Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

# Medical Safety Information

# Caution to ensure proper usage of blood glucose testing devices

No.21, August 2008

A case where a blood glucose testing device using pyrroloquinoline quinone (PQQ) as a coenzyme of glucose dehydrogenase (GDH) method was used to measure the blood glucose of a patient who had undergone blood dialysis with dialysis solution containing icodextrin, an abnormal higher value than the actual blood glucose level was displayed and insulin was administered based on that reading, was reported. (information collection period, from January 1, 2006 to June 30, 2008; the infomation is partly included in "Medical Adverse Event Information to Be Shared" in the 13th Quarterly Report).

**Blood glucose testing devices using PQQ as a coenzyme of GDH method may display readings higher than actual blood glucose levels for patients being given a specific treatment.**

## The following patients cannot apply for a blood glucose testing devices using PQQ as a coenzyme of GDH method.

Patients being administered a infusion which contains maltose
Patients being administered blood dialysis solution which contains icodextrin
Patients being tested by a galactose tolerance test
Patients being tested by a xylose absorption test
Patients being administered pralidoxime iodide

## Major blood glucose testing devices using PQQ as coenzyme of GDH method

| Corresponding device name | Marketing authorization holder |
|---|---|
| Accu-Chek Aviva | Roche Diagnostics K.K. |
| Nipro Free Style Meter | Nipro Corporation |

◆ For other blood glucose testing devices, please check the measurement method, etc, according to the package insert.

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## Case

The ward had two types of blood glucose testing devices, i.e. one which measures based on the GDH method and another which uses the GOD method (glucose oxidase). The staff normally used both without being aware of the difference. The device which uses the GDH method was applied for a patient receiving icodextrin dialysis solution, and insulin was administered on the basis of the reading.
Eleven days later, the patient's blood glucose level was occasionally measured by another testing device using the GOD method and a lower reading than usual was obtained. The staff wondered about the reading and measured blood glucose with both devices at a time. The reading with the GDH-based device was 215mg/dL, while the reading with the GOD-based device was 91mg/dL. After checking the package insert for the devices, the inappropriate application of the blood glucose testing device for this patient was discovered.

## Notification regarding "Precautions" of blood glucose testing device has been issued by the Ministry of Health, Labour and Welfare.

Issued by the General Affairs Dvision of the Health Policy Bureau,
No. 0207001, February 7, 2005

Issued by the Safety Division of the Pharmaceutical and Food Safety Bureau,
No.0207005, February 7, 2005
http://www.pmda.go.jp/operations/notice/2005/file/20050207001-0207005.pdf

Issued by the Safety Division of the Pharmaceutical and Food Safety Bureau,
No.0907001, September 7, 2007
http://wwwhourei.mhlw.go.jp/cgi-bin/t_docframe.cgi?MODE=tsuchi&DMODE=CONTENTS&SMODE=NORMAL&KEYWORD=&EFSNO=4369

* 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 “Comprehensive Evaluation Panel” to prevent 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 can not be guaranteed in the future.
* This information is neither for limiting the discretion of healthcare providers nor for imposing certain obligations or responsibilities on them.

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