DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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

Association for the Advancement of Medical Instrumentation. "American National Standard - Infusion Devices." ANSI/AAMI ID26-1992, 29 pp. August 1993.

Cohen, M. and Davis, M. "Recognizing the Dangers of Free-Flow From and E.I.D." Nursing 93, 56-59. June 1993.

ECRI. "I.V. Free-Flow - Still a Cause for Alarm." [Perspective], Health Devices, 21(9):323-328, September 1992.

Goetz, W., Fairfield, C., Soviero, C., Hoyte, M. "Infusion Pumps, Problem Definition Study." Center for Device and Radiological Health, Food and Drug Administration, Department of Health and Human Services. 46 pp. August 1987.

Goldstein H., Dinovo, J. "Final Report: Conformance Assessment to Voluntary Standards - Infusion Pumps." March 1993.

"Guidance on the Content of Premarket Notification [510(k)] Submissions For External Infusion Pumps." Division of General and Restorative Devices, Center for Device and Radiological Health, Food and Drug Administration, Public Health Service. 19 pp. March 1993.

International Organization for Standardization (ISO). "Infusion equipment for medical use - Part 4: Infusion sets for single use." ISO 8536-4, 11 pp. 1987.

Riley, C., Franke, K., Evans, C., Goldstein, H. "FDA Looks at Infusion Pumps." Medical Device & Diagnostic Industry, 13(10):32-33, October 1991.

Riley, C., Franke, K., Evans, C., Goldstein, H., Sierka, C. "Infusion Pump Report No. 1, Large Volume Pumps." Office of Training and Assistance, Center for Drugs and Radiological Health, Food and Drug Administration, Public Health Service, 11 pp. January 1988.

Riley, C., Franke, K., Evans, C., Goldstein, H., Sierka, C. "OTA Report on Ambulatory Infusion Pumps." Office of Training and Assistance, Center for Drugs and Radiological Health, Food and Drug Administration, Public Health Service. 19 pp. June 1988.

Riley, C. "Infusion Pump State Contract Investigation Summary Report." HHS Publication, FDA 93-4256, 52 pp. January 1993.