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Product recall decisions need balance to prevent overreacting

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As health care and technology become ever more intertwined, the importance of data-driven, evidence-based product recall decisions is only going to accelerate. According to published research co-written by a University of Illinois expert who studies technology adoption in health care, the timely detection of potential medical device recalls could both reduce the cost of and improve the effectiveness of health care delivery.

The research is motivated by several recent cases of medical device failures in which the manufacturers recalled the faulty devices only after several patients were harmed, leading to deaths in some cases, said Ujjal Kumar Mukherjee, a professor of business administration at the Gies College of Business at Illinois.

Managing the downside risks of technology in a health care setting poses a serious challenge to firms, doctors and patients, Mukherjee said.

"Health care delivery is becoming more technology-driven, and it's only going to become more tech-focused over time," he said. "There's no going back at this point, which is why it's so important to get this right because even the best technology may eventually fail."

In a paper published in the journal Production and Operations Management, Mukherjee and co-author Kingshuk K. Sinha, of the Carlson School of Management at the University of Minnesota, find that the "situated context" of the decision-maker – such as firm size or the depth and breadth of their product portfolio – is significantly associated

with judgment bias in favor of either overreacting or underreacting.

"The danger is twofold," he said. "We find that a high signal-to-noise ratio in user feedback is associated with a greater likelihood of underreaction, meaning that firms will take a more hands-off approach to a product recall. But we also find that user feedback related to high-severity adverse events is associated with a greater likelihood of high overreaction, meaning that firms will take an ultracautious and conservative approach to recalling the product and repairing, redesigning or remanufacturing the product."

Firms that underreact often fail to heed the signals and often delay their recall decision.

"We call this an 'underreaction to signal,' and the outcome or consequences of delaying such a decision for a product that has a design flaw or a manufacturing flaw is very severe in the medical device industry because you are dealing with life-or-death situations," Mukherjee said. "It's also led to many millions of dollars in claims and lawsuits in the past."

According to the paper, firms that tend to underreact to failure signals are larger firms with a diverse product portfolio.

"Larger firms tend to react much more slowly and delay their recall decision than specific or specialized firms that have clear divisional boundaries," Mukherjee said.

The solution would be for bigger firms to "divisionalize" their organizational structure around a product or a type of product or service to create greater focus on emerging new products and technologies.

"A firm that has an organizational structure in which specific divisions

take care of specific products will have a much more proactive approach to managing the problem," he said. "In some sense, there is a lack of attention to designing the overall product portfolio when you keep on creating versions and different features in the product, which makes the product portfolio very complex. That leads to inattention toward failure signals in the marketplace, which eventually causes a lot of loss of efficiency and effectiveness in the overall delivery of health care."

Failures of medical devices account for a significant chunk of losses in the health care system – approximately 15 percent of the total cost of health care delivery. So it's incumbent upon firms to try to look ahead of the curve, Mukherjee said.

"If you walk into a hospital now versus even 10 years ago, you'll see a lot more technology," he said. "And even the best technology may fail, with serious economic and social consequences."

Take the DaVinci Surgical Robot, for example.

"Those robots are very high-tech and very expensive," Mukherjee said. "The surgeon's involvement is mostly in controlling the robot, but it gives doctors much more accuracy, meaning clinical outcomes are that much better. So it's an innovation that has helped surgical delivery. All these innovations are coming in the health care domain, and they're improving health care delivery."

But it's "vitally important" to proactively manage the downside risks of the technology while it is already in use, Mukherjee said.

"Notwithstanding all the benefits, these are such complex pieces of technology that failure is all but inevitable," he said. "If the robot fails, and there have been some cases in which surgical robots have frozen mid-surgery, that's obviously a big problem."

But it's not just surgical robots. It's also implantable devices, "which have proved very effective and efficient in delivering consistent, high-quality health care," he said.

"It depends on how you manage the risks, which entails predicting the failures," Mukherjee said. "So being able to predict and proactively act upon signals of failures of medical devices is very important."

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