Customer Story

TSUKUBA MEDICAL CENTER HOSPITAL

Challenge

Ensure patient safety whilst also meeting the institution's business and financial goals.

Predicting the economic lifespan of medical equipment

Tsukuba Medical Center Hospital takes a predictive approach to equipment maintenance

With devices undergoing numerous cycles of repair over the course of their life cycle, there is a risk that some equipment may be used beyond its certified useful life. To continue using aging devices is to risk equipment malfunction, which may lead to – among other things – major budgetary discrepancies. Medical institutions must therefore weigh the conflicting interests of safety and economy in deciding if and when to perform device updates.

Tsukuba Medical Center Hospital (TMCH), operated by the Tsukuba Medical Center Foundation, is located in the southern region of Ibaraki prefecture in Japan. It opened in 1985 and has 453 beds. Not only a public interest incorporated foundation but a community-based health care provider, the hospital practices "patient-centered medical care in coordination and cooperation with the local community." It acts both as a center for emergency care and as a regional oncology hospital.

TMCH director in April 2011 founded the Medical Equipment Materials Unit, a functionality-oriented organization that supports safe and effective management of medical equipment. With a medical device safety manager at its helm, the unit was one of the first in Japan to link care workers, the hospital's purchasing department and clinical engineers in addition to doctors and nurses. Hideaki Kamijyou is a clinical engineer working in device management for the Medical Equipment Materials Unit.

A clinical engineer by training, Kamijyou's primary purview is equipment management, including the inspection and preventative maintenance of portable medical equipment, responding to device failure, investigating defect history, communicating repair requests to manufacturers, making backup plans and providing safety training for hospital staff. He is also responsible for quality improvement and total optimization measures.

One of the medical devices of primary concern is an external infusion pump. The hospital has many of these devices, and patients often walk around the facility with them in tow.

These infusion pumps are of course used under the watchful eyes of staff, but should anything abnormal occur the facility is equipped with an alarm that will sound, shutting the malfunctioning pump off. However, if an abnormality were detected on the ward, the offending device would immediately be replaced with another, triggering a repair inspection request. Such requests are often triggered accidentally when the external infusion pumps fall, are dropped, or are taken into a high magnetic field environment such as an MRI radiology lab. User error problems can be prevented with analysis of error factors, repeated training, awareness education and communication across the hospital. Although inspections which aim at preventive maintenance are performed on a regular basis, there are still many minor problems that occur, such as cracking or contamination, that do not generate errors. As such, this device remains one of the most difficult to manage.

"Patients have the right to be treated with devices that ensure the same level of safety as when they were first purchased," Kamijyou says.

Using JMP® to predict the lifespan of portable medical devices

Beginning in 2014, TMCH began to observe an increase in incidents linked to aging infusion pumps. By 2016, the number of failures in the first half of the year equaled nearly the total number in all of the previous year. Staff determined that the pumps operated normally when plugged into an electrical outlet, but that flow rate abnormalities occurred when the devices were switched to battery mode. The issue could not be resolved by simply replacing the battery.

Updating equipment appropriately is not a cost. It is an investment.

Hideaki Kamijyou, Clinical Engineer

"I guessed that, alongside electronic circuit board deterioration, current changes were causing malfunctions," Kamijyou says. "Repairs by the manufacturer cost a lot of money, and even if the equipment is repaired, that doesn't mean it will be like new again. Repairing equipment past its effective working life is a life-support measure, not a radical cure. In the case of portable medical devices, the deterioration of key components means the lifespan of the equipment. Straining to repair this equipment not only detracts from its safety but also leads to a jump in life cycle costs. We needed a scientific foundation to convince the administration."

Kamijyou therefore decided to use JMP®. As the hospital did not have a dedicated analytics department, Kamijyou requested a user-friendly tool that could be used effectively even by someone without a background in statistics. First, he examined the 166 infusion pumps used during the two-and-a-half year period from April 2014 to September 2016. In total, 33 of them had stopped working. Among these, 17 were out of service with abnormalities related to an aging internal electronic circuit board, while the remaining 16 had stopped working as a result of multiple complicating factors. Kamijyou also catalogued pumps that had experienced malfunctions for an unknown reason but which had been passed over for repair due to cost. Undoubtedly, aging equipment was not the only factor in pump malfunction. However, these findings were not adequate to persuade hospital management to invest in new devices. Kamijyou therefore felt strongly that it was important to clarify the risks.

So he dug deeper into the data. Using the Kaplan-Meier method, he applied a logistic 5P model for estimation and created a survival function for the infusion pump. With this, he could obtain the probability that a pump would stop working in the following year from a given point in time. Kamijyou set the estimated value of the number of devices that would stop working during the year as the sum of hazards. As a result, among the infusion pumps working as of Sept. 30, 2016, he predicted that about 28 of them would stop working within the following year.

"Infusion pumps that had reached their eighth year of operation had a probability of about 2.7% that they would reach the end of their lifespan in the following year," he explains. "When I did a simulation of medium- to long-term planned updates, I found that about 20 pumps a year were needed to balance the supply. I presented a report at a meeting stating that, as a result of setting annual failures during operation from deterioration due to aging at less than one pump, the threshold was a hazard of 5%, or one in twenty devices, and I wanted planned updates to take place by the time the ninth year was reached."

Reaching zero deterioration-related malfunctions

As a result of Kamijyou's detailed analysis, budgeting was soon implemented. As of April 1, 2018, the sum of hazards for individual infusion pumps during operation was greatly reduced. And entering the 2018 fiscal year, problems during use from deterioration due to aging, excluding accidents, was zero. But infusion pump malfunction wasn't the only thing that reached zero. In 2018, TMCH did not submit even a single infusion pump repair request to the device manufacturer. Maintenance was taken care of in full with either planned updates or in-hospital repairs. Manufacturers' repairs are costly, so the cost-reduction effect of these measures was big. A design approach has led to fundamental solutions and prevention of recurrence, Kamijyou says, adding: "Appropriate updating of equipment is not a cost. It is an investment."

Promoting data-driven decision making with a more statistical approach

In addition to the current initiative, in the future Kamijyou plans to dig into the hospital's unutilized data and link to objective, rational decision making. "Our biggest strength is that we know the site," he says.

If equipment is designed so that the products themselves are not affected by variations in users, most of these problems will not occur. And if the site can provide accurate feedback as to the cause of device malfunction, the speed of development will increase rapidly. Furthermore, Kamijyou notes that cooperation among Japanese government, industries, academia and hospital have begun to promote new medical-engineering business together to produce solutions.

As for the future of these partnerships, Kamijyou says that he thinks clinical engineers will play a major role. "This is because medical-industrial engineering is a concept linked to contributions not only within the hospital but in society at large."

He is committed to continuous improvement and works tirelessly to engineer quality into hospital practices.

As someone who puts patient safety above all else, Kamijyou's work – and curiosity – is never done. And JMP will continue to support his ambitions.

Please note that the medical standards discussed in this story apply only to Japan. Regulations vary greatly by country.

Solution

Clinical engineers use JMP® to construct predictive models that allow them to proactively manage medical device maintenance and repair. An optimized plan based on the results of their data analysis proved to be the deciding factor in the organization's budget acquisition.

Results

The risks of device malfunction during use have since decreased, keeping patients safer while also decreasing operations costs.

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