A fresh set of eyes: Rotating plant inspectors reduces risk of medical device recalls

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Putting a rotation strategy in place -- in which the FDA never sends an investigator back to the same plant -- could lead to about 100 fewer costly medical device recalls per year. Credit: Indiana University

More frequent rotation of plant inspectors at medical device

manufacturing facilities could benefit consumers and lead to fewer product recalls. That's the finding of a seven-year review of Food and Drug Administration inspections of and subsequent recalls at such facilities.

The study, by researchers at Indiana University, the University of Wisconsin and the University of Minnesota, found that plant inspections worked well when they were conducted by someone new, rather than by an investigator already familiar with the manufacturing facility.

"We found that FDA medical device plant inspection outcomes are highly predictive of future medical device recalls originating from the plant, but only when it is the first time that the FDA investigator has inspected that plant," said George Ball, assistant professor of operations and decision technologies at the IU Kelley School of Business and the study's lead author. "The newness factor really matters."

Ball and his colleagues found a 21 percent increase in the risk of a future recall the second time a FDA investigator inspected a plant. That risk rose to 57 percent by the third visit. These findings were independent of whatever score the FDA investigator gave the plant.

"These increased recall risks may be symptomatic of increased familiarity between plant management and a repeat investigator, enabling the plant to relax its standards," said co-author Enno Siemsen, executive director of the Erdman Center for Operations and Technology Management at the University of Wisconsin.

Previous research has noted the complacency that investigators may develop during repeated visits to the same facilities but has focused on the number of violations found during inspections. This outcome doesn't provide an accurate assessment of whether a plant is getting better or worse, Ball said. It is possible that fewer violations are due to improved

conditions.

Looking at recalls is a more objective approach, "because that's hard to manipulate," he said.

The study, "Do Plant Inspections Predict Future Quality? The Role of Investigator Experience," appears in the INFORMS journal, *Manufacturing & Service Operations Management.*

The researchers tested the predictive relationship between 4,767 FDA plant inspection outcomes and 2,863 medical device recalls originating from 2,244 plants from 2000 to 2006. Such FDA inspections normally occur every two years.

Compared to a low-quality inspection outcome, the researchers found that a high-quality inspection outcome from an investigator who has never inspected a plant in the past predicted a 31 percent reduced risk of a recall from that plant. This means that inspection outcomes provide important information for future quality performance from the plant when the investigator is new to the plant.

By the second visit, the relationship between inspection outcomes and future recalls disappeared. There was no statistical relationship between an FDA investigator's inspection outcome and future recall risks if the investigator had previously visited the plant.

Ball and his colleagues tested two potential solutions: rotating investigators so they never visit the plant more than once, and sequencing investigators so they never visit the same plant two times in a row.

"We found that rotating investigators provides the most benefit, and from the data in our study there appears to be enough inspectors to have

them never revisit the same plant in a normal career," he said.

Putting a rotation strategy in place—in which the FDA never sends an investigator back to the same plant—could lead to about 100 fewer costly medical device recalls per year (or about 20 percent fewer recalls) in exchange for an increase of $800,000 in additional travel expenses for the FDA.

"Is 100 fewer recalls worth $800,000 a year?" Ball asked.

Ball said these findings also demonstrate that the FDA—and likely other federal regulators—must navigate a fine line in their relationships with industry managers.

"While the FDA has worked diligently over the last decade to strengthen their collaborative relationship with medical device manufacturers, this study finds a clear risk associated with this approach," said co-author Rachna Shah, associate professor of supply chain and operations at the University of Minnesota. "Overly familiar relationships and unwanted complacency may creep in for FDA investigators with prior experience inspecting that plant. This comes at a high cost for medical device consumers in the form of a significant increase in medical device failures leading to recalls."

More information: George Ball et al. Do Plant Inspections Predict Future Quality? The Role of Investigator Experience, *Manufacturing & Service Operations Management* (2017). DOI: 10.1287/msom.2017.0661

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