Patient Safety Strategies and Tactics

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The Risks of Programmable Medical Equipment

The AMC PSO recently addressed anesthesia machine safety concerns. In a recent OR case, the vendor changed an anesthesia machine's default settings during routine servicing, without the knowledge of the anesthesia team. While there was no patient harm associated with this case, the team determined that a full review of all department anesthesia machines was warranted. A multidisciplinary group that included anesthesia staff, representatives from the clinical engineering department, and the biomedical technicians who support the OR examined this event and made several recommendations for anesthesia machine safety:

- Modify machine checks to include evaluation of default settings with each circuit change to ensure that settings are checked before every new patient case

- Standardize default settings for values and alarms

- Standardize criteria for use of a standby setting (stored memory preserved) or "off" setting (revert to default settings)

After initial discussion, the group broadened the scope of their review to include other programmable anesthesia equipment, such as smart pumps, and discovered additional issues. These included:

- Difficulty detecting and tracking equipment setting changes made after software upgrades or vendor repairs

- Overlapping or unclear responsibility for maintenance, repair, and purchasing of equipment at the departmental and hospital level

- Lack of communication and integration between equipment users and vendors resulting in unmanaged and undetected variability

The AMC PSO identified a broad array of programmable medical devices such as ventilators, cardiac monitors, and neonatal monitors that are distributed across many departments and lines of authority. Many organizations are responsible for large fleets of highly sophisticated equipment that were constantly on the move, both inside and outside of the hospital. Additionally, the combination of user fallibility, equipment complexity, and highly variable processes uncovered the need for further review.

The AMC PSO encourages you to work with your engineering staff to conduct an internal risk analysis and policy review.

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AMC|PSO is continuously working to identify emerging risks, address known risks, and share safety strategies. Our analysis is guided by malpractice claims data, the experiences of our AMC|PSO members, and consultation with clinical experts.