



FDA PUBLIC HEALTH ADVISORY:

Avoiding Injuries from Rapid Drug or I.V. Fluid Administration Associated with I.V. Pumps and Rate Controller Devices

**To: Health Care Administrators
Directors of Nursing
Risk Managers
Home Health Care Agencies**

March 1, 1994

The FDA has received reports of injuries and deaths from uncontrolled, rapid infusion of medications and/or fluids with the use of I.V. pumps and rate control devices.

In certain cases, the I.V. tubing and bag were removed from the controller or infusion pump before the I.V. set clamp or thumb wheel was closed. This resulted in rapid, uncontrolled flow, or what is commonly known as "free-flow."

FDA suggests the following precautions to prevent such incidents:

- Conduct in-service training and refresher classes on the correct use of infusion pumps for all staff involved in the care of patients receiving I.V. therapy. Training should **stress the importance of closing the clamp on the administration set prior to opening the infusion pump door or when shutting off the pump.** Staff should be cautioned to close the clamp while changing the patient's gown or during patient transfer.
- **Place a prominent warning label on infusion pumps** alerting users to close the administration set clamp prior to opening the infusion pump door.
- **Use infusion pumps and/or infusion sets with antifree-flow mechanisms** to reduce free-flow incidents. If exclusive use of antifree-flow devices is not feasible, ensure their use in the care of vulnerable patients, e.g., infants, patients with diagnoses that require fluid restriction, and patients receiving potentially toxic medications such as lidocaine or theophylline.

Note. When purchasing new infusion pumps, be advised that those pumps which meet the Association for the Advancement of Medical Instrumentation (AAMI) standards have features that aid in the prevention of free-flow.

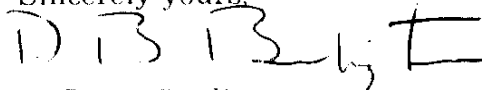
- **Use sets that incorporate limited volume reservoir chambers** for the continuous administration of potentially toxic medications from large volume bags, e.g., lidocaine or theophylline. These types of sets limit the amount of fluid readily available to be infused if free-flow occurs.
- **Limit the concentration of medication in the I.V. solution.** This would directly affect the amount of medication infused if free-flow should occur and would lessen the potential for undesirable effects.
- **Conduct regular inspection and maintenance of infusion pumps,** since free-flow incidents can also result from device malfunctions. Inspection and maintenance should include physical inspection of devices, tests for electrical safety and battery operation, and verification of calibration.

If you have questions regarding this advisory, please contact Sherry L. Purvis-Wynn, R.N., Office of Surveillance and Biometrics, CDRH, FDA, HFZ-510, 1390 Piccard Drive, Rockville, MD 20850, or FAX 301-594-2968.

Practitioners who become aware of device-related deaths, serious illnesses, and/or serious injuries, are asked to notify the FDA. The Agency is also interested in receiving information on free-flow occurrences that had the potential of causing serious adverse outcomes although the problems were corrected prior to actual injuries occurring. Please submit your reports to the **Medical Product Reporting Program, MedWatch**; by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178 or; by modem at 1-800-FDA-7737.

Under the Safe Medical Devices Act of 1990 (SMDA '90), device user facilities including hospitals and outpatient treatment facilities, are required to report device-related deaths, serious illnesses and/or serious injuries to the FDA, and/or the manufacturer, depending upon the circumstances. Please use procedures established by your facility to report such incidents.

Sincerely yours,



D. Bruce Burlington
Director
Center for Devices and
Radiological Health

References

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