



Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/
Adverse Event Information

Medical Safety Information

No.66, May 2012

Misconception of insulin content (1st Follow-up Report)

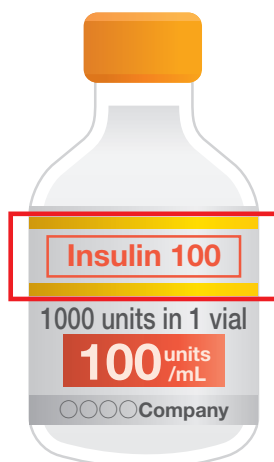
Information about the misconception of insulin content was provided in Medical Safety Information No.1 (December 2006). After that, eight similar cases have been reported, so that information is provided again (information collection period: from October 1, 2006 to March 31, 2012).

Cases of the misconception of the insulin unit, resulting in an overdose that caused low blood glucose, have been reported again.

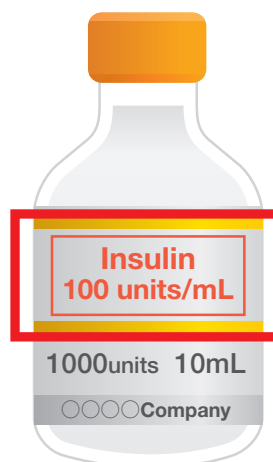
Insulin concentration has been unified to be 100 units/ml, 1 vial contains 1000 units (10ml).

Brand names have changed as a result of the notice entitled "Handling of the Formulation of Brand Names for Insulin Preparations". (Diagram)

Vial preparation in Medical Safety
Information No.1



Vial preparation following
the change of brand name



The brand name on the vial preparation now shows that the concentration is **100 units/mL**.

- ◆ Three out of eight reported cases were carried out by doctors or nurses who have had practical experience of less than 1 year.

Misconception of insulin content (1st Follow-up Report)

Case

Nurse A (a first-year nurse) was preparing Novolin R for the first time for a patient who was being administered a continuous infusion of insulin diluted in normal saline. The following was written on the order sheet: "Novolin R 100 IU/mL (10mL) 40 units + normal saline 40mL". The nurse looked at the order sheet and misconstrued it as meaning that 10ml of Novolin R was 100 units, so in relation to the order for 40 units, s/he prepared 4mL (400 units) with normal saline and made the total quantity 40mL. Four hours later, the patient did not wake even when spoken to and showed low blood glucose (BS17mg/dL).

The Ministry of Health, Labour and Welfare has issued a notice concerning the handling of the formulation of brand names for insulin preparations.

- Pharmaceutical and Food Evaluation Notice No.0331001 Pharmaceutical and Food Safety Notice No.0331001 dated March 31, 2008

<http://www.info.pmda.go.jp/iryoujiko/file/20080331.pdf#search>

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

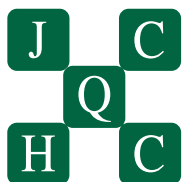
Thoroughly ensure widespread awareness among all staff that the concentration of insulin is 100 units/mL and that one vial contains 1000 units (10mL).

* 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.



**Division of Adverse Event Prevention
Japan Council for Quality Health Care**

1-4-17 Misakicho, Chiyoda-ku, Tokyo 101-0061 JAPAN
Direct Tel: +81-3-5217-0252 Direct Fax: +81-3-5217-0253
<http://www.jcqhc.or.jp/>