Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.75, February 2013

Total Dose Wrongly Entered as Flow Rate in Infusion Pump, etc.

Three cases have been reported involving the administration of an overdose of a drug due to the total dose having been entered as the flow rate when setting the flow rate on infusion pumps (infusion pumps and syringe pumps) (information collection period: from January 1, 2009 to December 31, 2012; the information is partly included in “Individual Theme Review” (p.84) in the 7th Quarterly Report).

Cases of the administration of an overdose of a drug due to the total dose having been entered as the flow rate when setting the flow rate on infusion pumps have been reported.

Drug Used	Flow Rate Ordered	Total Dose	Flow Rate Set
Parenteral nutrition	30mL/h	900mL	900mL/h
Novo-Heparin for Injection 7.5mL + normal saline 250mL	11mL/h	257mL	257mL/h
Dormicum Injection 10mg 10A + normal saline 30mL	3mL/h	50mL	50mL/h

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Case

When replenishing the patient's parenteral nutrition, the total dose was entered instead of the flow rate. The infusion pump used (Terufusion Infusion Pump TE-171 (purchased in 1999)) was a model that does not bear the Medical Safety Compliance Mark for Medical Devices, and the design was such that the same switch was used to toggle between functions when setting both the flow rate and the total dose. An hour later, the patient's respiratory condition deteriorated and it was discovered that the whole dose of parenteral nutrition had already been administered. When checked, the flow rate on the infusion pump was discovered to have been set at 900mL/h instead of 30mL/h. The patient suffered convulsive seizures and respiratory arrest, and his/her blood glucose level was 976mg/dL.

The Ministry of Health, Labour and Welfare has issued a notice to relevant companies concerning measures to prevent medical adverse events relating to infusion pumps, etc. and it is possible to purchase pumps bearing the Medical Safety Compliance Mark for Medical Devices, which demonstrates that safety has been taken into account in their design, so please bear this in mind.

○Pharmaceutical Notice No.0318001 dated March 18, 2003
http://www.info.pmda.go.jp/iryoujiko/file/20030318.pdf

Compliant with the 2003 Notice on Measures to Prevent Medical Adverse Events

This mark is awarded under an independent industry initiative and indicates that this product is compliant with the standards set by the Ministry of Health, Labour and Welfare for measures to prevent medical adverse events.

*The Medical Safety Compliance Mark for Medical Devices of the Japan Medical Devices Manufacturers Association, which indicates that infusion pumps comply with the standards set out in the aforementioned notice from the Ministry of Health, Labour and Welfare.

Preventive measures taken at the medical institutions in which the events occurred.

- **Checks after setting the flow rate and total dose on infusion pumps will be thoroughly enforced.**
- **Staff will be provided with an adequate understanding of the differences between different models of infusion pump used within the medical institution.**

Complementary comment by the Comprehensive Evaluation Panel

- **Please note that the infusion pumps, etc. currently used in clinical practice include some that do not bear the Medical Safety Compliance Mark for Medical Devices.**
- **Please ensure that staff are educated about the infusion pumps used within the medical institution.**

* As part of the Project to Collect Medical Near-Miss/Adverse Event Information (a Ministry of Health, Labour and Welfare grant project), this medical safety information was prepared based on the cases collected in the Project as well as on opinions of the "Comprehensive Evaluation Panel" to prevent the occurrence and recurrence of medical adverse events. See quarterly reports and annual reports posted on the Japan Council for Quality Health Care website for details of the Project.
http://www.med-safe.jp/
* Accuracy of information was ensured at the time of preparation but cannot be guaranteed in the future.
* This information is intended neither to limit the discretion of healthcare providers nor to impose certain obligations or responsibilities on them.

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