

AN INCREDIBLE JOURNEY

BY JENNIFER JACOBS

It was a clear April day when two young men walked into Jaffri Ibrahim's office in Bukit Jambul, Penang, last year. They had told the Malaysian Investment Development Authority (MIDA) that they wanted a place to manufacture their groundbreaking product — an artificial intelligence-powered, Bluetooth-connected stethoscope — and were sent to meet the CEO of Collaborative Research in Engineering, Science and Technology (Crest).

Jaffri and his team listened to Dr Nayyar Hussain and his brother, Dr Shamile, while trying to ignore how casually the two physicians were dressed. "My team and I sat there silently as the pair explained what they had done to effectively redesign the principal tool of every doctor into an Internet of Things (IoT) device. It was a stunning achievement even to dedicated technologists, but to find a physician, industrial designer, software developer and AI practitioner all rolled into one just blew us away."

Dr Nayyar is certainly an unusual person. Talk to him for half an hour and the conversation turns from the Stethee — the AI-powered stethoscope — to the beauty of primitive shapes (he had studied industrial design) and music (he had owned a music production outfit in his late teens and early twenties). He had even rejected an early recording of Britney Spears' *Hit Me Baby One More Time* because he thought it was not good enough to make it.

Dr Nayyar came up with the idea for the Stethee — a stethoscope that you could place against your chest to record the sounds produced by your heart and lungs and beam them to the nearest smart device via an app — when he was a practising physician. He had spent seven years working in a hospital and found the traditional stethoscope very limiting.

"When you use the traditional stethoscope to listen to something, everyone has to be quiet. You also have to be near the patient. Once, I was examining a sick child and she sneezed all over me. And I thought, there had to be a better way than this," he says.

Dr Nayyar bought a few electronic stethoscopes, but quickly discarded them. "They had been designed by engineers rather than clinicians. For clinicians, it is a very fast-paced environment, especially in an emergency room, where you have seconds to save or change a life," he says.

"So if anything was too complicated to use, you threw it down and grabbed whatever you else you could. With the technology that existed before, we had to put it in, get the setting, pair it ... it was so hard to use."

This, he says, is because most medical devices are engineering solutions rather than practical ones. "My design knowledge allowed us to solve medical device problems, both from an engineering point of view as well as a clinical one."

Dr Shamile, who is chief medical officer, helps the team to stay grounded. "He is a pure clinician and not

a geek. So, if something has more than three steps of complication, he says, 'No, it doesn't work.' He is a great filter as he looks at things very objectively," says Dr Nayyar.

A stethoscope may be a 200-year-old technology, but it performs a very crucial function. "It listens to the sounds produced by your heart and lungs. It is a diagnostic device that lets you know if you have a regular or irregular heartbeat," says Dr Nayyar.

"But the Stethee does that and more. It records your heartbeat and uses analytics to compare data. It also collects geolocation data — it knows your GPS location as well as the humidity and temperature of where you are, and attaches that information to your sample."

He points out that we currently do not know how our environment, location and altitude affect our heart and lungs. "Obviously, we know that pollution and pollen play a part in illnesses such as asthma. But with the Stethee you can track more than that. You can see where the disease is spreading. So, if you use this in a remote community and suddenly notice that people are having a fast heart rate and have difficulty breathing, you can track the disease as it spreads through the community."

The AI-powered device also provides objectivity. A traditional stethoscope, Dr Nayyar points out, relies on a doctor's experience and judgement. Sometimes, two doctors can listen to the same patient and come up with differing diagnoses. For example, was that a Grade 3 or Grade 4 heart murmur?

"It is all subjective and there is no research value in that data," he says. "With the Stethee, you can get quantitative data. You can put it in spreadsheets and you can do calculations. Then, you can compare the data. I can compare my reading with the one I did six months ago. By having all that data, you can become predictive."

INVENTING THE STETHEE

How did Dr Nayyar turn his idea into reality? "I discussed the concept with a friend from my engineering days and told him what the device should be like."

But it was not so simple. For one, medical devices are incredibly expensive to develop, simply because of the regulatory hurdles. "If you tell someone you are in the medical device business, the price goes up 10 times. Components have to be sourced from ISO-approved suppliers, so it is a very expensive area to get into," says Dr Nayyar.

The brothers invested US\$250,000 to come up with a prototype. "Once we had the prototype in 2015, we put it on Kickstarter. We knew we had something special because we got all this great feedback," says Dr Nayyar.

But two weeks into the Kickstarter campaign — by which time it had managed to raise US\$700,000 — the platform informed them that they could not proceed because the product was a medical device and was against its policy. "They gave us a choice: either we suspend the campaign or they cancel it. So, we decided



Dr Nayyar with the FDA-certified Stethee Pro

to suspend it," he says.

Dr Nayyar was not fazed by this because in those two weeks, Stethee had attracted the attention of the UK's National Health Service, the Massachusetts Institute of Technology (MIT) and doctors from all over the world, who were eager to support it. "That was how the MIT connection happened," he says.

"Immediately after Kickstarter, I flew to Boston, met the professors and presented the product at the MIT Media Lab. MIT is the best engineering university in the world, hands down. The best of the best go to MIT and the best of the best at MIT go to the MIT Media Lab."

Dr Nayyar received incredible feedback after presenting the product. "So much so that one of the professors there — Professor Anthony Sinskey, who had been at MIT for more 50 years — became the chairman of our clinical advisory board. He has a huge network and access to engineers that really helped us to develop the product into what it is today, which is fantastic! You can't plan these things: you pivot, you adapt and you look for opportunities. That is the journey of building something," he says.

Dr Nayyar started his company, M3DICINE, in 2014 and applied for the US Food and Drug Administration (FDA) certification the following year. The process took two years. "We only got our FDA certification in November last year, which is a huge milestone. It separates a gadget from a serious medical device because the FDA certification is the most stringent, robust, time-intensive and expensive certification you can get."

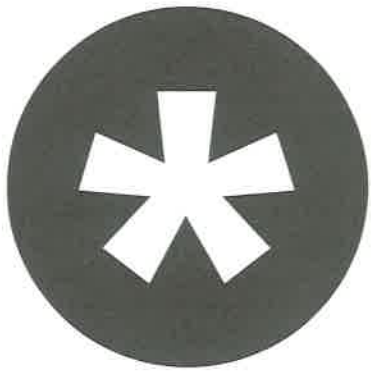
Dr Nayyar and his brother selected a Malaysian manufacturer (who was doing something completely unrelated) based on their perception of his actual capabilities. "We picked the manufacturer based on what we wanted and what we knew they were capable of. It took about a year and a half to get them up to scratch because to develop a medical device, you require the ISO 3045 certification," he says.

"It is a great partnership and a great story of people coming together to develop this product. I think we are very lucky because we found the right people to help drive the product, from MIT to Crest, who could help accelerate the manufacturing process."

"You need to have that support structure. It is not



TODD HELMANN



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> **Nayyar**

always about the product. It is also about the people around the product: the common vision, the common goal, the passion..."

GOOD MEDICINE

In 2004, Dr Nayyar and his brother were running some private clinics that were growing at a respectable pace. These clinics were acquired by a multinational corporation. Then the duo entered into a joint venture with the Australian government to set up an integrated care facility.

"M3DICINE is a spin-off of that company. Because of my engineering background, I wanted to start a medical device company. As we had run other companies, we were able to channel a bit of funding towards this initial development. There were three of us — an engineer, a software developer and me," says Dr Nayyar.

The "3" in the company's name stands for its core expertise — hardware design, software design and AI. "It is a play on words because medicine is good for you. Medicine will help you, so take your medicine every day. It is kind of a fun name and brand as well," he says.

The company came up with a basic prototype, software and analytics. "Once we had proven our prototype, we put in a bit more funding and brought in three or four more people. Right now, we have 14 people. We have hardware, software and AI divisions. It is not big, but we have a core group of developers. We work with engineers from MIT and the Cleveland Clinic. We also have advisers and clinicians to help us," says Dr Nayyar.

When the company unveiled the product on Kickstarter, it received offers from doctors all over the world. "We were able to tap into that to get some great insight and feedback. We grew a great network out of that — doctors from all the world, people from 103 countries, pledged to buy our product on Kickstarter. This was phenomenal because it showed that the device resonated globally," he says.

When the Kickstarter campaign was suspended, the team told its backers to go its website and register. "What we had was an army of believers and some great contacts from around the world. We had inspiration and validation," says Dr Nayyar.

After Kickstarter, the real work began. "We didn't quite realise what we were up for in terms of the FDA certification. So, it was a steep learning curve. Plus, being based in Brisbane and Boston, we travelled quite a bit between the two places and that is a long haul," says Dr Nayyar.

"In Brisbane, we would start work at 7am and finish at 6pm or 7pm. But then Boston would come online and we would work with them from 9.30pm until about 4am."

M3DICINE's FDA consultants were in Minnesota, the US — yet another time zone. "So there were late night calls and early morning Skype calls. It was pretty intense for about a year and a half," says Dr Nayyar.

Having advisers from MIT, the Mayo Clinic and Cleveland Clinic meant that the company had to be on its toes at all times. "These incredible people get

offers from top-tier companies all the time. So, for them to say that they want to work with you, that is pretty humbling."

THE MALAYSIAN CONNECTION

It was Professor Sinskey who suggested looking at Malaysia as a base for manufacturing. "We were looking for a place to manufacture our product. We went to Taiwan, South Korea and China. Then, he recommended that we look at Malaysia. So, we met up with Mida and they sent us to Crest," says Dr Nayyar.

Professor Sinskey had done a lot of work with Malaysian universities and research institutions, especially in the palm oil sector. He had written the first and second national plan for biotechnology and had become aware of what he calls "the outstanding device manufacturing capabilities in Penang".

"After talking with Jaffri for about 15 minutes, I was very impressed. He got the vision and he got the product. He made a phone call and two hours later, a manufacturer walked in. And the rest is history," says Dr Nayyar.

"I know Crest is a catalyst, but this was supercatalysm. The important thing was that Jaffri had the vision and the manufacturer also had the vision. And when they saw the prototype, they agreed that it had a lot of disruptive potential and could do a lot of good — in the sense that it is AI, it is something that can go global and help a lot of people."

Dr Nayyar met Datuk Dr Noor Hisham Abdullah, the director-general of the Ministry of Health, two years ago. "We showed him the product and within 10 minutes, he had put it on Facebook saying, 'This is the future of healthcare'. So, you have a director-general who is a great supporter and a champion of innovation, you have Crest, you have the manufacturer, who invested in a new line and got certified so that he could manufacture medical devices ... it is like everyone is trying to help, which is incredible," he says.

Everybody seems to want a piece of the Stethee. "I was speaking to a doctor at Institut Jantung Negara who offered to come on board in a clinical advisory role. He said the research value of this is off the charts because the data is novel and we can do incredibly high-end research on heart and lung diseases. He thinks we could potentially rewrite the textbooks on what we thought we knew about heart murmurs and heart patterns," says Dr Nayyar.

Before this, the data depended on the examining doctor's ability to listen and diagnose. But now, the machine is doing it and it can calculate things to the hundredth of a millisecond, he says.

M3DICINE has been approached by pharmaceutical companies that want to use the product in drug research and development. "With the Stethee, when a patient takes a new drug, they can immediately record whether the heart rate goes up or down. They can use it as a compliance tool. They can track how many times a day the patient takes the drug by checking to see if they have a Stethee recording. They can monitor these things from anywhere in the world."

Basically, says Dr Nayyar, all the experts have their own idea of how to best use the Stethee for their particular disciplines. "Every health professional I have spoken to — cardiologists, paediatricians, obstetricians, respiratory physicians — they have all had interesting ideas on how to use it. To me, that versatility is the sign of a great tool."

How much time can the Stethee save? "We did an evaluation in London at the Royal Brompton Hospital and found that it took a doctor, on average, four minutes and 26 seconds to capture six data points. It takes the Stethee 20 seconds to capture 16 data points. So, it saves four minutes of a doctor's time. And if you multiply that by 30 doctors, that is almost two hours of savings," he says.

Dr Nayyar says the Stethee has attracted so many good people who are eager to work together to help develop it further. "We have developed this really great R&D trajectory and partnerships. One of them is called the Medical Data Analytics Institute, which is a collaboration between MIT, Harvard and Stanford — the top three universities in the US.

"We are able to use the networks as well as brains and resources of these three institutes and work with collaborators in Malaysia and Australia to solve problems and to get the flow of information and knowledge. And that is the important thing — collaboration."