Academic Medical Center | Patient Safety Organization
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Patient Safety Strategies and Tactics

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Programmable Medical Equipment Risks and Interventions

The AMC PSO has continued its analysis of the risks associated with programmable medical devices, which were illustrated in an OR case involving changes made to an anesthesia machine's default settings during routine vendor servicing. Although there was no patient harm, the anesthesia team was not made aware of these changes. Our case review, conducted by clinicians and biomedical engineers, identified several key vulnerabilities, many with impact beyond the OR. As part of the group's ongoing risk assessment and best practices development, the following preliminary guiding principles for anesthesia machines were established and are intended to apply to other programmable devices.

Identified risks and interventions include:

Risk: *Uncertainty about how ventilator default settings are chosen for anesthesia machines.*

Safety Strategy:

- Foster close collaboration between biomedical staff and the anesthesia department designee. Biomedical staff can provide information about the multiple default configurations available and can guide the selection of uniform settings for optimal patient care.

Risk: *Unclear responsibility for maintenance, repair, and purchasing of equipment between departments and hospital clinical engineering.*

Safety Strategies:

- Create a centralized clinical engineering department.
- Provide manufacturer training to biomedical technicians on particular equipment types.
- Make biomedical technicians available daily and on-call as needed.

Risk: *Difficulty detecting and tracking equipment setting changes made after software upgrades or vendor repair.*

Safety Strategies:

- Implement specific equipment re-entry policies, requiring inspection and confirmation of the default settings before a device can be returned to the clinical environment after vendor repair.
- Document calibration parameters (including default settings) for each programmable device.
- Keep a copy of the software card for each machine.
- Restore default settings after any intervention with documentation in the equipment management system.

Risk: *Constantly moving fleets of highly sophisticated equipment both internally between departments and externally for vendor service and repair.*

Safety Strategies:

- Assign all newly acquired equipment a number for lifecycle tracking by an electronic equipment management system.
- Keep records of device repair, inspection histories, periodic maintenance, and service contract activities.
- Designate a clinical engineering staff member as an "expeditor" for equipment that is sent out for vendor service.
    - This staff member tracks the progress of the repair and facilitates

its return to the appropriate department when repairs are completed.

- Create a weekly rounding of biomedical engineering to review equipment functionality with department staff.

The case review also noted that distractions are omnipresent in ORs and often created by both external stimuli (pagers, staff turnover or questions from schedulers), as well as internal stimuli (time pressures and planning ahead for the next complex case).These distractions have become pervasive, well established, and normalized, resulting in a lack of insight into their impact to patient safety. The AMC PSO will continue study of this topic, including consideration of simulation/team training's role in the development of uniform standards for optimal attentiveness.