Innovations in Ostomy: Measuring Sh** for a Living

presented by Michael Seres, Founder & CEO, 11Health
at 10x for Design and Manufacturing – San Diego 2019

Michael Seres: As you're probably all aware, about 133 million people in the U.S. live with long term, complex chronic conditions. So it's a huge burden of cost to the healthcare system that continues to spiral out of control.

And really, we have to think about a healthcare system that moves from reacting to problems to one that prevents problems. And my company, 11Health, which I get the privilege to talk to you a little bit about today, focuses on those people connected to medical bags, and specifically as Joe said, ostomy bags.

In case you don't know, and hopefully you've digested the beautiful lunch, an ostomy is basically where part of your intestine, part of your bowel is brought to the outside of your body and you literally go to the toilet in a bag.

My son, sitting at the back with the mobile phone, takes great pride in telling his friends that his dad measures shit for a living. I might have put it a little bit more eloquently, but then he's 21. Actually, 11Health now is the only company that analyzes what comes out the body, to determine how we think about what we put back in the body. Let me explain to you a little bit why.

About Me
I was diagnosed with the incurable bowel condition, Crohn's disease, age 12. I had my first surgery at 14, and 25 further surgeries later, an intestine – most of you might know starts at around six foot in length – ended up at 40 centimeters and stuck to my pelvis. I was in what's called intestinal failure; kept alive through intravenous feeding for 22 hours a day.

Then, on October the 8th, 2011, at exactly 6:01, I kissed goodbye to my wife and didn't know if I'd see my kids again. And I became the 11th intestinal transplant patient in the UK at a hospital in Oxford. Since that moment, I'm a two-time cancer patient and currently waiting on a stem cell transplant.

So, now you know my background and you know more about my insides than most people know about my outside, you'll understand why 11Health is not simply about making money. It's about the ability to make a difference to someone else's life. I've been connected to medical bags of a different variety for about 35 years, and so I'm also a customer of 11Health, so to speak.

As Joe very eloquently put, you go home after ostomy surgery not just with sheets, but a plastic jug, and with a request from your doctors: “please measure your shit in this jug and tell us how much is coming out your body.” Because unless we know how much is coming out, we don't know what to put in and you're going to be readmitted on a regular basis.

The reason I put this slide up is actually the icons you can see to the right, because the icons to the right, as we talk about medical devices and we talk about solutions in healthcare, are really how I live my life today as a 21st century patient and about how we all are going to start to live our lives in the future.

How we interact with patients is very different today to, perhaps, how it has been in the last few decades. The National Health Service, NHS, is the UK National Health Service that saved my life. The doctors you see up there. But there's also a lot of social media icons. That's where I met Joe, obviously online, not Tinder, or Grindr, but, I swiped left. Didn't work. But no, Twitter, YouTube, Google, Skype are really all how I consume my life today; and it's really about building a toolbox, a kit for patients and how we interact.

And now as I'm a patient in the U.S. health system, I get to see the difference between healthcare that's a right and healthcare that's a privilege. But we won't go into the politics of that. But fundamentally, healthcare, for me, is just a series of relationships. It's not actually about the device or the technology or the compliance. It's about a series of relationships. And the closer you get to those relationships the

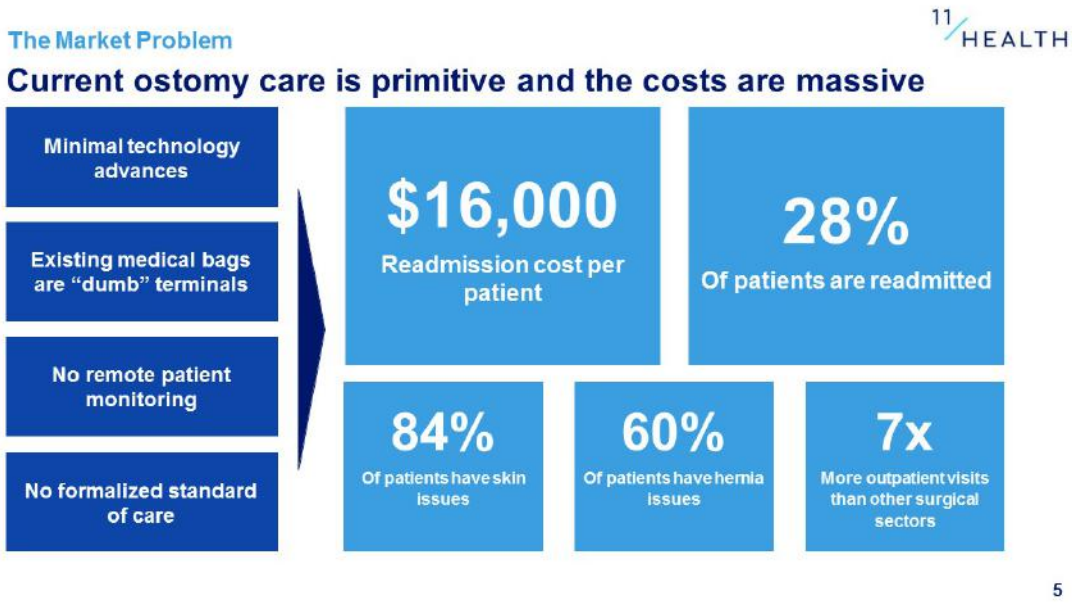
closer your outcome will be. Because as a patient, from my perspective, I don't actually want to consume health. I want to consume my life, and I want to live my life. And I want to have the tools and the equipment and the technologies and the devices around me to allow me to engage in life, not have to think about health the whole time.

The Market Problem
So, why medical bags? A few facts for you that might actually be quite interesting.

The ostomy market itself is a $14 billion market. That's a lot of shit. And it's part of a wider medical bag market. There are about five million patients around the world, one and half million patients in the U.S., and 130,000 people will have a bag attached to their body every year in the U.S.

For those of you who may have experienced it in your lives or know families or friends that do so, the challenge with managing a bag is they do burst. And they do leak, and they do spill. And, as Joe mentioned, your nerve endings are cut, so you don't actually know when it's going to happen. So, quality of life for patients in that situation is quite a challenge.

Just to give you a few facts and figures, because we're in that industry. An ostomy, of which there are three types, but the two biggest, colostomy (closest to the colon) and ileostomy (further up the body) are the number one and number three most readmitted surgeries in the United States. So, huge problems.

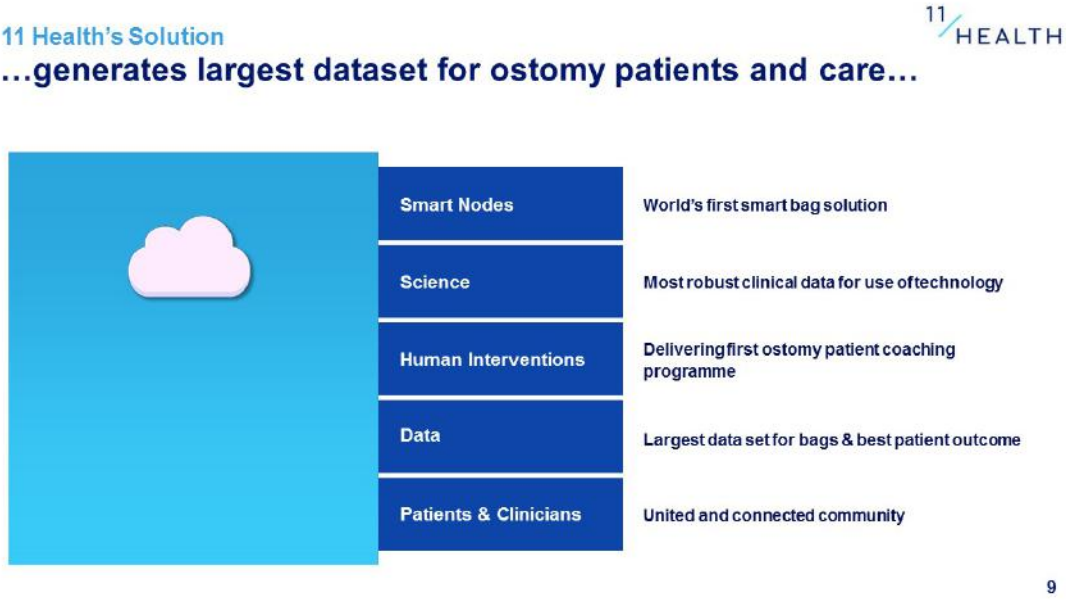


84% of patients have skin, wound issues, lots of complications. And there's no standard of care, sadly, for patients living with bags. It's quite an antiquated sector, generally coming out of people that have bowel cancer or inflammatory bowel disease. So, quite well-known, quite established conditions. And actually, it dawned on me, lying in bed in Oxford as these bags were leaking, that healthcare companies in this sector have actually had long enough to try and fix the problem. But what we see quite often is, we build further products to patch a problem the previous technology or the previous thing has created. And, actually, why are we doing that?

There are 2.1 billion dumb bags produced a year. That's 2.1 billion bags that are causing other things to happen that we can then layer it on with other products and sell more things. And we can just spiral and spiral. So, you have to be a little bit crazy to think you can fix it.

11Health's Solution

So, what we did was, at 11Health, we built a smart bag. We dissected an ostomy bag; we put sensors and technology in the bags to actually try and measure what's coming out in real time. And see how we can get from there, we can start to pick up early warnings of the leaks and spills and infection markers, et cetera.



The big challenge everybody is talking about in healthcare is data. What about all that data? What about all that technology that's coming out? What about that information we all know everybody's thinking about, data? How do we manage it? How do we deal with it? And, oh my goodness, what about HIPAA and compliance around data?

There's an interesting fact out there that the majority of patients share more of their healthcare data on social media than they do anywhere else. So, as a long term patient, there is nothing I wouldn't share of my data to give me an opportunity to live a longer life. Or be at a school concert with my daughter or be at my kid's events. Because actually, what happens when around data is, we get caught up with a vocal minority who say we can't share this and we can't share that. And you're absolutely right. There have to be standards, and there have to be opportunities.

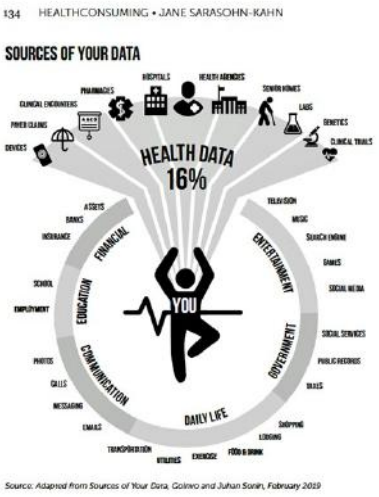
But, actually, sharing the data gives us an opportunity to find solutions. What we happen to do in ostomy is create the largest data set of information so that we can actually try and deliver a solution. And what that allows us to do is work out in real time not only what's happening from the bag but what's happening around contextual data. Because just as important to people on devices and people on equipment is, what's happening in your everyday life? When are you consuming your food? Are you sleeping, are you eating, are you walking, are you talking? All the information we can pick up from Fitbits and Apple watches and this and that.

But how do you bring it together to look at a patient's life in the whole? How do you think about putting that together? And then what is the difference between clinical data, clinical evidence, and real world data? And how does the industry and how do clinicians and how does the FDA and how do other bodies look at the difference between clinical data and real world data?

For me, it's the combination of two that actually allows us to deliver some personalization around healthcare. Because as we move to a healthcare industry that's going to be about outcomes, about value-based care, moving away from fee-for-service to bundle payment models to outcomes, we have to understand what's important to an individual in order to deliver those outcomes. And you can't do that without talking to the individual.

Sources of Your Data

I mentioned to you that we share more of our data on social media. In fact, only 16% of our data comes from a health environment. The rest of it comes from outside, our real world. And as you can see on the top right there, it's Google and Facebook. And the others are starting to try and predict trends.



So how do we use that data to deliver better outcomes? Facebook and Mark Zuckerberg conducted an organ donation campaign on Facebook. It got more people registered for organ donation than any other healthcare campaign in the history had ever done. So, we have to think about where all this data is coming from.

11Health – Combining Technology and Human Interventions

At 11Health, I think what I'm particularly proud about is how we then interact and what we do. And this is the combination where you see technology and human interventions. What we have the privilege to do is buddy up a brand new patient with an osto-mate.

From pre-op to the continuum of care, they get a buddy; they get a support network. They get someone who lived that experience, who's not only using the technology but has walked in their shoes. Part of pre-op set up, and we now have 40 patients that have gone through our health coaching program.

As you're starting to see with Medicare and other commercial pairs, you can start to bill and get reimbursed for patient coaching. And we can start to see how that changes outcomes. As an example, with our coaches, we've been able to reduce the clinical interaction by 40%. We've been able to take a readmission rate of about 30% of patients in the first 90 days down to zero, through a combination of technology and human intervention.

It's not rocket science. Because the single biggest reason patients like me get readmitted is dehydration. Can't stay on top of fluid balance. Too much output, not enough input. Logic to most people. Most of you will go, "I feel a little bit thirsty. Maybe my lips are dry or maybe I'm feeling a little bit tired. I'll take onboard some more water." Patients like myself can't absorb that. We can't regulate our fluid balance in time. So constantly you're dehydrated, you go back. IV hydration, $16,000 of costs. How do we prevent it?

The New Gold Standard in Patient Care

Well, we can actually prevent it with a combination of human interventions. And what we're trying to do is deliver a new gold standard. Because what also strikes me as you start to build solutions and we start to all think about how we build new technologies and the impactive devices – how many different standards are out there?

Just by way of a little anecdote. We were working at Cleveland Clinic. Cleveland Clinic have 18,000 ostomy patients and 21 colorectal surgeons and no standard of care. Every single person from every single different surgeon will be discharged with a different protocol. And a different way of doing it.

So how do you cope in that environment as a patient? And also, how do you build a solution, that doesn't have a standard of care? Well, that's where it goes back to, hopefully, the data and the ability to do things.

Patient Innovation
And as I come to the end of my talk, because Joe told me to be brief-ish, I wanted to raise a couple of challenges with you guys today as you think about it.

In healthcare, we have amazing people that deliver amazing solutions. You know, healthcare is predominantly paternalistic. The very best go to med school, trained unbelievably well, and we have to deliver a solution. But, as an end user, that solution is always given to us. It's not often co-created with us.

So as we start to think about designing and developing solutions of the future, why wouldn't we ever start with the end user? Why wouldn't we ever build a solution from all those end users? Because in my case, the end user is me, the patient. But it's the surgeon who's operating. It's the nurse who's got to deal with it. It's often the CIO, because I've got to integrate the data. It's regulatory and compliance. Why wouldn't we sit around the room together at the beginning and build a solution from the ground up?

In almost any other sector outside of healthcare, we start with the end user. Tesla wouldn't make an update if it wasn't what the customers wanted, et cetera. So my challenge back is, as you build CEOs, CIOs, chief nursing officers, chief this, chief that, why wouldn't you have a chief patient officer on board?

There's a movement in the U.S – #WeAreNotWaiting. It was created by a great friend of mine, Dana Lewis, who's a diabetes patient, and she built an artificial pancreas and is now partnering with Medtronic in building that. There's Sara Riggare, a Parkinson's patient in Scandinavia, who effectively built the quantified self-movement. She sees her doctor once a year. Everything else is monitored through her Apple watch and other gadgets.

So there's this movement of patients. Patients like me going, “We can't wait for all you guys and all the companies to build solutions. We have to do it ourselves.” I live with a 50/50 survival rate. That's the odds I live with every day. I can't wait for years for a sector to come up with a solution.

So this is my last slide. My final request, other than putting chief patient officers, on all of your companies and boards, et cetera – Why are we not obsessed? Why do we not start with an obsession with the end user? We have to think a bit differently to change healthcare. Thank you very much.

(Applause)

Joe Hage: As a performer in a chorus, when we sing a ballad, the audience is just like, and there's this pause before they applaud. And that's how I felt about your presentation. Because it was so personal and so relevant. And my first question is not for you.

Michael Seres: Good.

Joe Hage: It's for your son. So you're going to have to put down your phone. 21 year olds, I mean, am I right?

Michael Seres: Please embarrass him.

Joe Hage: First, I'll ask a question, to which I know the answer. Are you proud of your dad? But then, a quick follow up, I understand you're 21. Dad's been having surgery as long as you've been alive. What's it been like for you and the family? Please stand, introduce yourself and tell us what it's like to be the child of patient like that.

Nathan Seres: So I'm Nathan, and I'm his son. And, I would say it's been tough, but I have an extremely strong dad. I want to say just dad, but my mom as well. They're both incredible. And I work for him now as well. I'm the digital content producer for his company. So, good things come from bad things basically.

And he hasn't made it hard for me, you know, there would be Sunday visits. Every weekend after my Bar Mitzvah, we'd go up to the hospital and see him in bed, every Sunday. And my mom would stay up, stayed up there for, I think, about 8 weeks. But, we were around a community of people that helped us and people that loved us and, you know, supported us. And it wasn't hard because they made it easy for us. Yeah.

(Applause)

Joe Hage: So, I'm sure there are other questions. But I do want to ask you, I recognize this has been basically a life-long journey for you. And you mentioned, you were diagnosed with Crohn's at age 12.

So, even at that stage, it's been part of your entire adult life. You have the skills needed to become an entrepreneur for a business that's so meaningful for you. I think it's a rare situation, certainly as a teen, that someone would be diagnosed with such a situation and, then, make it his life's work to do something about it. Can you talk to us, just briefly, about, did you then go to school and say, “I'm going to be an engineer,” or “I'm going to enter medicine”?

Michael Seres: Ah, no, I really didn't. All I wanted to be was a soccer player. And, then, realized I was pretty shit at that, so that was never going to happen. Excuse my language.

Joe Hage: We've been talking about shit the whole time, so you're fine.

Michael Seres: I think the truth is there were two defining moments. One, I was 14 at the time, I went to see a gastroenterologist who ended up becoming the Queen's physician. So, I guess if he could stick a tube up the Queen's backside, he could do it to me, it was fine.

Joe Hage: Classy.

Michael Seres: Classy. But he said to me as a 14-year-old, “I won't take you on as a patient unless we're a team. You're going to teach me as much about what it's like to be you, and I'm going to teach you what it's like to be me, and we do it as a team.”

And, then, when I went through transplant, my surgeon said the same thing, “This doesn't work. You won't survive unless we do this together.” And after transplant, I was given the greatest gift, another life. Out of some family's worst possible moment, they gave me the chance of another life. So the opportunity to give back is huge. That's the mission. It's just to give back to something.

Joe Hage: What became of the 10 before you?

Michael Seres: Three are still alive. And, I was actually the first of a re-started program at Oxford because survival rates hadn't been good. But I had an amazing surgeon, a guy that came from Miami. Came from Miami Jackson Hospital and re-started the program at Oxford, a genius. And, yeah, my best friend, we speak every week.

Joe Hage: Just the idea of it, I mean I'm sure everyone has someone in their life. I'm thinking if I were to kiss Beth goodbye and say, "I don't know if I'll ever see you again." I mean, you must have just been terrified.

Michael Seres: Yes, of course, but I had absolute trust in my medical team. And I think, there isn't a person in this room who hasn't faced challenges or their family faced challenges of different degrees. Everybody will have had something. And so, you choose which way, you either go left and you give up or you go right and you get on. And you know, I'm lucky like that.

Manish Sharma: Manny Sharma. It's very interesting about you, which I find fascinating, is you had a near-death experience literally, right? That's why you had such clear perspective on what it makes work. And that's what I find when we look at medical device industry. Patient centricity that we all talk about it, but not most of us are able to do it. We always think physician is our customer. But really, patient is our customer.

But only folks who have that near-death experience does it truly understand where the value really lies. Whose life really matters. Can you talk a little bit about, as you've taken this journey, like what is your advice to device companies and others? Once you have all of these, and you're talking to them about creating a chief patient officer. But they can't get out of their own way, because they're still doing the things the way they are doing. And only the folks like you who have that type of experience have the clarity of thought, what really matters.

Michael Seres: I think, it's also very hard because, if you're building a med device company from a company perspective, you have to follow the money. And, ultimately, you get focused on – how am I going to get paid and how am I going to get reimbursed?

But I think you've got to have clarity of, why am I doing this and who am I doing this for? And quite often, the patient isn't the only end customer. The physician is a customer. The payers are customers in their own way, and patients or others.

And I think what's happened over time is, that's got skewed so heavily towards physician and payers that the patient has, in a sense, been an afterthought, or just re-delivering a solution.

I think the advantage people like me have got today is, the healthcare trend is moving towards the consumer. It's moving towards the patient. We are making more decisions. We are much more informed than we ever were in the past. And love it or hate it, Google and other things, we all come to the table now with a different mindset.

The challenge for medical device and for anybody in the medical sector is, in a sense, are you brave enough to engage with patients? It's really hard for them to move, effectively, 180 degrees now. But I think, those that don't, will be the ones that won't survive. Because the power now is going into the consumer's hands. It's coming away from physicians, fee for service is changing. Value-based care,

outcomes-based care, how do you know how to deliver a solution for an outcome unless you ask the end user what outcome's important to them? So I think the timing is also important.

Joe Hage: I'm so glad you joined us today, Michael. Let’s hear it for him.

(Applause)