Good catches by Mayo staff contribute to 2 FDA recalls, protecting patients nationwide

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GOOD CATCHES FROM MAYO STAFF RESULTED IN TWO MEDICAL DEVICES BEING RECALLED BY THE FOOD AND DRUG ADMINISTRATION, PREVENTING HARM AND SAVING LIVES AT MAYO CLINIC AND NATIONWIDE.

Promptly reporting faulty medical equipment helps protect Mayo Clinic patients from harm. In some cases, it can lead to recalls and changes that can save lives far beyond Mayo Clinic.

That was the case last year when staff submitted dozens of reports regarding two device safety concerns. One group of reports focused on battery failures in Baxter Healthcare Sigma Spectrum Infusion pumps. Another reported missing radiopaque markings on Medtronic Strata II ventriculoperitoneal shunts.

The vigilance of Mayo staff in spotting faulty medical equipment resulted in these devices being recalled by the Food and Drug Administration, preventing harm and saving lives.

Erratic battery failures in Baxter Healthcare pumps

In early 2020, several nurses across Mayo Clinic noted that Baxter Healthcare's Sigma Spectrum Infusion Pumps were randomly shutting down without triggering alarms or alerts. These battery-related malfunctions were identified as a high patient safety risk since the pumps release timed fluids and medications to patients. Any delay or interruption to these treatments could create life-or-death situations.

In response to the influx of incident reports from the nurses, a team that included staff from Patient Safety, Healthcare Technology Management and Supply Chain Management began investigating the situation and finding ways to resolve it.

The team was led by Kannan Ramar, M.B.B.S., M.D., Mayo Clinic's chief safety officer; Ryannon Frederick, Mayo Clinic's chief nursing officer; Mark Manning, chair of the Division of Healthcare Technology Management; Ryan Motl, Healthcare Technology Management; and Rodney Severson, Healthcare Technology Management.

Team members identified the roots of the problem: Residue buildup and corrosion were causing the batteries to shut down. They notified Baxter Healthcare, and the company sent an urgent device correction statement to all affected clients. Also, the FDA issued a Class 1 recall — the most serious level of recall — indicating the battery failures could cause serious injuries or death.

Within Mayo Clinics, nearly 8,000 pump cases were safely replaced in less than 45 days. Also, cleaning practices were changed, and upgraded battery modules were installed. While there were no adverse patient safety events, near misses were caught by nurses in several areas, including the ICU, Emergency Department and Radiology.

In appreciation of Mayo Clinic's proactive efforts in the recall, Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health, presented Mayo Clinic with a certificate for "Outstanding Contribution in

Promoting Patient Safety With Medical Devices."

Missing markers on Medtronic shunts

Richard Zimmerman, M.D., Neurologic Surgery, and his team at Mayo Clinic in Arizona came across an interesting postoperative discovery when one of their patients received a Medtronic Strata II ventriculoperitoneal shunt implant, a device that relieves pressure in the brain caused by excess cerebrospinal fluid.

After the procedure, Dr. Zimmerman ordered X-rays to confirm the shunt's orientation and pressure settings. However, the markers necessary to verify the orientation and settings were not present in the X-rays. Dr. Zimmerman's care team filed a patient safety incident report and detailed analysis with images to communicate their findings.

These efforts were led by Kara Curley, a physician assistant in Neurosurgery; Kimberly Howard, Surgical Services; Nora Schaefer, Surgical Services; and several other staff from Surgical Services and Radiology.

Risk Management and Patient Safety staff at Mayo Clinic evaluated the concern and collaborated with Supply Chain Management to issue an internal recall across Mayo Clinic. This involved removing the current supply of devices from use. Staff were required to radiograph all inventory, report and remove affected items, and replace them with substitute products.

Mayo Clinic reported the defective equipment details to the FDA and Medtronic, the shunt's manufacturer. As a result, the FDA formally issued a Class 2 device recall in February, and Medtronic began to resolve the production issue shortly afterward**.**

"These narratives exemplify how safety reporting from staff can mitigate risk and improve safety across the nation," Dr. Ramar says. "Your commitment to creating a safe culture at Mayo Clinic truly carries a ripple effect outside of our walls. Thank you for making a difference in health care."

You can make a difference

There are many ways you can help keep Mayo Clinic patients and staff safe.

Study and use these five safe behaviors:

1. Pay attention to detail.
2. Communicate clearly.
3. Speak up and respond respectfully.
4. Hand off effectively.
5. Support each other**.**

Follow these steps to recognize, remove and respond to faulty equipment:

- Recognize when medical equipment isn't working perfectly.
- Remove it from use, and save all packaging and accessories.
- Report the issue. For patient safety issues, use the Patient Safety Reporting form. For broken electronic medical equipment — such as defibrillators, infusion pumps or ventilators — or for monitoring issues — such as bedside vitals monitor or telemetry — file a report through Healthcare Technology Management. For issues with disposable or consumable products, such as gloves or tubing, file a report through Supply Chain Management's Product Issues Tracking System.

More information

Direct questions to the Patient Safety Team.