

- Speaker 1: [00:01](#) Quality improvement in the time of COVID-19 is brought to you by the American Heart Association with support from Novartis pharmaceuticals. As physicians, scientists, and researchers worldwide struggle to understand the COVID-19 pandemic, the American Heart Association has developed its COVID-19 CBD registry powered by Get With The Guidelines to aggregate data and aid research on the disease, treatment protocols, and risk factors tied to adverse cardiovascular outcomes. For more information, visit us at heart.org/covidregistry.
- Sandeep Das: [00:32](#) Hello and welcome to the American Heart Association podcast series on quality improvement in the time of COVID-19. My name is Sandeep Das and I'm a cardiologist at the University of Texas Southwestern Medical Center in Dallas. In addition to clinical work, I spend a lot of time thinking about systems approaches to how to improve quality of care. Today we're going to talk about another aspect of providing high-quality care in the time of COVID-19.
- I have the pleasure of hosting Dr. James de Lemos, professor of medicine here at UT Southwestern and an internationally known expert on acute coronary syndromes and cardiac biomarkers. James has been a mentor and friend of mine for more than 15 years and together we serve as the co-chairs of the steering committee of the American Heart Association COVID-19 cardiovascular disease registry, powered by Get With The Guidelines. Today we'll talk about the registry and how the cardiology landscape has been impacted by the COVID-19 pandemic. But first I'll let Dr Lemos say a little bit about himself.
- Dr. James de Le...: [01:24](#) I'm a general cardiologist at UT Southwestern who have been here for a long time and spend a lot of my time thinking about risk assessment and how to better identify who might develop heart disease in the future. Like you, I think we sort of pivoted our clinical and research portfolios, our family lives, and everything when COVID hit. And I think the genesis of this registry was just sort of human need to do something in the face of a pandemic when we weren't really on the front lines. That was really what got us started. But that's sort of how I got into this whole COVID story.
- Sandeep Das: [01:58](#) So looking back at that time myself I was so struck by how fast and effective the American Heart Association team was in building a new national registry really from scratch, I'll be it powered by the existing Get With The Guidelines infrastructure. Can you talk a little bit about how the registry was launched and how it's grown?

Dr. James de Le...: [02:14](#) It's sort of an interesting story. Many of our cardiology fellows were deployed home in those first days of the pandemic, actually before the pandemic hit in Dallas, when the hospital was preparing for what they thought would be an onslaught that actually ended up coming a couple of months later and many of us were newly working from home and trying to think about what we could do to sort of fight back, if you will, against this pandemic that was coming. And the fellows really were the driving force behind this. They created a pathway to study COVID with our own hospital system to try to understand what the cardiovascular complications might look like. Whether we could anticipate them with the biomarkers we were measuring and even we're looking in on the hospitalized COVID patients sort of behind the scenes to see if they could understand trends.

And then you and I had a number of conversations and realized that this was unbelievably interesting, but to be impactful we really needed to get beyond a single center and think about how we might do this on a national level. And so it helps to have former HA presidents on our faculty and our CEO is John Warner, who was a past president of the HA. I sort of bounced it by him and then as you recall, couple days later shot this to Nancy Brown and some other former HA presidents and to their credit, they leapt on the idea of launching this within three days. It was just a flurry of activity to get this thing up and most of the credit really goes to the team of professionals at DHA. I've really never worked with a group like this and hadn't ever really worked with this group before, but they are just seriously good at what they do, first of all, in guided you and I along the way, but more importantly we're so committed to the process.

I think they were in the same boat we were. Everybody's wanting to do something they're afraid for their families and their parents and wanting to do whatever they could even outside of their usual scope of work to contribute to the fight against this virus and pandemic. And what happened was we obviously leveraged on the talent and expertise and experience of the AHAs team and got a case record form written, again, using our fellows, the young people, and leveraging off of them and launched, it was off to the races and within a couple of months we had several thousand patients in.

Sandeep Das: [04:28](#) And how big is the registry growing now?

Dr. James de Le...: [04:30](#) We're at about 40,000 plus from well over 100 centers in about 35 states. So it certainly exceeded our wildest expectations

where we started. What we hoped to get, which was a broadly representative group of individuals enrolled across a whole spectrum of practices, urban, rural, different peaks of the pandemic as everybody will recall. It really peaked on the East coast first and then moved its way South and West and so we've really been able to capture all of that and try to understand what has been happening and even now, since we've been at this for nine months or 10 months, the ability to capture trends over time.

Sandeep Das: [05:09](#)

Yeah. It's really amazing to me how the AHA and how many individual centers took on this type of responsibility in the middle of a logistic challenge of COVID. And it's really a testament to people rising to meet a worldwide public health challenge. One really unique aspect of this registry is the HA precision medicine platform and how it democratizes the research process. Can you tell us a little bit about that?

Dr. James de Le...: [05:30](#)

One of the more lasting contributions of the registry will be sort of how we've used the precision medicine platform to capitalize really a different way of thinking for registry research. For the listeners out there who don't do registry research and think about this all the time, the way this is most often been done is that a group would submit a proposal and that proposal would be reviewed by a committee and then if the proposal was accepted, analytical center would run the analysis and do this, but there's a limit to how much they can do. They would typically do one or two projects at a time and sort of the time from the onset of the idea to the publication and dissemination of the results typically is about 18 months with a normal registry project. But obviously when you and I were talking about this with Jennifer Hall and [inaudible 00:06:17] and people at AHA, we realized this timeframe would not work in the setting of a pandemic when everybody was desperate for immediate knowledge.

So we had to come up with a way to leverage the registry in a very short period of time, both for scientific and pragmatic and clinical reasons. Also we hoped that the registry wouldn't be needed for a long time so we wanted to get as much out of it as quickly as we could. And then we needed to do that at the lowest expense possible and we needed to also factor in the entire research workforce that we're contributing. This really didn't have to be limited to sort of the usual suspects that the analytical centers and the top researchers in the registry, but we could open this up to all the people that were contributing. And so what the precision medicine platform offers is basically a

place to store the data and allow teams of investigators to come to the data and do their own analysis with some guidance from our research and publications committee.

And it democratizes the approach, it sort of spreads it out, the responsibility of the data analysis, the writing of the papers, to a much larger group. And so what you're able to do is generate quality research output because the data sets so robust, much faster and much greater scale than you could with a usual pathway. And I think it's been sort of wildly successful. 40 or so proposals approved. At last count there's about 14 papers done, about four or five that either been accepted or published in really a record time when you think about the registry being launched in April.

Sandeep Das: [07:51](#)

Now what are some of the unique things about this registry in comparison to other attempts to gather COVID related cardiovascular data? I know there's a lot of people out there diligently putting in thousands of biomarker elements and things like that. Could you maybe tell us a little bit about what makes this registry special and maybe even give us a teaser of a couple examples of interesting things we've learned so far?

Dr. James de Le...: [08:11](#)

Sure. The first thing is that it's focused on cardiovascular disease and many of the other registries out there and COVID are focused on the respiratory components of the illness and basically the broad, critical care elements, but this is squarely focused in the HA in our wheelhouse, which is cardiovascular disease and stroke and so we collect a lot more detailed information on those variables so that we can really define the full spectrum of cardiac complications, in the hospital at least, of COVID. And then we'll come back hopefully and talk about some of the leverage opportunities outside of the hospital data. The other piece that unique is, and this is sort of in the HAs tradition of granular detailed data, is that we collect a lot of information. It's quality information because it's taken from the record, it's not billing data, but real on the ground patient data and that includes all of the past history medications that patients were taking before they developed COVID and were hospitalized there.

And then we collected a whole trove of laboratory and biomarker data that really allow us to drill into different phenotypes, if you will, of the cardiac complications of COVID. So it's the number of data elements, the fact that we're collecting or intending to collect consecutive cases so that we have a broad representation, and then we're in so many

different hospital states so we can get the full spectrum of different care patterns and make sure that what we're seeing is generalizable, which was one of the reasons you and I started this thing is because we realized that what we were seeing, and we're both editors at, from these single center studies may not be what we would see at our hospitals, Parkland and Clements, and what our listeners might see in their hospitals, but what's needed is really generalizable data that reflects not just a single center experience. At HA sessions in November, we presented three abstracts, two of which were published simultaneously in circulation. We presented sort of a broad overview of the cardiac complications.

And interestingly, the cardiac complications were less common than we feared they would be when we set up the registry based on some of these selected series that we were seeing from Wuhan and Italy and places like that. We're seeing rates of cardiac complications in hospitalized COVID that are generally in aggregate less than 10% in the individual cardiac complications, like myocardial infarction or heart failure, stroke, all happening in 2% of patients or less. Having said that, when you think about the scope of the pandemic and how many patients have been hospitalized, even a small percentage of them getting major cardiac complications like the ones I've mentioned or cardiogenic shock or even mild carditis, which is even less common, are going to happen on an aggregate level quite commonly and most cardiovascular specialists are going to see these complications. So even though, on a relative basis, they're not that common on an absolute number basis they're still a major source of what cardiologists and specialists are going to see in hospitals during the pandemic and we all need to know really how to evaluate, treat these patients.

So that was sort of the first one. And then there were two, I think, really impactful papers that were published. One from Fatima Rodriguez at Stanford and Tracy Wang at Duke that looked at race, ethnic disparities in hospitalized COVID and outcomes. And this is a message that has been told to some extent before, but given the granularity of our data and the broad representation was able to be really dissected in great detail. And what they found was that black and Hispanic patients made up 58% of the people hospitalized with COVID, which is absolutely remarkable and when you compare that to the census tracks where the hospitals in the registry exist, the rates were much higher than the proportion of black and Hispanic individuals in those communities.

But the second piece of this, which was equally instructive is that once you account for differences in clinical characteristics, and those include higher rates of obesity in younger age in the hospitalized black and Hispanic patients, the in-hospital outcomes are similar across race and ethnicity. So what this highlights is that the lesion, and it's a terrible lesion in terms of health equity, with COVID it is really happening before patients get to the hospital. It leads to higher rates of COVID infection and more severe COVID infection that requires hospitalization, but we're not seeing disparities in hospital care with COVID that lead, at least, to measurable differences in outcome. And obviously what's driving those upstream factors are long-standing health inequities including structural racism, inadequate access to health, and then the economic factors that drive family crowding, essential worker status that lead to more COVID infections.

And then the second one that we published early on that I think is really impactful from Nick Hendren, one of our fellows who actually was on the ground, as you remember, leading our local effort. It's really a great story for him because he started developing the local protocol that eventually led to the HA registry. He helped us design the case record forms and now here he was presenting results from the registry as a late-breaking trial and then publishing them in circulation. And what Nick looked at was the effect of obesity on outcomes in COVID. And what he saw was that obese patients were much more likely to be hospitalized with COVID than their proportion in the US population. So it is a risk factor for hospitalization. And then when individuals were hospitalized there was a striking association of morbid obesity or class three obesity, a BMI above 40 with cardiovascular death, all cause death, and ventilation.

And also I think importantly that the association with the need for mechanical ventilation was sort of a straight line association so that any excess body mass increased the risk for respiratory complications, but the big take home message from his paper was that he saw an interaction with age so that the hazards of obesity were strongest in younger people. And we felt that, as you recall, that this was a really important public health message at the time and still is because so many young people have gotten a message that COVID's not as big a deal to them as it is to old people like us. And his data suggests that's certainly not the case for those that have very high BMIs.

People with very high BMI's are at high risk for hospitalization and if hospitalized for major complications. And I think it's interesting that work has partially, I think, contributed to some of the states prioritizing overweight and obesity in their vaccine decisions, which I think is a great idea. Now obviously we're at a point where vaccine distribution in the US is opening up more broadly, but in those first months, overweight and obese individuals in many states were prioritized. And then since then, obviously we've got a bunch of other stuff in the pipeline, but nothing yet published that I'll mention.

Sandeep Das: [15:00](#)

So you mentioned that COVID's changing the landscape of what we're seeing as cardiologists. I'm wondering if you could just elaborate that on a little bit just on how COVID has affected the way we deliver care perhaps, maybe with the use of wearables or telehealth or anything like that.

Dr. James de Le...: [15:17](#)

Yeah. I'm certainly not an expert on technology or even telehealth and I'll start with the caveat that I personally don't enjoy telehealth in the same way that I do seeing patients face to face, but I have done a fair bit of telehealth myself. I've been a telehealth patient. It's certainly a brave new world. As many of our listeners will know, a lot of this, at least in certain states, has been catalyzed by at least temporary insurance reforms that have allowed practitioners to basically be compensated for telehealth visits in ways that they couldn't have been before. And if those payment reforms persist I think it is likely that telehealth will be here to stay in a much more meaningful way after the pandemic. And it's interesting to me that there are certainly best practices with telehealth. Some people do it very well and enjoy it a great deal and some patients like it a great deal.

There's obvious situations where it has tremendous value for people that have difficulty getting to a patient visit, who live long distances and don't need physical exam. There's clear advantages of efficiency and being able to sort of, again, democratize care. I can do a telehealth visit. I'm doing one next week with somebody who reached out to me from Florida who wanted to get a second opinion visit and now doesn't have to fly across the country to get the second opinion visit. And I think there will definitely be durable changes in that regard. How durable and what proportion of our patient visits are done that way I think remains to be determined. And given the way healthcare in the US is so driven by market forces, a lot of that will depend on what the durable changes I think are and payment models.

The wearable stuff is fascinating. I'm both optimistic and skeptical, I guess I would say. I'm optimistic because the technology's pretty amazing and obviously offers the ability to democratize. My skepticism is sort of based on the fact that I haven't yet really seen it translate into meaningful differences in either research studies, for the most part, or even in clinical practice in terms of what we could do to improve behavioral or clinical health. So there's a lot that has to be done. And the other part I worry about, with the augmentation of wearables and just the data, is the massive amount of data that comes back and how that's going to be processed and handled.

I mean, I get nervous just dealing with ambulatory blood pressure for my patients, but if I'm also being responsible for integrating all kinds of additional health data in the context of a usual practice pattern, I think that's going to be challenging. And so, in my opinion anyway, the technology is advancing very fast. Our understanding about how to incorporate it either from a research standpoint or more importantly to clinical practice is a long way away. Certainly things like COVID catalyzed at least discussions around this, but I don't think the wearable stuff is anywhere near as actionable as the telehealth stuff, which is obviously made tremendous [inaudible 00:18:09].

Sandeep Das: [18:10](#) So thanks. That's fascinating. As a cardiologist, any other big lessons you've learned from the pandemic, things that you think we did well, we did poorly, or we should do differently going forward?

Dr. James de Le...: [18:21](#) I'd say one thing for me, in our institution at least, and I know in some places the cardiologists were on the front lines at least for short periods of the pandemic. And I just would acknowledge that the sacrifices from nurses, laboratory technicians, emergency providers, hospitalist, pulmonologists has been out of proportion to the rest of us. So after the first few months of the pandemic, we've been largely been able to do our usual cardiovascular care, obviously with modifications including telehealth and masking and social distancing. But the impact on our practice has been a fraction of what's been impacted by others. So I'd just like to thank our colleagues and acknowledge the sacrifices that they've made that are out of proportion to the sacrifices that I've made. One other group I think we ought to recognize both for their contributions and sacrifices during the pandemic, but also for innovation is in palliative care.

At our institution we've seen tremendous commitment from the palliative care folks, but also some real innovation in terms

of how to handle palliative care during the pandemic, including using telehealth and communicating with families across the country. And I think some of that's going to be enduring and they'll be lessons learned from the pandemic that we can use well beyond social isolation on either people presenting late or not at all with their cardiovascular diseases, perhaps dying more at home, and then what people are calling the fourth wave, which may come, is the longer-term effects of social isolation, less exercise, deferral or denial of chronic preventative medical care on what might happen in the next year or two with regard to the chronic cardiac diseases that you and I take care of. So I think there's a lot that may be coming, even though the immediate US burden of the pandemic may be waning that these longer term effects remain to be determined.

And I guess the other point we haven't talked about, but we should acknowledge is that the long-term cardiac effects of COVID have not yet been defined. Would say that when you look at some of the stuff you and I have seen it referred to circulation or published in other journals, some of the early series made it probably exaggerated what the long-term effects might be, but there may be, in a small subset of individuals, durable, cardiac effects of prior COVID infection, even infection that wasn't terribly serious initially. And that's going to be sort of the next phase of COVID research. And in fact we're actively looking for opportunities to link our HA registry with the ability to track long-term outcomes after discharge, either through linkage with other data sources so we can see what happens to these patients long-term or even prospectively following them to see whether some of these patients develop what people are calling long COVID or the post acute Sequelae.

But that's sort of, I think, the next couple of years here is going to be, okay, yes we've defined what happens in the hospital, that in hospital pandemic wanes and then now the next phase is, well what is the scope of cardiovascular involvement long-term after COVID. I'm hopeful that that's going to be only in a small number of patients and relatively modest. And then what's the indirect effect of the pandemic on chronic cardiac conditions long-term and I think that will keep a lot of us busy for the next couple years.

Sandeep Das:

[21:31](#)

Awesome. Really some things to think about. And I wanted to echo your comments about the sacrifices others have made on the physician side, certainly the medical intensive care doctors, the critical care doctors, the hospitalists, at least at our institution have done by far the lion's share of the heavy lifting.

And then of course there's a lot of support services within the hospital that extend far beyond clinicians to things like environmental services or other clinicians like physical therapy and occupational therapy, people that are in the room seeing these patients every day while we're doing cardiology consults over the virtual connection.

So I do also want to echo the appreciation for the enormous amount of work and sacrifice that has gone in on the part of so many people to help us get through this pandemic. So thanks. It's been a really interesting discussion. I enjoyed it. Appreciate your taking the time to come here and share your perspective as a leader in this area with us and thanks.

Speaker 1: [22:27](#)

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