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'SoomSafety': How A Real-Life Recall Scare Led A Father To Develop A Free App That Gives Detailed Device Safety Info

by Shawn M. Schmitt

When Charlie Kim and his family was taking care of their sick child Isabella inside their home, tragedy struck. A tracheostomy tube that Isabella depended on to keep her alive failed, leading to complications. Later, Kim wanted to get to the bottom of what happened and was shocked to discover that Isabella's tube had been recalled. "I was thinking, 'Wait – how did we get this if it's on recall?'" he said. That's when Kim became an advocate for patient safety by launching a company called Soom that developed a software platform to help device-makers iron the kinks out of their distribution chains. But beyond that platform, Soom developed the SoomSafety app, which allows users to scan device barcodes to get up-to-date information about the products, including whether they're subject to an ongoing recall.

Isabella Kim was born in 2012 with a rare airway disorder that required her to undergo a string of surgeries. To survive, she relied on a medical device – a tracheostomy tube – to help her breathe.

Because Isabella required long-term care, her family transformed space in their home into a virtual hospital room where she could receive the best possible treatment.

"Many families that come home from the hospital and then need to give that type of care basically bring home a hospital and create a hospital setting in their home," Charlie Kim – Isabella's father – told *Medtech Insight* in an interview.

In a home-care setting, caregivers must become familiar with "a lot of medical devices, durable medical goods, consumables, pharmaceuticals – all of these things," Kim said. "It's extremely

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overwhelming, because you are trained for two or three hours at the hospital, and then you go home, and then basically a distributor comes in and sets up a bunch of medical devices for you to work with and live with. Those devices are very different from what's in the hospital, so they drop some owner's manuals on your lap and say, 'Here you go – and good luck.'"

Home-care nurses also traipsed in and out of Kim's home to make sure Isabella received the attention she needed. "It was just like a hospital," he said. "You live in a world where a lot of people and a lot of products keep coming and going.

"You just presume that everything is working and everything is great."

But everything wasn't working as intended. Little did Isabella's family know that one of those products – the very breathing tube that was designed to help keep her alive – would turn out to be an unsafe, recalled product that one day caused her to stop breathing. Isabella was rushed to an emergency room where she was eventually stabilized.

"After everything was OK, my wife and I wanted to figure out what went wrong, because we're both people who like to find a root cause," said Kim, who noted that his daughter is now a healthy, happy 7-year-old. "We eventually figured out several things, but the biggest thing we discovered was that her medical device – the tracheostomy tube – was a device that was recalled and was supposed to be pulled off the shelf. But it wasn't."

> *When you're a home caregiver, "nobody contacts you if there's a recall on a drug or a medical device that you're using." – Charlie Kim*

Kim said he was shocked that such an important lifesaving device wasn't properly recalled and had made its way into his home-care setting, and ultimately into his daughter's airway.

"I was thinking, 'Wait – how did we get this if it's on recall?'" he said. "After all, you presume that there's not many of these very specialized devices out there in the world."

Kim went on: "We live in a world today where, if our car gets recalled, we see it on the news, we get emails, we get letters. Or, if we buy Brussels sprouts or broccoli, and there's a nationwide recall of those, the stores are contacting us – there's email, there's just incredible amounts of information that say, 'Bring it back or throw it away.'"

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But when it comes to medical products, it's a whole different ballgame, as Kim discovered.

When you're a home caregiver, "nobody contacts you if there's a recall on a drug or a medical device that you're using," he said. "In reality, when [a medical product] is recalled, there's a certain number of deaths that happen – or something else really bad has to happen – before something is done, and by the time you as the caregiver finally receive that recall information, it can often be too late."

In investigating what went wrong with Isabella's recalled tracheostomy tube, Kim found that the distribution chain for home-care devices can be highly fractured. Such fracturing was to blame for that tube not being promptly pulled from shelves, he said.

The recalled tube "didn't come directly to me from the manufacturer," Kim said. Instead, "it went from the manufacturer to a distributor, then the distributor gave it to a smaller distributor who then got it to us. It was a very, very fractured distribution chain. It wasn't integrated whatsoever, and it wasn't sophisticated."

He pointed out that in a hospital setting, such a recalled device likely would be quickly captured because hospitals operate under a closed-loop recalls system – something that home caregivers and patients aren't privy to.

That's when Kim knew something had to be done to bridge that gap and ultimately benefit patients that are outside the hospital setting.

"I basically made it my mission to say, 'This should not happen in today's world,'" he said. "It should not happen because we live in a time with the greatest technology innovations. Data is absolutely prevalent. Internet is everywhere. Why is this happening and why is nobody tackling this problem?"

Soom Launches In 2015

In 2015, Kim took matters into his own hands by launching a company called Soom – Korean for "breath" – to ensure enhanced safety awareness around medical products. The firm's first project was a software platform for device-makers to help them better manage their distribution chains.

"The Soom platform makes it possible to query information dynamically, reconcile data conflicts and fill in the gaps between related data," the company explains on its website.

In our interview, Kim elaborated: "Firms can use our software technology to help them connect the dots internally, for their supply chains, in order to create full interoperability – to give that full picture of their supply chains in order to have that full lineage of the product through the manufacturer, supplier, down to the patient."

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Companies that use the platform pay a licensing fee that is scaled based on their size and the volume of products they're making.

"If you're a small company and not moving that much product and it’s not complicated, you pay less. If you’re a huge enterprise and you’re moving a lot of product information, and we’re filtering and ranking and sorting databases from all over the world, you’re going to pay a little bit more," Kim said.

Soom's Free SoomSafety App

Beyond its distribution-chain platform, Soom developed the SoomSafety app. Released in June for free-of-charge, SoomSafety allows users to scan medical device barcodes to get up-to-date information about the products, including whether they're subject to an ongoing recall.

The app – which can be *downloaded via iTunes* – draws from information found in the US Food and Drug Administration's *openFDA* collection of databases.

Pharmaceutical information will soon be added to SoomSafety.

The app's "search functionality takes barcode information, product information and lot expiration, combines all that information, and searches the FDA's recall database and product database to compile highly accurate and relevant information about a particular medical device," Kim said.

If the app discovers that a device has indeed been recalled, it provides the user with next steps to take to make sure the product is removed from circulation. The app also stores the scanned device (until the user removes it) and pushes alerts if the product is recalled in the future.

"You can scan the device once and add it to your inventory, and then the app will constantly ping and search, and look for any recall information," Kim said. "If recall information comes up, the app will alert you. So, until you delete that product out of your inventory, you're going to constantly have that device monitored.

"SoomSafety isn’t a reactive app; rather, it's proactive."

The app also gives users the latest safety and use information for whatever product they're scanning. And it allows users who might be caring for multiple people to categorize each of them

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within the app.

"We wanted to make the app consumer-friendly, so we went through a lot of iterations with testing groups, with home-care nurses, and some hospital nurses and providers," Kim said. "It took about seven months to get to that final version that's in your hand. And that's not even the final version. That's actually a version that we're going to upgrade and enhance in the coming quarters."

One of those upgrades will be adding pharmaceutical information to SoomSafety so users will have the latest information on drugs, including recalls. When Soom finishes that upgrade, it will push it out as an update to the app.

Kim also said Soom is finalizing a partnership with a recall service provider so it has access to even more recall information.

"This is just another party and partner to vet against, to compare and contrast, to make sure we're covering all bases," he said. "So, the power of our platform is that we're pulling from public and private sources. That's a huge benefit because recall services can cost a lot of money.

"And our app also takes the difficulty out of using the openFDA databases," Kim noted. "While openFDA is free to everyone, it isn't necessarily easy to use."

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Soom also wants to scale SoomSafety for the commercial market.

"We are looking at how can we put this in the hands of a hospital so it fits seamlessly into their procedures for safety and recall, to make sure they can remove products from the shelves faster and absolutely ensure that all those products are out of circulation," Kim said. "So, we are collaborating with industry trade organizations and individual providers to talk about how we can do that."

App Doesn't Collect Personal Data

SoomSafety doesn't collect personal medical data, Kim says. Instead, it gathers general data based on what products users are scanning.

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"We really want to build trust within the system so people can exchange information and have that trust," he said. "So, we want to make sure that people trust us, first, and then trust the system that we've created, that they are actually accessing correct and accurate information, and that they are not concerned that we are going to be using that information in any way to profit."

Kim went on: "The only thing that we know is if something has been scanned and if that product has been recalled. So, if all of a sudden we start seeing a lot of product recalls being scanned or a specific product, we will try to contact that manufacturer and say, 'Hey, we're seeing a lot of activity around your one product.' That's the only type of information we can see."

And with and eye-opening 200 recalls initiated by industry in the second quarter of 2019 – a 22% increase over Q1, when 164 were reported – that type of information can be gold to device-makers. (Also see "*Q2 Recalls Snapshot: It's A Mixed Bag For Industry As Recall Events Jump Slightly And Recalled Units Fall Dramatically*" - Medtech Insight, 12 Sep, 2019.)

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