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PSO Monthly Brief

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Accident Investigation: "User Error" Does not Mean User's Fault

In a medical device accident investigation, the term "user error"—or as some say, "use error"— does not necessarily mean that the user is to blame, according to a recent ECRI Institute Patient Safety Organization (PSO) webinar on the steps of a medical device accident investigation.

Mark E. Bruley, CCE, Vice President, Accident and Forensic Investigation, ECRI Institute, was one of the presenters who led the webinar.

Though user error is a common finding during accident investigations, says Bruley, "User error does not mean it's the user's fault. An error by the user can be predicated by bad design."

He clarifies further: "What we've found is that up to 70% of health technology-related accidents are related to the user's technique of use—but again, many of those can be related to poor human factors design and poor labeling," he explains.

Therefore, a thorough accident investigation requires a review of the evidence and incident documentation, discussions with the product users whenever possible, rigorous device testing, and attempted recreation of the incident conditions during device testing.

"When you're considering the issue of user error versus device malfunction, you want to determine if it was used according to instructions and properly assembled. How familiar is the user with those instructions?" Bruley asks. He points out another consideration: "In some cases, the design may invite user error."

When an accident happens, the organization should have protocols that take effect immediately. These include the following steps, from ECRI Institute's "Accidents Happen" poster:

- Take emergency measures to minimize injury to the affected persons.
- Act to minimize damage to equipment.
- Notify the attending clinician.
- Impound all equipment attached or contiguous to the injured person.

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- Do not disconnect or change relative positions of equipment except as absolutely necessary to avoid further damage.
- Preserve disposable products (and packaging materials) that may have been involved.
- Enact organization policies for reporting and managing events.

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How Can We Help You?

Whether you have questions about the final rule or want to learn more about ECRI Institute PSO and/or support for other PSOs, we would be happy to hear from you. Please contact ECRI Institute at pso@ecri.org or call (610) 825-6000, ext. 5558.

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