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Top 13 Priorities for Infusion Pump Safety Named

The Association for the Advancement of Medical Instrumentation today released the 13 top priorities for infusion device safety as identified by attendees at the AAMI-FDA Infusion Device Summit, held Oct. 5-6 at FDA headquarters in Silver Spring, MD. The top issues, which will be addressed in an upcoming action plan, are:

1. No process for collaborative failure analysis.
    a. Lack of safe space for infusion incident related disclosure (access to information about problems). [Consider Patient Safety Organizations (PSO).]
2. Incompatibility across devices and with systems (e.g., consistent bar coding, wireless, power supplies, health IT systems). [Consider unavailability of wireless in a natural disaster.] Lack of cleared products for sale that support data transfer.
3. A high percentage of sentinel/adverse drug event (ADE) are due to use errors. Address issues related to high percentage of sentinel events due to use errors. Figure out how to develop design safety features that make it easy for the user to do the right thing. Examples of considerations: applicable human factors, automatic identification (bar coding), value of all the steps involved.
4. Standardization of terminology used in the infusion related systems (upstream and downstream) devices—same wording, same spelling across the process and devices, containers, etc.
5. Lack of knowledge/familiarity with the device; lack of effective training—from both manufacturer and facility.
6. Alarm management is not effective.
    a. High number of false alarms. Can also lead to true alarms being ignored.
    b. Alarms difficult to prioritize.
    c. Unclear how to resolve.
7. Injuries caused a differentiation in terms of hospital use versus use in other environments (e.g. home use) — design and user issues and differences among home, hospital, and other environments. Products designed for the hospital environment are being used in home environments and vice versa.
8. Inability to determine root cause of incidents due to difficulty accessing and analyzing incident data. Also applies to CQI.
9. Poor (incomplete, inadequate) system for reporting aggregate state/national adverse event data [e.g., FDA's Manufacturer and User Facility Device Experience (MAUDE) database].
    a. Lack of standardization that supports data aggregation.
10. The numbers are not conveying the bigger picture in terms of volume of incidents involving pumps. "Close calls," "near misses," and their root causes are not required to be reported.
11. Uploading/managing/maintaining drug libraries can be difficult.

   a. Lack of coordination between pump requirements and hospital capabilities.
   b. Steep learning curve on configuration / management.
   c. Difficulty in managing the same drug used in multiple units in multiple ways.

12. Lack of formulary and standards — standardization of concentrations and transparency (e.g., sharing between facilities) of drug libraries.
13. Difficulty in line management — including containers, manifolds, catheters, transport — dealing with the complexity of multiple infusions, including secondaries, disposables, etc.

NOTE: The top 13 priorities were reviewed by the AAMI Infusion Device Committee at its meeting on Oct. 7, 2010. This list reflects their input to clarify some of the items. The priorities, as listed above, are not necessarily arranged in order of importance.

Founded in 1967, the Association for the Advancement of Medical Instrumentation (AAMI) is a nonprofit organization representing a unique alliance of nearly 6,000 members from around the world united by one mission to increase the understanding and beneficial use of medical instrumentation through effective standards and educational programs, and publications.

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