Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.93, August 2014

Wrongly Registered Antineoplastic Drug Regimen

Four cases have been reported involving the administration of an antineoplastic drug to a patient in accordance with a wrongly registered regimen (information collection period: from January 1, 2011 to June 30, 2014). The information is compiled based on “Individual Theme Review” (p.93) in the 25th Quarterly Report.

Cases of the administration of an antineoplastic drug to a patient in accordance with a registered regimen containing an error have been reported.

Name of Disease	Drug Registered	Details Registered in Error		Details Intended to Be Registered
Small-cell lung cancer	Campto for I.V. infusion	Dosage	100mg/m^2	50mg/m^2
Invasive mole	Methotrexate Parenteral	Unit	/m^2	/body
Prostate cancer	Endoxan	Usage	1,000mg/m^2/time once a week for 3 weeks, with a drug holiday in the 4th week	1,000mg/m^2/time once every 3 weeks
Acute myeloid leukemia	(Details unclear)	Number of days of administration	6 days	5 days

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Case 1

When the hospital was introducing a new computer system due to the transition to an electronic medical record system, the pharmaceutical department entered the full regimen for the anticancer drugs that had previously been administered to treat lung cancer, and the clinical department checked what had been entered. When registering the regimen "CBDCA (Paraplatin Injection) + CPT-11 (Campto for I.V. infusion) combination therapy for small-cell lung cancer," medical staff failed to notice that it had been registered showing a dosage of 100mg/m^2 of Campto for I.V. infusion, when it should have been 50mg/m^2. Drug therapy using the registered regimen of "CBDCA+CPT-11 combination therapy" was subsequently prescribed, so double the planned dosage of Campto for I.V. infusion was administered to the patient for 8 days. When considering the next course, the physician checked the dosage again and realized that an overdose of Campto for I.V. infusion had been administered.

Case 2

When applying for "Methotrexate therapy for trophoblastic disease," the physician failed to enter "/body" as the unit. The Chemotherapy Committee considered the new regimen and approved it without noticing that the unit had not been entered. Although "/body" had not been noted on the new regimen when it was registered, the pharmacist registered it as "/m^2" without checking the package insert or querying it with the physician who had applied for the regimen. Drug therapy using the registered regimen of "Methotrexate therapy for trophoblastic disease" was subsequently prescribed, so the dosage was calculated using "/m^2" as the unit, with the result that 45mg/day of Methotrexate Parenteral (1.5 times the planned dosage) was administered to the patient for 5 days. After administration, the patient suffered severe side-effects, including stomatitis, bone marrow suppression, febrile neutropenia, and hair loss; the cause was investigated and the error in the registered regimen was discovered.

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

- **Physicians and pharmacists handling regimen management will check the details of the regimen against the content of the literature accompanying the regimen application form when registering a new regimen.**
- **The applying physician and the pharmacist handling regimen management will check the content of the registered regimen before putting it into operation.**

Complementary comment by the Comprehensive Evaluation Panel

- **Errors in registering an antineoplastic drug regimen can have a serious impact on patients.**
- **When preparing and registering a regimen, use a checklist to check that there have been no oversights or errors when filling in the details.**
- **Immediately before finalizing the registration, check again that the details to be registered are correct, referring to the 6Rs*.**

* Right patient, Right drug, Right purpose, Right dose, Right route, and Right time.

* 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.

Department 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/