Can This Man Save American Healthcare?

Patient Safety Movement Foundation To Re-engineer Healthcare And Eradicate Preventable Deaths By 2020
SafeCare Person of the Year

A Commitment to Patient Safety

By Yisrael Safeek, MD, MBA, CPE, FACPE, FOUNDER

In-depth interview by SafeCare Founder Dr. Yisrael M. Safeek with Joe Kiani, CEO of Masimo Corporation (NASDAQ:MASI) and SafeCare Person of the Year.

Yisrael Safeek: Welcome Joe. I read your Forbes interview titled “Re-Engineering Healthcare to Eliminate Preventable Deaths.” You’ve received several awards, including the Dawn of Life Award. This is an award only a few people in the world have received, and it’s an honor previously reserved only for members of the United States Congress. You’ve also received the Society for Critical Care Medicine Technology Excellence Award. What is it that drives you about patient safety and health care?

Joe Kiani: Well, I feel like I was born into this industry. My mom was a nurse, and my dad was an engineer. As a child, my mom used to take me to work with her during the summertime, and I just ended up having a lot of empathy for the patients. My hope was to become a doctor so that I could take care of patients. But I wasn’t that good in chemistry—it just didn’t come naturally to me.

I was drawn into physics, and that led me to engineering. I thought, “What could be better than trying to invent things that can help people, especially during their time of need?” And then, on the patient safety side, it was nice to see the good things we are doing with Masimo’s products and innovations.

But then I started seeing an even bigger opportunity. I’ve met with some incredible people around the world and created partnerships with amazing companies and hospitals. So, it felt like I was supposed to step up and try to fix this problem of preventable deaths in hospitals.

As for the awards, I’m very proud of the Dawn of Life Award and the SCCM Technology Excellence Award. As you said, these awards have never been given to anyone like me. The SCCM Technology Excellence Award is only given to doctors, and the Hubert H. Humphrey Award is only given to Congress, so these are very special to me.

YS: That’s quite a big jump, going from taking an interest in delivering good healthcare to being actively involved in patient safety like you have. So, when did this interest in preventing medical errors first begin?

JK: Well, I remember being shocked by the IOM reports in 1999, which said that about 100,000 people are dying from medical errors each year; and at the time, some very notable successful people, doctors mainly, jumped in to fix the problem. I thought that this problem would be solved by these incredible people. It wasn’t until I saw the 2011 Medicare report, which noted that Medicare patients suffer harm and death to a tune of about 200,000 each year, and they’re only half the patients in the hospitals. That is staggering.

I was shocked that things had not gotten any better or maybe had even gotten worse. That really made me think that maybe I should try tackling this issue. As entrepreneurs, we are very action-oriented people, and it’s not about trying to be politically correct or being academic. We are very scientific, but we don’t get caught up in some of the things that I think can be impediments to progress.

I was very moved by what President Clinton had done with the Clinton Global Initiative (CGI). I noticed how well the commitment-based approach to meetings worked. So, with his permission, we shamelessly stole his formula and added some unique pieces of our own and started the Patient Safety Summit, not knowing it was going to trigger a movement. By the first break, I realized it had turned into a movement.

People came up to me saying, “We’re in!” I remember healthcare providers and hospital administrators coming to me saying, “We will commit to zero preventable deaths.” Med Tech companies did the same, the CEO of Zoll, and the the CTO of Cerner came up to
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me and said, “We’ll sign the pledge to share data.” So, it just all came together in a very nice and surprising way.

YS: The way you involve others is to be highly commended. So, you’re a very busy CEO. You’re running a global medical technology company. Your organization has branches in the Americas, Asia, Europe, Africa, and the Middle East. Now, how do you find time to devote yourself to this patient safety cause?

JK: I’ve been really blessed because I came up with the right missions and, somehow, amazing people gathered around the missions, whether it was at Masimo and our work to improve patient outcomes and reduce cost of care by taking noninvasive monitoring to new sites and applications or the Patient Safety Movement Foundation. The Patient Safety Movement Foundation was created to eradicate preventable deaths by 2020. These incredible people are much smarter than I am and work much more than I do. They gathered around and made these missions their missions. I only have so much time and so much ability. I really commend the people who have embraced both of these missions.

YS: You’re an engineer by training. How does the healthcare industry compare to engineering when it comes to dealing with human errors, you know, the human factor, etc.?

JK: First of all, engineers are analytical and, by nature, they’re generally creative. I think the process of becoming an engineer, along with what’s expected of you, makes engineers like that. Doctors, on the other hand, are taught over and over again to follow guidelines and follow standards.

I’m generalizing, forgive me, but some hospitals don’t believe they’re in the business of figuring out the best way to deliver medicine. When a hospital is starting, they think their job is to provide infrastructure, staff and tools, and the rest is up to each doctor and nurse. At a med-tech or a tech company like ours, we think we’re supposed to start from scratch and figure out the best way to establish a company, establish a corporate culture, and establish procedures and ways to encourage not only innovation, but also better manufacturing process and better quality. So, I think I now see some of those principles entering the hospitals. But I think there are still two differences: one is what hospital executives think their jobs are; and the other is the different types of training that doctors receive versus what engineers receive.

YS: There’s lots of talk about patient safety, but you walk the walk as well because you’ve put your talent and skill and also your money and efforts into creating technology that save lives. Tell us a little bit about your company Masimo.

JK: I’d be happy to. I wanted to make a difference. I really wanted to make a contribution to medicine, so I wanted to go solve the problems that people thought weren’t solvable. That was really the genesis of Masimo and is still the way we think. We probably could have become more financially successful had we focused on packaging what was there and getting it out there in a cool way to people. However, I really wanted to solve the hard problems such as: How do we measure pulse oximetry, even during motion and low perfusion? Many patients were suffering due to that limitation.

I wanted to solve other hard problems, such as: How do we measure total hemoglobin noninvasively? How do we go about breaking the barrier of what’s considered a noninvasive measurement versus invasive? So, I gathered a bunch of incredible people around me who are creative and inventive. They weren’t just engineers—they were inventors. They took on this challenge with me, and we worked tirelessly. I mean, during the first seven years of Masimo, I took two four-day weekends off other than when I got sick.

I’m very proud that we continue to innovate. We conducted a survey with many anesthesiologists, nurses, and other specialists and asked them, “What do you think of when you think of Masimo?” The majority of participants said, “Innovation.” So, it looks like we actually did what we set out to do, not only in our own minds but in other peoples’ minds as well.

YS: Joe, we know you have several products that contribute to improving patient safety and quality of health care—there’s no question about that. I want to talk a little bit about two products. Can you tell us a little bit about Masimo SET® and Masimo Patient SafetyNet™, because we know they work and we know they save lives. What prompted you to come up with these life-saving products?

JK: Sure, I’d be happy to. As you know, I’m an electrical engineer. I have my bachelors and masters degrees in electrical engineering, with an emphasis on signal processing for my masters degree. I was fortunate enough to have this brilliant and down-to-earth professor, Fred Harris, who
to this date is my mentor. He turned me on to signal processing and adaptive filters. He was a consultant to the Pentagon, and he was working on satellite communication and anti-submarine warfare using these technologies.

And then, I was introduced to pulse oximetry. I noticed that when I had the sensor on my finger and I was just fiddling with the knobs and buttons, my oxygen went from 100% to about 60% because I have low perfusion, and I can make it fall very quickly.

I couldn't believe how much the motion artifact affected this product, and I thought I could use adaptive filters to get rid of that noise. Adaptive filters are really amazing technology. Imagine you have a screen on your window, and you want the maximum amount of air coming in. That means the holes in the screen have to be big, but then you don't want bugs to come in. So, imagine instead of holes in the screen being fixed in size, they are big so a lot of air can come in. Then when a mosquito or a fly wants to come through the screen, the screen figures out where the bug wants to enter and closes up that area. That's sort of how adaptive filters work electronically.

With that thought, we started Masimo, and we began trying to make it work. That's where Signal Extraction Technology (SET™) came from. There are five engines in our algorithm that make this work so well, and they're sort of these complementary algorithms. When we were developing our technology, we discovered that venous blood moves around every time a patient moves or breathes. The typically erratic nature of this movement causes conventional pulse oximeters to display false readings. However, our algorithm uses signal processing to separate the arterial signal from sources of "noise," including the venous signal. This enables Masimo pulse oximetry to measure oxygen saturation and pulse rate reliably, even during motion. The other pulse oximetry companies assumed that the only thing that pulses is arterial blood, so that realization led us to come up with some really unique algorithms that help differentiate the arterial oxygen from the venous.

For Patient SafetyNet™, one of the things that we recognized from the beginning is that we were killing patients with kindness. Opioid-based drugs given to reduce pain were leaving patients without breath. I knew that once we made Masimo SET™ pulse oximetry technology, it could successfully eliminate the false alarms and become a really useful tool for patients in the general wards. It was important to monitor these patients in case they were suffering from respiratory depression, but we needed to figure out how to do it inexpensively so that hospitals could afford to implement it and do it reliably.

At the time we developed Patient SafetyNet™, the industry was making custom systems that worked on medical bands. Each company had its own band, and it was a real nightmare for hospitals to implement. It was expensive, and I thought, "This is ridiculous. The whole world has adopted the 802-11abg Wi-Fi system. I'm using it in my home and in my company." I believed that eventually hospitals would use it.

So, we decided to take a gamble and build Patient SafetyNet™ on a platform like a PC using the regular Wi-Fi band. Then, we had multiple meetings with doctors and nurses to develop the user interface, making it easy to admit, discharge, and track patients so it didn't become a distraction; it became a really useful tool.

SET™ was this amazing invention solving the unsolvable, but Patient SafetyNet™ was the right product for the right time with the right user interface; and together, as you know, they've made a huge difference in saving lives and saving costs in hospitals.

YS: In 2012, you founded the Patient Safety Movement Foundation, and I would like you to tell us a little bit more about the Masimo Foundation for Ethics, Innovation, and Competition in Healthcare.

JK: I was a 24-year-old starting a company from my garage, bright-eyed and bushytailed, and entering a market that was really restrictive. We had these monopolist companies working hand in hand with group purchasing organizations that were paying them to keep their monopoly.

I realized that of all the industries in which you wish you had a competitive landscape, it should be healthcare because our lives depend on hospitals being able to get the best products at the lowest prices. If your Internet providers are monopolists, it's not a life-and-death situation. But if the med-tech industry or healthcare industry is not competitive, then it stifles innovation and causes harm to patients.

Despite having a breakthrough technology that was saving lives and neonates from
blindness, we were effectively shut out of the US hospital market. Fortunately, Walt Bogdanich, who broke the nicotine story while at Wall Street Journal, heard about our story, while at 60 Minutes and was so moved by this problem and its effect on patients, that he wanted to do a series on it. One that he thought could be done at the New York Times. He asked if we were willing to tell the truth since at the time many companies were afraid to speak up about this problem. We said, “yes!” He and his colleagues began a 2 year investigative report and broke the story to the American public in March 2002. The same day, I was called by the US Senate to see if I would testify at their Judiciary Subcommittee. In April, I testified at the Senate hearing and as they say the rest is history. After seeing how messed up this hospital purchasing system was, when we won an antitrust suit against Nellcor—which at the time was part of Covidien—we took a big chunk of that money and started the Masimo Foundation for Ethics, Innovation, and Competition in Healthcare. The goal was to fund economists who are usually funded by big companies to protect big companies’ interests, and have them instead write the truth about how anticompetitive practices hurt consumers, patients and innovation. We wanted to do things that would spur competition and innovative companies. At the end of the day, the economists’ publications are where the people at the Federal Trade Commission and DOJ get their clues from.

So, that was the genesis of starting that foundation. Unfortunately, we realized that many of these economists did not want to write about things that protect the consumers, but preferred to be aligned with the big companies. We had a very tough time giving money to that cause. So when the Patient Safety Movement idea came, the Masimo Foundation basically committed itself to that effort, to help the movement get started, and it has been the biggest funder of the Patient Safety Movement Foundation.

YS: You also founded the Masimo Political Action Committee. You’ve been able to bring in very important people to the patient safety effort. You brought in a former President of United States. How can this contribute to improving healthcare?

JK: Well, we have a democracy, and it gets hijacked by special interest groups all the time. If you’re not at the table telling politicians your side of the story, they only hear one side. So, I think it’s so important that every citizen gets involved.

Unfortunately, money talks, and if you donate money to the politicians, then they’ll listen to you; and if you don’t, they might listen to you once in a blue moon.

I think it’s really important that you and others do your best by combining our resources together to get the attention of these elected officials, and share our passions with them so they get a full picture. And then, hopefully, when they’re making decisions, it’s something that they believe in after they’ve heard everything instead of hearing half of the story.

YS: It takes a lot of effort to go against the high winds, and you’ve done that very successfully. Let’s talk about some of the successes you’ve had with the program so far—the Patient Safety Movement Foundation as well as the Political Action Committee.

JK: I just want to add one more thing. We have had a huge impact, and yet we don’t have as much money as some of these very wealthy people and companies that donate hundreds of millions if not billions of dollars. And I think what I’ve noticed is that if you have the truth on your side, then you don’t need all that much money to get your message heard. So, I think telling the truth, being on the right side of history and a little
money spent, takes you a long way.

YS: What do you think are the biggest obstacles to reducing medical errors in the U.S.? I take it you’ve thought about this quite a bit.

JK: Apathy. Apathy is our enemy. And because healthcare is a third-party system, apathy thrives there. What do I mean by that? We, as family members of patients, are not directly paying the hospital. Our employers have insurance companies that are paying the hospitals for our care. So, with the consumer of healthcare not being the “paying” entity, that creates some issues. We rely a lot on heroes. Patient safety is thriving in places where the individuals in those hospitals are very empathetic people. They have a lot of love for not just their family members but for humanity, and they go the extra mile without getting paid for it, without getting recognized for it. If we wanted, our summit could be focused on just technology and process, and that would be fine, but the other piece of the formula is love and caring.

YS: Now, you’re committed to reducing preventable patient deaths to zero by 2020. What prompted you to set the target of zero preventable patient deaths, and is this really achievable by 2020?

JK: Each death is a tragedy, and so anything greater than zero is bad. One of the successes in our work that I think really turned into a movement was bringing in the voice of the family for the lost loved ones. When they tell their stories, it transcends the numbers into human experiences that capture our hearts; and then nothing gets in the way of passion. When people become passionate about something, they make it happen. As I hear each individual’s story, I have a tough time sleeping because I start thinking about how it could happen to my daughter or my son. It makes me realize that there’s really no other number but zero. Now, are zero preventable deaths in the U.S. possible by 2020? Yes. Are we going to achieve it? I hope so. But I think unless you have zero as a target, you are settling.

Even with an organization like Masimo, zero defects must be our target. If it is not, then you don’t look for the root causes that lead to other wonderful solutions. So, you know, I’m really proud that after one year, we reported 650 lives saved annually. The second year was 6,500 lives saved.

This upcoming summit, because of the commitments that already more than 800 hospitals have made, we think the numbers are going to be more than 20,000 annually. If we can keep up this pace year after year, I really think zero by 2020 is possible.

YS: What do you consider to be the most important—the people, the culture, the system of healthcare, or are all of these needed for large-scale changes?

JK: All of them. Number one is that you can’t start without a culture of safety. I mean, there is a Bible in every hotel room in Las Vegas, yet you know all the Ten Commandments are being broken. So having the Bible or the Old Testament there hasn’t caused adherence to the Ten Commandments. You need leadership, you need people, you need Moses, you need Jesus, you need Mohammed, and you need people who hopefully will care whether they’re the CEO or the nurse or the anesthesiologist. They become natural leaders, and they evangelize this movement at their hospital. But you also need a process that you continue to improve; you need the right technology, and it’s really the combination that can make it work.

YS: How optimistic are you about overall patient safety efforts in the United States?

JK: I’m very, very optimistic.

You know, I travel around the world because of Masimo, and one of the things that I realized is that in the U.S., in every hospital I go to now, there is a buzz. There’s an effort to eradicate preventable deaths, and that’s not the same in the rest of the world. In countries like Japan, the doctors can’t even talk about a mistake, because if they do, the police show up wanting to take someone to jail for murder. So, I’m very optimistic that the movement is happening in our country. Some amazing institutions, like MedStar Health, are doing some incredible things like actually being transparent. Their team apologizes to the family within 30 minutes. They’re not charging patients for any procedures if the patient was harmed. They’re on the right track! So, I think we really can do it.

I’m also excited. We have countries from Brazil to Spain to Germany to Saudi Arabia and Israel that are coming forward saying they want to join the Patient Safety Movement and take what we have done and make it part of their country. So while the effort is beginning in other parts of the world, I really think the United States can get to, if not zero, then very close to zero preventable deaths by 2020.

YS: We clearly are making some progress. Joe, thank you very much for making a difference.
Patient Safety

Call for a Legislative Response

We know Congress and the administration have been actively focused on this issue of reducing preventable deaths and increasing patient safety with many programs, but we humbly suggest the following:

Create a System of Transparency

Transparency is a critical component in measuring and understanding the total number of preventable hospital deaths and the root cause of each death. This information will allow clinicians, policy makers, and others to take proactive steps to reduce and eliminate needless mortality, going forward. The current reporting systems do not require consistent, accurate, measurable and electronic reporting on the total number and causes of deaths, especially related to whether the death was preventable. We cannot improve what we do not measure. You may be surprised as I am, that today no one knows the exact number of deaths due to preventable causes. That has to change immediately.

Recommendations:

**Government** should take the lead in this effort. To create transparency, and improve consumer choice and knowledge, we believe there should be standardized processes to define, measure and report Hospital Acquired Infections and Conditions by hospital and in total. Reporting should be electronically facilitated through the Meaningful Use program and via claim submissions. Congress should require HAI and HAC rates to be publicly reported to facilitate quality comparisons, much like SEC does for finance.

Use incentives and disincentives to reduce preventable deaths

**Recommendation:** We believe Congress should expand the current HAC Medicare policy to include list of causes of preventable death. We believe Congress should suspend payment for even the primary condition until it is determined whether the cause of death was preventable. If preventable, and the hospital has implemented evidence based strategies for prevention, such as those indicated by the Patient Safety Solutions, the hospital would receive payment for the primary condition. If the hospital had not implemented the strategy, then payments for both the primary and secondary conditions would be denied.

Also, if hospitals implement evidence based practices such as the Patient Safety Solutions, they should be shielded from malpractice lawsuits to the fullest extent possible, such as through an affirmative defense and limits on damages.

We believe Congress should also expand the current HAC Medicare policy by expanding the non-payment policy for secondary conditions that develop after a patient is admitted to a hospital. The current list of conditions has not been updated since 2012, partly due to limits on what conditions can be added. Currently, only preventable, high-cost, high-volume conditions for which there are evidence based precautions are eligible. Congress should eliminate the “high-cost, high-volume” limitation so that any known preventable condition is eligible for the list if there is a clinical intervention strategy to prevent it.

Create the “Patient Data Super Highway”

For more than a decade Congress and the Administration have devised and implemented policies to spur the use of information technology in healthcare. The reasoning behind this is clear: seamless information technology should enable us to identify problems in real time and resolve them before they become deadly. As a result, medical professionals have begun to increasingly rely on medical technology and information systems to treat their patients.

Today, however, these technologies are not always able to communicate or interoperate. But this isn’t always an issue of design or standards: some technology vendors—as well as some providers—pursue business practices to create what are called “walled gardens,” which are strategies that block information sharing between different systems in order to capture market share and/or additional revenues in the future. This is an issue that has been identified by the Office of the National Coordinator as a barrier to progress in the Meaningful Use program. This practice fundamentally diminishes the value of health IT; undermines Congressional intent in enacting programs to incentivize the use of technology in healthcare. These practices are harming our progress to protect patients and must be stopped; technology solutions must be required to openly share information particularly when their purchase is subsidized with taxpayer dollars and patients’ lives are dependent on it. Rory Staunton’s case is an example of the problem and opportunity that lies ahead. In fact, according to an article in the Los Angeles Times, 80% of medical errors in hospitals involve communication problems between healthcare professionals.

**Recommendation:** We believe Congress should grant the Office of the National
We are excited to welcome Congress to the Healthcare Ecosystem and work with Congress on solutions to this problem and together achieve **ZERO Preventable Patient Deaths by 2020.**
SafeCare magazine is a private sector, wholly self-funded venture to deliver information to healthcare's most influential leaders on the individuals, ideas and novel technologies affecting safe and quality healthcare. The SafeCare magazine Person of the Year is an annual recognition provided by SafeCare magazine that recognizes and applauds the one individual who contributed significantly toward improving patient safety and healthcare quality across the globe. The designation seeks to spotlight, highlight, and draw attention to the one individual who overwhelmingly fulfills the following three goals set forth by The SafeCare Group:

1. Commitment to improving patient safety, quality and efficiency of healthcare in the US and internationally;
2. Take tangible and quantifiable steps toward addressing the current challenges and future perspectives of patient safety, quality, and efficiency of care; and
3. Offer leadership toward advancing patient safety, quality, and efficiency of care within the healthcare sector, the general public, regulatory, and governmental domains.

We feel that this year’s 2015 SafeCare Person of the Year not only embodied all these areas, but also exceeded them. Our selection is the one individual who aligned medical technologies and IT infrastructure with relevant information, intelligent and predictive algorithms, and physicians and patients so lives could be saved globally, and costs could be dramatically reduced. Moreover, the very fact that the individual selected for our inaugural award is not a person with a medical background and from the private sector makes him even more remarkable.

We congratulate this year’s 2015 SafeCare Person of the Year, Mr. Joe Kiani. Here are some highlights detailing Mr. Kiani’s great accomplishments.

Innovative Patient Safety Technologies:
His company has been a pioneer with pulse oximetry technology that revolutionized surgery and critical care medicine by improving outcomes through early detection and treatment of low blood oxygen levels. Since its inception, pulse oximetry was plagued by unreliability when it was needed most – during patient motion and low perfusion. The industry had given up and considered the problem “unsolvable.” Clinicians were forced to live with the results – excessive false alarms, delayed notification due to long averaging times, inaccurate data, and an inability to obtain data on the most critical patients. Today, clinicians at thousands of hospitals around the world count on Masimo SET® every day to help them care for patients. In addition, many leading hospitals have already integrated Masimo SET® pulse oximetry technology with fewer false alarms, thus allowing clinicians to focus on the patients who need the most attention. And with more timely detection of true events, clinicians can intervene earlier with better patient outcomes and improved patient safety.

Smart Outreach with Legislation and politicians:
Mr. Kiani truly embodies the aspirations of the SafeCare Person of the Year through the work of his private sector not-for-profit Patient Safety Movement Foundation. This organization seeks to unify the healthcare ecosystem, identify the challenges that are killing patients to create actionable solutions, ask hospitals to implement Actionable Patient Safety Solutions, and promote transparency. He has reached out to politicians like President Bill Clinton as well as prominent patient safety authorities to advance the message of safe care.

Patient Safety Advocacy and Patient Voice:
Finally, Mr. Kiani has engaged medical technology companies to share the data their devices generate in order to create a Patient Data Super Highway to help identify at-risk patients. He has asked the US Senate Health, Education, Labor and Pensions (HELP) Committee to correct misaligned payment incentives, promoted patient dignity, and outlined steps to ultimately get to ZERO preventable deaths by 2020!

Congratulations Joe Kiani.