw that implants grew. We expanded to different sites with cardiologists and even recruited people from our team. And what we saw was that as the hospital started to develop as a heart failure sort of regional referral center, heart failure cardiologists wanted to join, and heart failure cardiologists joined the groups. We helped recruit for other hospitals. We now have advanced heart failure transplant cardiologists and heart failure nurses in almost each of these hospitals as part of our extended team.

And what we learned early on was that you really need to have-- to demystify this therapy. You've got to kind of go to where the patients are and travel to those sites, to try to provide both outpatient and inpatient consultation, ask a cardiologist and his advanced practice nurse to do that, find a champion. Like Erin said, we need to find somebody who really wants to get involved and believes in the therapy, show their patients that they've referred to that they can actually be living, breathing examples of doing much, much better. And always say yes to your referring doc. So learning to say that you can always get a patient over as quickly as possible when they need you, and say yes when they need you is the most important thing.

And really to empower the staff that's on site there-- Erin mentioned this as well, talking about education and development. And then appreciating the levels of shared care-- and I would just add to what Erin said. You could want to individually do a certain level, but if you don't have subspecialty buy-in from your GI docs to deal with GI bleeding, or even as significant as strokes, having a neurology team and infectious disease specialist-- you need to have subspecialty buy-in to kind of advance your involvement. And we also vetted that very carefully, with how involved our staff would be, really with the comanagement and really careful management of our outstanding VAD coordinators who are in constant communication with these sites.

And we would just share protocols, complete transparency between the programs, go out and do education about echocardiograms. I've been in the echo labs of many of these hospitals, doing imaging with some of our experienced echo techs and a VAD coordinator, to teach them both how to do and how to read echoes. And then lastly, just know your role, when you're comfortable, when you're not comfortable, and learn to decide, is this something that you're able to provide, to advance your level of care at these sites? Because really, at the end of the day, all that matters is getting this therapy to as many patients as possible and allowing them to be managed, even in their backyard, especially during times like we're dealing with right now, for the proximity issues and the ability to manage people locally.

And like Erin said, the big question for us was always-- and thank god they did this study-- because we thought that demystifying the LVAD and getting it out there-- but does this really work, and is it safe for patients? And so with that, I think we'll talk about the results of Erin's study, which are really very, very profound.

ERIN DAVIS: This has been a long time in coming to prove that this can be safe, and there's still some doubters out there. So if you're a doubter, we want to put this to bed and rest this. But the proof is in the pudding.

In this 10-year review of our program, we found that patients that we're seeing with shared care, especially the higher levels, level two and three, have the exact same rates of survival and adverse events, compared to patients that actually came back to our implanting center. We absolutely believe in 100% transparency. Just like Chicago said, [CHUCKLES] we share everything. We share every protocol, and every guideline, and all our education.

And we feel, a lot of questions we get is, do you have to be exclusive? Do you have to have contracts with these shared care centers? And my answer is no. If you do not need to be exclusive, you give excellent care.

So of these patients that were in this study, 76% lived of average of 423 miles from us. We followed them for three years, at least. We follow, of course, longer, but for this study, three years. We looked at A, adverse events, or survival at three years for the primary and adverse events for secondary outcomes.

And it's good to note that 70% of our patients into this-- that we were looking at for shared care-- 70% came to us in intermixed levels, 1, 2, and 3. So these are very sick patients. 18% of them end up on our beds temporarily initially.

And then of the pumps, we had a very wide range of devices that we looked at. We implant-- pretty much any device, we've attempted to do a trial here at our center. But in this study, at least 40% were centrifugal pumps. The majority were HVAD for centrifugal. And then we had a mix of axial, of Jarvik, and Heartmate II. And 2/3 of these patients were destination therapy.

And all of their baseline characteristics were same. And what really stood out, though, was if these providers in these shared care areas, that these patients that are being monitored remotely don't have to come back to us every single month, or every three months, or every six months, like normal implanting center patients would come back. They could be seen remotely in these shared care areas.

In our level two areas, the community provider was seeing them solo, with us touching base as needed. In the level three care, again, seeing them solo. Sometimes, we actually did have some outreach clinics, where we'd go out there and comment or consult with them because the patient is staying in their community forever, and they weren't coming back to our center at all.

But we found this to be very satisfying to know that these patients were safe in their communities, that we could dedicate the resources and really continue to support shared care in all these areas. And all of our cardiologists have bought in, all of our advanced practice physicians, clinicians, as well as our surgeons. So we're very proud of this.

ROBERT KOWAL: That's really impressive work. Quick question. So Erin, how much investment did it take to get this going and off the ground? And then in follow up, what do you have in place to kind of maintain it?

ERIN DAVIS: Great questions. So the first one, how does it get going? It starts very small. We started with having the patient do a takeback. So you take a patient back, and show them into the community, and talk to the referring provider, and make them comfortable at the pump. And then that turns into another patient referred and another patient sent back.

And the cardiologist starts opening up, or even the primary care physician starts communicating with us. Our coordinators were integral in this. We also have our medical doctor and surgical director that we would schedule-- I don't want to say dog and pony shows, but kind of dog and pony shows-- to communicate with physicians. We wanted them to know that this is not that scary, that you can do this.

And so we started doing those type of presentations, mini symposiums. But everything was done small initially. When we started to grow these areas-- I want to say we have over 36 various shared care partners now at different levels. We now have a dedicated outreach RN coordinator, and she was previously a VAD coordinator. She knows a lot about this therapy. And now she's dedicated to-- all she's doing is following these patients closely, making sure we're connecting with these referring providers, bringing back feedback, staying in contact with the different communities.

ROBERT KOWAL: Great, and Greg, one more quick question for you. So when you set this up, how have you streamlined or worked through the communication stream with your shared care partners, so that you're not always chasing each other--

GREGORY MACALUSO: Yeah, that's a great question. Well, we still have physicians, heart failure cardiologists, and in some cases, nurse practitioners that actually are traveling to the sites. But as the time has gone on, there's been a huge buy-in from the folks that are actually at the site, so that we have secured communications, either through text or telephone calls, to constantly streamline patient care on a day-to-day basis. I mean, our coordinators are really the life force behind this.

We have just under about 300 outpatient LVADs that we have implanted, that are alive at our center and managed at any one of these various sites. And so usually, there's just bidirectional, easy communication amongst all of the folks on site. And it may be from an attending physician who actually travels up there that day as well, that's seeing those patients. So we always decided that, in this model at least, we would try to go to the patients as well.

ROBERT KOWAL: Great. And Erin, one more question before we go over to Liviu. So among your partners in these shared care centers, how often are they cardiologists, versus cardiologists with advanced heart failure experience, versus primary care doctors?

ERIN DAVIS: I think when you get to a level three, where you're actually going to keep the patient, majority, if not all-- I have to think off the top of my head-- a majority, if not all, of level three shared care providers have someone in their practice that is advanced heart failure. Or-- we've actually done many fellowships with them to get them up to speed on their heart failure. They may be cardiologists for years and years, and then come spend six months with us to get their heart failure training.

Level two, most of them have at least a general or an EP cardiologist that's willing to take this on. And there are actually a few primary care physicians in level two too that are just very dedicated to their patients. And then level one can be a mixture of anything.

ROBERT Great--

KOWAL:

GREGORY I think what's interesting to add-- just to add real quick, Rob-- is, as those hospitals that were part of sort of the hub and spoke model, where they've now become even regional centers of excellence, it's attracted other heart failure specialists. So like I said, there's other heart failure cardiologists now that have joined on staff at those places that we partner with. So the necessity to travel has been less, but that's attracted people because they've now become a center that they know they can rely on for heart failure care.

ROBERT Terrific. So Liviu, let's go over to you in California. Your demographics and your referral pool are a little different.

KOWAL: You've taken a little bit of a different, but equally or very effective, approach to managing patients. Can you walk us through what you're doing?

LIVIU KLEIN: Absolutely. I hope everybody can see my slides.

ROBERT Yup, good.

KOWAL:

LIVIU KLEIN: I think that the challenges that we had with our program and the way we had to design the program five or six years ago, which is really helping us now-- you know, our patients come also not from within San Francisco but from northern California, southern Oregon, western Nevada. And even though it's not 400 miles away as in Erin's case-- it's only about 130, 140 miles away-- it's really hard for those patients to get to San Francisco. The traffic in the Bay Area has become really-- it's probably in rivalry with Chicago, [CHUCKLES] one of the worst traffic situations in the country. And it's extremely expensive to park here. So patients really did not want to come.

The other thing that we've encountered is the practices in northern California are very scattered and small practices. We don't really have huge groups outside Kaiser. So the opportunity to find shared care sites was much less compared to what Erin and Greg have shown.

So with that in mind, we set out five years ago to think about what EP has done a decade ago, which is remote monitoring. And if EP can do it, we can do it as well. And what we did, we've established a really very well thought out infrastructure, where we partner with ActiCare, for instance, and had all our patients get discharged with a lot of tools that were helpful for remote monitoring.

They had a tablet. They had a blood pressure cuff. They had a weighing scale. They had a INR machine. And then a lot of these patients, if not all of them, had ICDs and CRTs. So we took over their device and we integrated a CareLink system in our practice.

And we made it in such a way that-- again, what EP has done a decade ago-- that this was not an option. This is what the patient was going home with. So it was not an option. It was just-- we're not just implanting a VAD. We're taking care of you with a certain package.

The other thing that we've done, we've integrated all this data into our EMR because we realize that coordinators don't really have time to be spending-- navigating three or four different websites. So we integrate all the data into the EMR and has-- it really helped with the workflow.

So with that data, we realize that the patients, you should explain to them that this is not an added activity for you. This is part of your LVAD package. If you really want to thrive with an LVAD, if you really want to have a quality of life with no adverse event, you really have to be part of this program. You really have to put in your weight every day, your VAD parameters, your blood pressure, your INR twice a week.

And we show a pretty decent compliance. So if we look at our VAD and weight parameters, 84% of the patients input data more than three times a week, and 75% actually do it daily. Similar with the blood pressure. And then when we look at our successes in terms of being able to decrease adverse events, we realize that's really due to the-- what we call the time in therapeutic range.

So we look at our blood pressures. 87% of our patients are really controlled in their blood pressure measurements, and we define that as a target map, 75 to 85, or at their percentile systolic below 100. Similar with the INR. We've used the remote monitoring INR, the Roche tools, and patients get INRs twice a week if they're stable or more frequent if they're unstable. And then they get covered with low-molecular-weight heparin if their INR drops below two.

So with that, we had 77% of patients spending their time in therapeutic range. And again, that has translated into a very low incidence of strokes or pump thrombosis. Finally, we've integrated the labs from Quest and LabCorp, and we've made sure that each patient knows to go to a certain lab to get this data. So we don't have to wait and not have the labs.

And this is an example of our charts. So if I was a coordinator at UCSF, that's what I would see when I come in the morning. I turn on my computer, and I have a list of patients. It tells me the date of the implant. It tells me what else that they have, who is the vendor for the remote monitoring program. And it gives me data information from the LVAD, so again, the speed, the flow. And then it gives me the peak and trough.

And what's very important, we realized very early that the power calculation, it's so important, predicting adverse events. So we have the power, the actual power that the patient has. And then we have the power that's predicted based on their speed. And whenever we have a difference more than 15%, 20%, that's a signal that something may be going on, and that patient gets sent for labs. And you can see, they get LDH and other measures there. We can get their home INRs.

And you know, the coordinator wants to review data from, let's say, the previous 10 days, they don't have to switch the chart or anything like that. Just from that same screen, they can go, and they can see back 10 days of patient data. They can see blood pressures, the heart rates, temperature-- they put in temperature-- weight, and INRs, and so on. So it's very easy for the coordinator to understand who are the patients that have problem for that day, so they don't spend hours, and hours, and hours, and resources to work with that.

And I just want to show an example of how, I would say, cool or how [CHUCKLES] great this system is for identifying adverse events. So this is a patient that was implanted a few years ago. And if you see here, one day, the patient logged in abnormal flow. So you can see, his flow is around 4 liters. And on this day, he logged in 2.5.

So that immediately triggered an alert on our end, and the coordinator asked the patient, "Hey, can you send your ICD data to see-- maybe you have an arrhythmia. Maybe something else is going on." So at the same time, they sent the alert, and you can see in CareLink very nicely how the pacing, the ventricular pacing, has dropped.

And then if you look at-- the ventricular threshold has risen significantly on that day. The impedance stayed the same. So our thought was, well, there's only a few things that can make your lead impedance go-- lead threshold go up, and one of them is ischemia. This was a patient that had a prior CABG.

So we brought the patient to the emergency room, and we sent log files. And lo and behold, that exactly very same time when he lost his basing threshold, you can see a drop in the flow. So essentially, his heart rate dropped to his native rhythm in the 40s, and the LVAD was not filling. And that's why you had that.

So we immediately took the patient to the cath lab, and this was really crazy because the patient didn't even have a troponin. We had a lot of pushback from the cath lab, but we did manage to take him. And they actually found an acutely thrombosed graft to the RCA. So the patient was stent and left within 48 hours.

And again, this likely avoided artery failure because patient, otherwise, symptomatically, should have gone into an infarct. He'd have had RV failure, would be symptomatic, come to the hospital, and probably would be in RV failure for a few days. So that tells you how adequate we can make a rapid diagnosis in real time for a lot of these patients. And again, lo and behold, a few days later, once ischemia has resolved, the pacing threshold went back to normal. So I think this was really a beautiful case to prove early intervention really can prevent adverse events.

And we felt that our program-- we've been doing this for about five years, and we compare ourselves with INTERMACS. We see very good results. So our rate of bleeding, device malfunction or pump thrombosis, infections, strokes, renal failure, rehospitalization, both in the early periods-- so the first three months post implant-- and in the long term-- after three months-- are much, much lower than the INTERMACS, despite having 90% of our patients being INTERMACS 1 to 3, and actually, 50% are INTERMACS 1 and 2 profile. So very high risk patients. We've seen really good long term outcomes, which I think, again, are due to our coordinators working very, very hard and smart using remote technology.

So how did this help in the current year? Well, we were really doing telehealth before, so it wasn't a huge change for us. The only thing that has changed was, how can we reimagine the in-person clinic visit using telehealth?

So we've decided to use Zoom. And then literally, over a weekend in March, after our mayor and governor have declared the shelter-in-place orders, over a weekend, we switched all our appointments to telehealth. And I think in our practice, we went from maybe about 10% to close to 90% telehealth literally over a weekend, and at the hospital level, to about 60% from about 10%.

So our workflow is very interesting. Our AAs call the patient the day before. They set up Zoom, make sure that it works, make sure the patient knows how to connect their camera, and so on. Then the coordinator calls, and then they go over their medications. They ask them to make sure that they send their ICD data. They get the pictures of the drive line, and they update the note.

And then if there's any question about the VAD-- let's say there are some funky power going on-- we do have VAD centers in northern California and Sacramento, Fresno, or down in the peninsula, where we can ask the patient to go. And then we call the coordinators. These are competing centers, but we all work collaboratively. And then they would send the log file for us. So that has been really, really helpful, and patients don't have to travel all the way to San Francisco.

And then on the day of the visit of the clinic, we actually have a Zoom with the coordinator, the physician, the patient. Very often-- you know, we have six languages in our program, and oftentimes, we have to use interpreters. So we have an interpreter also on the line. We have fellows that are joining. So it's literally like one of those Zoom commercials [CHUCKLES] where you have all these people being at the same time.

And yet, we're very efficient, and we are able to keep the visit at 30 minutes, again, very similar to what is done in person. And this is what it looks like. The coordinator preps the visit beforehand. So you have the VAD interrogation that was done the day before or the morning of. You have a picture of the drive line with the staging. And then you have the ICD data right there.

So when I walk into the Zoom visit, let's say, I have everything that I need, which is exactly what I would have in an in-person visit. So for me, it's really the same thing. It doesn't add any time to my visit.

So I think the unique opportunities that we had was that we have thought about how to structure the follow-up care, and we sort of planned it ahead, again, using the EP model. And I believe firmly that technology will always help and will make patient care much, much easier. And because we had that infrastructure, we were able to instantly change our care model. And we used our existing infrastructure with seamless patient care literally over a weekend, and we did not increase the provider fatigue that has been experienced at other centers.

And I think the really nice thing is that I think future LVADs will integrate the remote monitoring tools even better, so this cannot only be available to UCSF but can be available all over the country, with much, much less investment. And I think if there is one winner of this whole COVID epidemic, it's really the ability to redesign patient care. We've seen a reset in how payers have thought about it, right? Two months ago, we had no billing for telehealth.

Now we have the billing that's in parallel with in-office visit. We can see new patients in clinic with telehealth, which has never been done before. There's no more state lines. So I think, really, we have this opportunity to really redesign patient care.

**ROBERT
KOWAL:**

That's fantastic work. There have been so many places that have tried to do this kind of work, and it's been difficult. A couple of questions come to mind. First, I'll say that it's been said, "Never let a good crisis go to waste."

And I think we've seen this in health care now, particularly in outpatient clinic, a rapid turnover of what was often an afterthought, with telehealth and remote monitoring, or considered a nuisance, is now front and center. And I think part of the battle for all of us is, how do we keep that to stay? But so Liv, you've shown really great results with regard to patient outcomes. Have you extended that work to look at cost reduction, patient satisfaction, need for the efficiencies of your clinic?

LIVIU KLEIN: Absolutely, so I think the efficiency, we have documented that. And we have a paper being submitted with the outcomes, and that has the efficiency in it. And we have looked at the cost reduction as well. And initially, when we go to payors, we said, "Well, here's-- our implant cost is much lower than our neighbors, so please send your patients to us."

What we've done, we've actually went to a 3-year, 36 months cost from the time of the implant. And we are able to show about a 40% reduction in the whole cost package and mainly because of decreased hospitalization. So if we look at our patients, 54% of our patients never set foot in the hospital after the implant, like, never.

The other patients, 26% of the remaining, are coming in for hip surgery, cancer treatment, gallbladder surgery, so really non-cardiac or non-VAD-related. So the VAD-related admissions up to 36 months, it's only about in 25% of the patients. So again, we've shown a huge cost reduction, and we're going to be publishing that.

ROBERT KOWAL: That's fantastic. The other question is, the transferring of data between groups, whether it's EPs in your group or around, even within cardiology, is difficult. How did you-- it looks like you have a free access to-- unrestricted access to getting the CareLink data. How did you set that up?

LIVIU KLEIN: That's a great question, Rob. So I think as you probably know, I'm trained in EP. So I also speak two languages, let's say. And I've gone to both parties, both the MCS and the EP world, and tried to appease everyone. So what we've done, we've--

ROBERT KOWAL: Not an easy task.

LIVIU KLEIN: It's not an easy task but I think was very worthwhile. So what we've done, we've created a separate login for our data, and we have a separate login into CareLink. And we've trained all our coordinators, so they're not just VAD coordinators. They are truly heart failure coordinators, being able to manage VADs, being able to manage arrhythmias. And it's amazing how our nurse practitioners and PAs are so smart. And again, they enjoyed doing this.

And for them, it's-- when they see an abnormal VAD parameter, they really start thinking, OK, let me look at arrhythmias. Let me look at filling pressures. They really have a complex thinking model. So they've learnt. They've learnt how to log into CareLink and how to pull the data.

And what we've done, we have not interfered with the EP workflow. So we're not interfering with their scheduled interrogations. We have not interfered with their billing. We're just doing these for comprehensive patient care.

ROBERT KOWAL: Great. I have one more question that just came in for you before we go back to all three in a joint conversation and that is, do you incent or reward your patients for adherence to remote monitoring? And what do you do when you struggle with a patient who just doesn't get it or doesn't want it?

LIVIU KLEIN: I think it's a great question, and I think most patients get it. And I have to give kudos to our coordinators because what they do, when they discharge the patient, they bring all the remote monitoring equipment in the patient teaching. So we're not just teaching them how to change their batteries and connect their control. We're teaching them how to use remote monitoring, how to input their data for weight, blood pressure, how to take their blood pressure, how to take their INRs.

And we explain to them that, look, the reward is you not having a stroke. And if you do this, we can help you. If you don't do it, we can't help you.

And then of course, there are stragglers and people that are not really doing this all the time. And then the coordinators call them. And then, again, we have a checklist, and if we see that data hasn't come in for three or four days, the coordinators call the patient.

But I think educating the patient from the beginning that this is a package-- it's not separate. This is a package. They are all in tune.

And again, when you ask them, "Hey, can you send me your CareLink transmission?" No one's going to say, "Well, I don't know where my CareLink monitor is. I don't know how to do it." They're all-- they're OK. A minute later, it's done because they understand that this is a package that keeps them safe

ROBERT KOWAL: Yeah, we're excited about this kind of work. As you know, we have a Bluetooth line of pacemakers, and we're extending Bluetooth across a large swath of our portfolio, and just had some data at the Heart Rhythm Society meetings about the high level of adherence when you use a Bluetooth device linked to an app to transmit information. So more to come there across the rest of the portfolio.

But I want to open up to all three of you now. You know, we've talked about getting care where the patients don't have to come in, and then you are the recipient of more interaction. There is still good information that can come out of these devices, in the form of log files, audio logs, et cetera. How have you guys set up the ability to get those when you need them? And now in this setting of COVID-19, what's your threshold to get a patient to-- either into you or into one of these shared care centers? And so Greg, I'll start with you on that.

GREGORY MACALUSO: I'm glad you asked because I think one of the things-- and Liviu pointed this out on his slides when the note is set up. You know, the paying attention very carefully to the peak and the trough on the actual interrogation that the patients can do. And if they do need to have audio logs generated, they can be brought in, and it may be a limited fashion to be put on a clinical screen. But I think assessing all the information that a patient can toggle through on their own device has become much more vital for us. I don't know if Erin has any additional thoughts on that as well.

ERIN DAVIS: So I think you've kind of realized the Achilles heel that we have right now with the shared care. What we've done to address this over the years is we have been placing monitors all over the states, all over the different shared care centers. So either we've purchased them or worked with industry to be able to provide monitors. I believe Medtronic has been really great to actually provide a lot of our shared care providers these monitors, so that we can get them into the local-- whether it's emergency room or the local clinic.

We have a low threshold for getting patients to go in and get checked if they'll do it. We do collect the information, and I wish-- and we're working towards it to be like Dr. Klein and UCSF, so it will come into our EPIC automatically. But I think it's critical to be able to track this, and it's always about trends, right? It's not about one snapshot in time. It's about the trend.

And so the better we can have when the-- future devices-- hopefully, you push a button, just like you have an ICD and be able to send this data. That is going to be crucial to help the staff here and the patient, ultimately.

ROBERT Great. So--

KOWAL:

GREGORY That's really--

MACALUSO:

ROBERT Greg, were you going to add something or?

KOWAL:

GREGORY No, I think that's exactly on the point. I was just going to really ask Liviu, just because the data is so provocative that he presented. One of the Achilles heels we know about these pumps is the [INAUDIBLE] complications. And I noticed you had mentioned in your slides that you were achieving time in therapeutic range of well over 70%, almost 80%, which is-- for those of us who are missing our meetings, we're going to be having virtual presentations coming up.

But we have a review of some of this in an upcoming abstract, looking at time in therapeutic range, and the endurance, and endurance supplemental trials. And you know, there is definitely a difference when you achieve a therapeutic range that is within the prespecified INR of two to three, both for bleeding and thrombotic events. And I just wanted to-- obviously, your numbers are less than the INTERMACS had mentioned. So just wanted to get your thoughts on that, Liviu, and what you-- how you check people at home, and if there's a particular device you're using, finger sticks, or just, how you guys did that.

LIVIU KLEIN: Absolutely, so I think, two things. We've shown-- again, it's in our upcoming paper that, for instance, even for GI bleeding, every 1% more time that you spend in the therapeutic range translates into a 5% decrease in GI bleeding. So our GI bleed rate is about 8% of 12 months. So it's very, very low.

Similarly, with pump thrombosis and strokes, it's totally related to TTR. And in fact, if we look at our patients who had ischemic strokes, we have almost zero of those patients being within the range. So all the patients that had a stroke were outside the range or low, and for some reason, they were not covered.

The other thing is, we do cover the patients automatically if they drop below two, unless they are bleeding. We do cover them with Lovenox. What we use at home, it's the Roche monitor. We've had issues, as you probably know, across the country, across the world. Their strips have been a little bit off.

So what we do, we oftentimes match the result that they have, and we do a QC every month or every six weeks with their local lab and see how far away they are. And we kind of know, based on the batch that they have, what their home level or home INR should be. And again, we do it usually twice a week if the patient is stable, and if not, more often. We've had some patients that their results were so off that they had to go twice a week to Quest to draw their blood. And again, they realize that that's what they need to do to stay safe, and they're willing to do that.

**ROBERT
KOWAL:**

Great, so I do want to add too, going back to what Erin said, we do have-- at Medtronic, have a loaner program for the monitors, for centers, shared care centers that need them. So in the last few minutes, we have-- what I'd like to do is ask each of you where are you going next with this work and the research you're doing, what questions you want to answer. And then maybe from each of you, a quick prediction on what the legacy of COVID-19 is going to be for the outpatient management of MSC patients. So Erin, you want to start?

ERIN DAVIS:

So where we're going next, I think it kind of ties into the second question of COVID. I think telehealth is here to stay. I think we are going to learn to really use the telehealth, and patients are going to become more tech savvy. We're going to become more tech savvy.

In our specific program, we're definitely exploring the EPIC integration, as Dr. Klein offered. In regards for our research, something we've already started is looking at the AEs that came out of our paper. One that really stood out, we had an infection difference, a huge infection difference. They're at level one shared care. Their infection rate was so much higher than level two, three, and the implanting center. Why is that?

And we gave them our protocols. We told them to do the dressing change the same. But why is that? And actually, our TTR wasn't different between centers, although the pump thrombus and stroke rate was different. So is it having to do with infections?

So I think we're going to go down those lines and start looking at better ways to manage these adverse events remotely and in our own implanting center. And with COVID, it's telehealth. We're going to figure it out. And I love the stuff that's coming down the pipeline that we hear about, about remote monitoring and abilities to make these pumps work for us and work for the patients better.

**ROBERT
KOWAL:**

So telehealth and getting level one centers to look more like level two and level three in their outcomes. Great, Greg?

**GREGORY
MACALUSO:**

Yeah, I think that's exactly what-- yeah, echoing Erin's saying, we're integrating into EPIC as well. And I think it's hard to ignore this stuff that Liviu has presented and how provocative that is for patient outcomes. I think, also, it's just trying to advance the field and working with the folks.

It's still-- the relationship that you guys have established with Medtronic is still pretty new. So we want to try to use-- get as much information that is actually in the hands of patients. So if we can start getting these clinical screens to be more provocative and provide more information, some of the controls to actually give us more information, it'd be great to see what we can learn even further at the remote side. And obviously, try to go in the totally implantable space would be great. So--

**ROBERT
KOWAL:**

Well, while I can't talk about what's coming, we hear you loud and clear. So I'll say that. And Liv, you have the final word here.

LIVIU KLEIN: Yeah, I mean, I think as everyone has hinted, I think telehealth is here to stay. And I don't think it's only here to stay. I think it will become the predominant mode of seeing patients, not just for MCS, but for every patient. I think everyone has talked about home, moving the hospital to home. And I think this is it. I think this is the year where we're going to do it.

I think 80%, 90% of the patients will not set foot in implanting center. I think in the next few months, hopefully, we'll have the ability to get waveforms on demand from home when we need them, just the way we do it with the ICDs and CRTs. And I think that's going to be the future of patient care. It's home care. It's physician-prescribed home care, where it keeps the patients safe at home with continuous connectivity, so we know what's going on with them.

ROBERT KOWAL: That's fantastic. Well, listen, thank you to the three of you. I know you all have busy schedules. It's a crazy time. And thanks for taking the time out of your schedules to be part of this. Thanks also to our MCS team for pulling this all together and pretty seamless hour.

I want to make an additional announcement coming up. Well, first off, this will be, like I said, available on tape coming up. We also have a program-- if we could put that slide up-- coming up in the next month or two, June, July, time frame, around optimizing best practices in LVAD patients, working through the whole spectrum of care, from patient selection all the way to patient management, post implantation. And that's part of our commitment to the ongoing education and management of these patients.

So with that, I'd like, again, to thank our three guests for a great conversation. Wish everyone a great weekend. For some of us, it's a holiday weekend. And I wish everyone that they're all safe. Thanks, everyone.

ERIN DAVIS: Thank you.

GREGORY Thank you.

MACALUSO:

[MUSIC PLAYING]