

Smaller devices, more data, and connected healthcare is leading to better outcomes for patients says Medtronic's Dr. Laura Mauri.

Produced in partnership with Medtronic

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Full Transcript

Laurel Ruma: From MIT Technology Review, I'm Laurel Ruma, and this is Business Lab, the show that helps business leaders make sense of new technologies coming out of the lab and into the marketplace. Our topic today, is telemedicine. The coronavirus pandemic has led to more collaboration between healthcare providers and increase the use of digital technologies, which allows doctors to safely connect with patients virtually and to monitor them remotely.

This is prompting changes in medical devices, from clinical research, to physician training and education, to doctor and patient use and informing new technologies that are coming out.

Two words for you, open-source ventilators.

My guest is Dr. Laura Mauri, who is the Vice President of Global Clinical Research and Analytics at Medtronic. Before that, she was an interventional cardiologist and clinical researcher at the Brigham and Women's Hospital here in Boston. And a professor of medicine at Harvard Medical School. She's also one of the world's leading experts on clinical trials. Dr. Mauri, thank you for joining me on Business Lab.

Dr. Laura Mauri: Thanks Laurel, it's great to be here.

Laurel: So, let's start off by talking about your primary research before you joined Medtronic. Bio says here that you led clinical trials to evaluate novel medical devices and pharmaceuticals. Could you give some examples of what medical devices and how they are used in healthcare?

Dr. Mauri: Yeah. So, I practice as an interventional cardiologist and I also was very interested in, how do we make sure that we're treating our patients with the safest and most effective therapies, and that we're also continuing to advance healthcare? It's been just an incredible past couple of decades I think in cardiology where you've seen miniaturization of devices and movement towards less and less invasive procedures.

So, some of those areas include the use of coronary stents to treat patients with heart attack or with the chest pain as a way to save lives in the setting of a heart attack, but also avoid more invasive procedures like open heart surgery.

And then similarly using catheter-based valves to be able to open narrowed heart valves that prevent blood from flowing to the rest of the body, which is a complex surgical procedure but more and more is able to be performed through small catheters through the blood vessels instead of doing open heart surgery. So these are complicated areas where when these technologies are first introduced, the first aim is to make sure that they can be performed safely and to test out those therapies, but then really to better understand the benefits that patients might derive from them in different settings.

Laurel: What is an overview of how a device goes through a clinical trial versus say a pharmaceutical drug?

Dr. Mauri: Yeah. A medical device is interesting because the background leading up to medical devices involves so much technical engineering and then understanding how the devices perform in animals. But it's really not until the devices are in the hands of expert physicians and then used in real settings, taking care of patients that we really come to understand the feasibility of a device. So usually a medical device will start out in a simple study to make sure that there's proof of concept essentially. Does the stent open the blood vessel effectively? Does the valve open the valve effectively and safely?

And then the next step is to make sure that the patient gets benefits from that, that is, do they avoid having heart attacks or strokes or stay out of the hospital more frequently or avoid having heart failure as a result? And those things are measured in clinical trials which can be randomized to be able to compare to what the standard of care is. That overall structure is not that different than it is for drugs. The main difference though, between a drug trial and a medical device trial is because the devices are so mechanically based in general, we have a good sense of how they work before we go in and so there are fewer questions perhaps about less predictable effects of a medication for example, where we may not understand the biology quite as clearly or the side effects of the medication. With devices, we tend to have a lot more bench testing and understanding of the mechanism of action as well as the potential side effects.

Laurel: So you could actually volunteer to be in a medical device trial just like you could as well if your doctor was recommending it for a new pharmaceutical drug or something like that?

Dr. Mauri: Absolutely. I mean, I think that one of the challenges that we face that we'll, maybe we'll talk a lot about a little bit more is, how do we make it easy for people to find those trials? If you have a medical problem, how do you know that you might be eligible for a trial? And that's something that's becoming more and more easy now that there is more information available digitally to be able to connect patients with the trials.

Laurel: Do you... I'm thinking about how you'd have a medical device trial. Is it sort of a simulation that the device itself goes through that you can sort of record the results to make sure the machinery itself works correctly and then when you implant it into the human it's more of the assumption of knowing how now that the body works itself and then the device works itself so you can, like you said, better guarantee a health outcome because you have done extensive testing on the device so you have a very good idea of how it's going to react? Unlike, as you mentioned, the pharmaceuticals where there could be a host of possible side effects.

Dr. Mauri: Yeah. I don't want to oversimplify how clinical trials are done for medical devices because, we don't know everything that's why we do clinical trials. We usually have a good sense of the mechanics and the engineering based on the bench studies in the animals work. And then some of these medical devices as you

know, things like pacemakers and other electronic devices, we're able to record information directly from the devices. That being said, at the end of the day, what the patient cares about is how they feel and what the results are to their life and how they experience life. And those are things that we can't really assess except for, by asking a patient or checking what their health outcomes are in their follow up, in their medical records for example. The clinical trial really does come down to the patient experience, and how it's improved.

Laurel: As you mentioned, one of the purposes of this device is actually to help gather data and improve the outcome for the patients. So, how does the medical device help doctors and healthcare practitioners use that data to improve outcomes?

Dr. Mauri: Well, when you think about something like a pacemaker for example, the way that pacemaker works is that it's constantly monitoring what the heart rhythm is doing, and then it's adjusting within the device, what the output of that device is to correct the heart rate, if it's too slow for example. In other situations, there are other heart devices that will treat fast heart rhythms that are dangerous to the patient, but they're doing that based on a closed loop system essentially of sensing what's going on and then applying the appropriate treatment.

And that's all being done automatically within the implanted device that now is less and less invasive to be honest. They're smaller and smaller and sitting right within the heart. There're similar devices to manage diabetes where they're sensing of the blood sugar and then application within the device to be able to release the right amount of insulin to correct a high blood sugar and avoid a low blood sugar. Then there're similar devices to treat things like Parkinson's disease or different types of pain syndromes.

These are devices that are collecting information all the time and responding real time. There's been incredible innovation in making these therapies able to provide the right adjustment internally without even having any direct interaction with either the patient or the physician. And so the ability to sense and apply a therapy is constantly evolving and developing in many new spaces and it's really, very exciting.

Laurel: That's a really interesting phrase, sense and apply because that gives this kind of impression that the devices are now smart enough to do that with like, as you mentioned, without the intervention of a human. So again, it's not necessarily a form of artificial intelligence what it is, what the device will understand as being basically correct behavior or incorrect behavior and that's how the device decides to correct the behavior. Is that a simplification of it or is there artificial intelligence involved?

Dr. Mauri: No, you got it exactly right. I think it's interesting that you brought up the comments about artificial intelligence because you're right, classically, it doesn't involve artificial intelligence. It involves algorithm that's programmed into the device that is fixed. But that being said, more and more, we are developing applications of artificial intelligence that are learning either within the patient data or across multiple patients sets of information to be able to apply artificial intelligence. Many of your listeners will know depends on the access to excellent and high fidelity data and large amounts of it as well as access to the outcomes that we're trying to impact. And that's really what has become more and more possible is collecting better and better data, being able to collect it across multiple patients and being able to start to apply that to outcomes. And so therapies like image recognition, for example, are pretty advanced in that regard, and we now have methods to visually recognize things like intestinal cancers and really make it simpler to detect those things and those use artificial intelligence.

And then also in the diabetes space, what I was mentioning before, in the past, we relied solely on the blood sugar measurement to adjust the application of the therapy insulin, and in a way that's reacting to something that's already happened in the body, but by using AI, we hope to be able to integrate things like what a patient

is doing, their activity, and what they're eating in terms of the types of foods that they're eating and how that can be predicted to later impact their sugar and therefore, know what the action should be even before the sugar starts to change. So I think it will get us to better and better therapies over time.

Laurel: That's astonishing. It makes sense though, right? Because you... I don't know, we are very familiar now with kind of inputting calorie counters into our phones or Fitbits in Apple Watches and having these personal health devices around us all the time, but you could... With those actions of a regular consumer becoming very used to something like that, it's not too much of a stretch, right? To say your doctor may prescribe you, someday, an app that helps you actually account for the food that you eat and the activity that you do, and that will then help or be one point of information for your entire health ecosystem.

Dr. Mauri: And that's what we're striving for is to be able to put together these multiple sources of information that we know impact patient's lives and their experience through better management of their illness. Those have sat traditionally in multiple different locations and haven't been linked together. So the more that we can do to bring these good sources of information together and really tailor therapies, I think the closer we'll get to continuing to improve care.

Laurel: So just to stay on that a little bit, I know the Fitbit and Apple Watch is a little bit of a distinction between a medical device that's used for healthcare purposes, but it's not too much of a difference there because those consumer health devices are becoming smaller and easier to wear and they're tracking more of our data every time there's a new release of them, right? So is it possible that there is some kind of hope to have this consumer device, telehealth, and remote monitoring at some point all combined?

Dr. Mauri: Absolutely. I think we... I guess the first thing is to make a distinction between consumer health and a medical device. The Fitbit or the Apple Watch give interesting information to individuals to be able to observe your heart rate in response to something. Medical devices really are held to a higher standard to actually show an impact on a medical condition that improves the way that patients are feeling or the way that they'll be able to perform their activities or even the lifesaving in the case of somebody who requires them to survive, which is the case for many of our technologies. So there is a pretty clear distinction between the two.

That being said, there's value in being able to use these consumer devices to be able to understand how people are doing. When I think about things like telemedicine, those are things that exist. Most people think about using Zoom as a way to be able to talk to their doctor for their healthcare visit and that that's a really new thing. The truth is that we've been looking at telehealth for quite some time. You look at people who have pacemakers to keep their heart rhythm normal, they are used to doing monitoring through the... This has been true for decades, that there've been ways for them to monitor their devices through the telephone. Now because of Bluetooth technology, we can now have them interrogate their devices through an app on their phone. And by making it that much easier, we actually see better and better outcomes because we can look for dangerous heart rhythms, but in a much simpler way and without really being as cumbersome for patients. So I think there's a real value to remote methods that are getting better and better through technology.

Laurel: That's a very good distinction to make and something I think as consumers just want to have that better understanding and perhaps just behave better, right? Like now I care enough about my health and these are the devices that I'm using. And, oh, I understand how much more complex and specific medical device may also now be used to help me in ways that perhaps 10 years ago even, we wouldn't have seen before. So to zoom ahead to this obvious focus of this day and age right now, which is how is telehealth actually being used during the COVID 19 pandemic. I just have a short story here. I had to have an X-ray taken this week, nothing to do with COVID except the fact of course, it's a very different experience right now going to see a doctor during a pandemic.

And while I was in the room at the X-ray machine, the nurse was in the hallway with this extended cord that came out of the X-ray machine and she shut the door and she took the X-ray from the hallway, and it made me think about how physically close you usually are to your doctor during a visit. So there's clearly a need to create a safe distance, a physical distance between a healthcare worker and a COVID-19 patients. But how is that actually prompting companies like Medtronic to change the way that medical devices are used? Are there longer cords or is the assumption that some of this can be done remotely by other devices? Interesting pivot when you're used to being so close in the same room with your patient.

Dr. Mauri: Yeah, I think that you're right. So the pandemic has highlighted the need for these types of solutions and has really accelerated the application of these innovations, many of which were well underway already. And in other cases, it's actually pushed for totally new innovation. So I guess maybe starting with one of the examples that I think is the most exciting, as you know, Medtronic manufactures ventilators, and in addition to simply dramatically increasing their production of ventilators over a few months, the other need that we clearly saw from physicians was the ability to take care of patients without going in and out of the room frequently. The physicians right now and nurses in ICU have to go through really very cumbersome procedures to put on gloves and masks and gowns in order to protect themselves from being infected, as well as to prevent transmission to others in the hospital.

One of the things that we collaborated with Intel on was the ability to manage the ventilator completely remotely. So not through a cord, completely remotely so that one could program the ventilator to change. When you have these acutely ill patients who are dependent on a ventilator to keep their respiration going, it's not uncommon to need frequent adjustments from a technician. And now that technician could do that safely outside of the room. And that kind of innovation happened in a matter of weeks.

Other types of innovation already were of interest to us before, and simply took off because of a greater need during the pandemic. And so those are things like having Bluetooth enabled devices to treat patients with life threatening heart rhythm disturbances. So like I was mentioning pacemakers before, there are other devices that are more sophisticated that are for patients who require monitoring for those dangerous heart rhythms, not just slow ones, but some of the dangerous fast ones. Those can now be also managed remotely. And that's important because it... Much of the barrier, I think, for patients to be able to receive the care they needed during this setting was related to the obstacle of trying to avoid contact between people during the social distancing time. And by being able to perform procedures with a minimum amount of physicians in the room, not requiring a technical expert in addition to be able to program the device and being able to do that from outside the room, it really is helpful for patients, but also for the healthcare providers who are doing the procedures.

Laurel: I hadn't really thought about that. You're right, it's not usually just one person in the room with you, of course, and especially in a complex situation as being admitted to the hospital with, obviously, very serious disease. So the techs who usually run the machines do it from outside the room. Does that also help them scale? Because obviously, during a pandemic, there can only be so many techs on site in general, shift work, et cetera. But then it doesn't help kind of improve that way they can give care because they can do it a little bit more easily to many patients all at once as need must?

Dr. Mauri: Yeah. I mean, I think that's a great example of how something that became a necessity out of something that we didn't necessarily anticipate a pandemic, that that then becomes something that has value going forward even after we recover. Obviously, it's good to have these things in case the need for this in future pandemics comes up again. But like you said, more importantly, it changes our ways of thinking about how care is provided, how healthcare work is performed, that more and more things can be done at larger scale and more efficiently by having these innovations. And just to take it a little bit further, one of the limitations in

being able to introduce new technology is that these are complex procedures, in many cases. We're constantly changing and making less invasive the way procedures are performed.

But that also means training physicians in new methods. And what's really exciting is that we now can have programming of new devices or education around new devices that can happen across countries. As you know, in the pandemic, travel's been really limited even across states. And by being able to perform remote training, either through a web interface or through augmented reality type interfaces, we can really kind of be there virtually to be able to support the training of new types of procedures for these types of devices, and that's really exciting. And I think what that means to the post-COVID situation is that it gives a broader global access to helpful technologies that might otherwise geographically be difficult to achieve.

Laurel: For sure. I'm thinking because of the coronavirus crisis hitting countries sort of one by one in this very slow moving train across the world. So for example, would doctors in Italy be able to help doctors in other countries, say America and then Brazil, et cetera, as the crisis kind of went ahead to each country because they were learning on the spot and then able to kind of give those best practices and lessons learned forward?

Dr. Mauri: Yeah. I mean, I think we certainly saw that. We had examples where we couldn't have our clinical support staff travel to Spain, for example, when they were in the midst of the pandemic, but we were able to provide support to physicians there by having people in other countries in Europe, present virtually, and engineers present for those cases present from the United States. So I think all of that's possible. As a clinician myself and as a researcher, I think we can continue to do better. I do feel that those global shared experiences for what's happening in one part of the world, learning for the next, it's critically important. Our organization is global so we had the ability to see how hospitals adapted, for instance, in China and other parts of Asia before the crisis reached Europe and the United States and other parts of the world.

And that was very important learning for us to be able to share with the medical community that we work in.

Laurel: Yeah. I can imagine that being thrilling and really weighty at the same time, because you are taking this responsibility, obviously, for this enormous community and sharing that information on as well as learning about it. And I'm sure at the same time, as you mentioned, the whole point is to reach a point where teaching these methods and teaching on these devices becomes more of a global practice where it's not just during crisis, it's every day. So do you feel like you learned something about remote teaching now and then how it can be used in the future to that audience of up and coming doctors in med school, or just doctors who are continuing education and trying to learn new things?

Dr. Mauri: I think it's interesting, there's some things that come really easily at that level of medical education. When I think about the generation that are in medical school and residency, they're really accustomed to learning a lot virtually. I think it's a balance. We won't be able to do all of this virtually. There's an element to the interaction. With patients, that's just so much in the moment and will be difficult to replace. But everything is getting better and getting stronger in terms of, we can see more about how patients are doing, we can hear more from them through apps on their phone, whether they're directly to the patient or through their devices. And so it's constantly improving in terms of how much closer we can get to an in-person contact through these virtual methods.

But I think as we were alluding to earlier, the most exciting thing is that, in a situation where you might have remote communities within the same country, or geographic locations, where there may not be specialist available, this really just takes it a step further at being able to communicate more remotely and in a more specialized way. So it's not just being able to pick up the telephone and it's more than using a video conference call, but it's actually being able to see how a device is programming, program a device remotely, and educate

physicians and other caregivers on how to optimize the use of the device, even without having to send people back and forth across locations that might make it difficult or cumbersome.

Laurel: You mentioned that remote training on these devices, it's an evolving field. But is it possible to remotely train on a complex procedure like surgery?

Dr. Mauri: That's a great question. I think one of the really exciting areas that we're working on is, again, back to the topic of AI that you brought up earlier. It's taking data across multiple surgical procedures in order to use that as a roadmap for individual surgeons to improve their individual care of patients. We have data across multiple similar procedures, and that can be used for image recognition. And when that's applied directly during a procedure or to prepare for a procedure, it can help a surgeon who's either in training or doing something complex that they don't do frequently avoid critical errors. So I think this is just around the corner for being applicable. I don't know if it's a full scale turnover of the way that training is performed. The model for medical training is really through apprenticeship.

You see a procedure and then you do it. Well the motto is you "see one, do one, teach one." And this makes that process hopefully safer, as well as more effective and efficient. So that in-person work together with a mentor, I think, will still continue, but I think this is a way to be able to experience things that you haven't been exposed to and to learn in a more efficient manner, if one can learn from thousands and thousands of prior procedures through data.

Laurel: It's really quite remarkable when you think about how quickly all of this progresses. And year over year, the AI gets faster and smarter that there's more data, where we can get more information from that data and all of it is to really progress the benefit of patient outcomes and help doctors just be better at what they do. Are you sometimes astounded when you think about that from when you were in med school and starting out to the progress that has been made today, and then in 20 years, 50 years, what the progress will be then as well?

Dr. Mauri: Yeah. I am. I mean, I think whenever you have a conversation like this, you take a step back and you realize just how dramatically the world of healthcare has changed in the past 10 to 20 years. It's very exciting to imagine what's next and I don't think that these things are that far away. Obviously, there are challenges, right? It's the getting the high quality data, being able to make sure it's put together in a meaningful way. There's a lot of work in that. It's not simple, but at the same time, it's getting easier to do that work. And I think it's incredibly exciting. You can literally see the progress happening.

And when I look back on the last 20 years and think about, we're already doing a lot remotely, we're already doing just the innovation that's happened in terms of the application of Bluetooth technology, but then even more importantly, miniaturization as well. Even something that seems simple, it's really revolutionary just by scaling down on the size of batteries, on the size of implantable devices. It makes real impact for patients because smaller devices mean faster recovery times. It means the difference between somebody having to stay in the hospital overnight or staying in the hospital for a week. And when you think about it that way and how quickly that transformation has happened, it's really exciting to be a part of it.

Laurel: We should bring back in that transformation, which I feel really is with your role within the company, right? So Medtronic is a 70-year-old organization, it's been through many evolutions. And then your role, sort of being the chief of analytics here. What is it like to focus on data strategy? I mean, you're also thinking about it in a bit of a broader area as well. Of course, the data from the devices and exceedingly important how you treat the data and what you learn from it is very important. But how do you then really corral all of the data to

build a strategy, to help evolve the company itself? And then in turn, what you're doing becomes basically the example for the rest of the healthcare community.

Dr. Mauri: If I had to boil it down, I think... I've been at Medtronic just for two years now, before that really worked as a clinician and as a researcher. But I think that the motivating factor there, both for me personally, but also for the work that we do in the company, has been to support the advancement of technology as a way to improve health for people. That really is the motivating factor and drives all of the work that we do across the company and, specifically, motivates how we approach data science. Data science, I think when you think about it, it's not an abstract science. It's the application of data skills to specific areas of interest and in this case, it's healthcare. And so, I think what's exciting about the company and setting is that we have this amazing technology that, in many cases, is able to also collect data and give us this strong link to our patients and also to physicians.

And we also have this core engineering and data science and medical and clinical expertise. And it's by bringing all of that together, that I think we can continue to really have an impact on health for people. And that's really powerful and motivating, I know for me, but also really important for the company. So I think we're just in a really unique position, but it's also important to know how dependent we are on partnership with the multiple parts of this ecosystem. These are the hospitals and patients and regulators and technology experts. And so it's through that collaboration that we can make this most significant advances that have the most impact.

Laurel: And I think that's what everyone wishes their job would be, right? You use the data, you create good things to help people have better health and a good life, right? And a longer life.

Dr. Mauri: Mm-hmm (affirmative).

Laurel: Just to kind of wrap this up, during the COVID crisis, obviously companies have had to step up in various ways and you mentioned the ventilator project. I couldn't help but hear in the news that Medtronic had opened sourced plans for one of the ventilator designs. What would that take? What was that like behind the scenes? Was that a complicated – I must've been a very complicated way of doing this, but what were the results? What did you see happen?

Dr. Mauri: So first I think the motivation there was just to be able to do whatever we could as fast as we could. And we recognized that our most complicated ventilators that we could scale up production, maybe will be scale up five-fold, but it was still wouldn't meet the demand was that was out there. And that a simple design could be something that could be scaled by collaborating or even just providing the code to the many companies that were interested. And this was in a period of time, as we all know, where a lot of manufacturing was reduced because of reduced demand for other types of products. So we wanted to respond to that and be able to supply more than we could do on our own. And that's really why there was this real excitement to providing the open source code for how to manufacture these ventilators.

And it was through collaboration with the FDA that really facilitated our ability to do that because we needed to get their approval as well, which happened very quickly. I think one of the interesting learnings there is that even our simpler designs are pretty sophisticated. And so some of the most successful programs in terms of actually manufacturing the ventilators were through collaboration. But at the same time, I think being able to provide it and then see who's able to do it was just a very good learning experience.

Laurel: Are you expecting one of the shiny lights that comes out of the covid-19 crisis is this spirit of collaboration and community and working perhaps a bit quicker than was possible in the past?

Dr. Mauri: Absolutely. Absolutely. It's really heartening to see people come together all over the world. The one amazing thing about it has been just how small the world seems across disciplines, across countries when we're all facing a similar foe.

Laurel: So true. Dr. Mauri, thank you so much for joining us today on what has been a just fantastic conversation on the Business Lab.

Dr. Mauri: Thank you, Laurel. I really enjoyed it. I appreciate it.

Laurel Ruma:

That was Dr. Laura Mauri, the vice president of Global Clinical Research & Analytics at Medtronic, who I spoke with from Cambridge, Massachusetts, the home of MIT and MIT Technology Review, overlooking the Charles River. That's it for this episode of Business Lab, I'm your host Laurel Ruma and I'm the Director of Insights, the custom publishing division of MIT Technology Review. We were founded in 1899 at the Massachusetts Institute of technology. And you can find us in print, on the web and at dozens of online and live events each year around the world. For more information about us and the show, please check out our website at technologyreview.com. The show is available wherever you get your podcasts. If you enjoyed this episode, we hope you'll take a moment to rate and review us. The Business Lab is a production of MIT Technology Review. This episode was produced by Collective Next.

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