



# Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/  
Adverse Event Information

## Medical Safety Information

No.86, January 2014

### Administration of Contraindicated Drug

Eight cases have been reported involving the administration of a drug to a patient of a type listed in the "Contraindications (The drug is contraindicated in the following patients)" on the package insert of a prescription drug, even though the patient's disease and/or clinical condition was known to the person involved (information collection period: from January 1, 2010 to November 30, 2013; the information is partly included in "Individual Theme Review" (p.127) in the 29th Quarterly Report).

**Cases have been reported in which the person involved was aware of the patient's disease and/or clinical condition, but administered a drug without knowing that the disease/condition was listed on the package insert as a contraindication.**

Disease/Condition	Drug Administered (Main Efficacy)	Number of Cases
Severe renal dysfunction/ renal failure*1	Glycoran Tablets (oral hypoglycemic agent)	1
	Xyzal Tablets (therapeutic agent for allergic diseases)	1
	TS-1 combination drug*2 (antimetabolite)	1
	Visiclear Combination Tablets (oral bowel cleansing agent)	1
Parkinson's disease	Serenace (antipsychotic)	2
Suspected gastrointestinal perforation	Bari-Enema HD 75% (disposable contrast enema)	1
Hemophilia	Neolamin Multi V Inj.*3 (multivitamin preparation used in parenteral nutrition)	1

\*1 Other diseases/conditions listed on the package insert include renal dysfunction (including mild impairment), patients on dialysis (including peritoneal dialysis), and patients with serious renal dysfunction.

\*2 The form in which the TS-1 combination drug was administered (i.e. combination capsules, combination granules, or combination OD tablets) is unclear.

\*3 The contraindications section on the package insert for Neolamin Multi V Inj. states, "Hemophiliacs [because it contains panthenol.]"

## Administration of Contraindicated Drug

### Case 1

A patient with Parkinson's disease had post-operative delirium, so the physician ordered an intramuscular injection of Serenace, which the nurse administered. The package insert for Serenace listed "patients with Parkinson's disease" in the contraindications section, but neither the physician nor the nurse knew this. After administering the Serenace, the patient's Parkinson's-induced muscular rigidity worsened.

- ◆ The contraindications section on the package insert for Serenace (antipsychotic agent) states, "Patients with Parkinson's disease [There is a risk of exacerbating extrapyramidal symptoms.]"

### Case 2

The physician prescribed Visiclear Combination Tablets to a patient with renal failure, as a pretreatment before a colon polypectomy. The package insert for Visiclear Combination Tablets listed "patients with severe renal dysfunction" in the contraindications section, but the physician did not know this. The day after taking the Visiclear Combination Tablets, the patient developed symptoms of acute hyperphosphatemia and tetany due to hypocalcemia.

- ◆ The contraindications section on the package insert for Visiclear Combination Tablets (oral bowel cleansing agent) states, "Patients with severe renal dysfunction, including dialysis patients; patients with acute phosphate nephropathy."

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

- When administering a drug to a patient for the first time, physicians will ensure that they prescribe it only after confirming the contraindications on the package insert.

#### Complementary comment by the Comprehensive Evaluation Panel

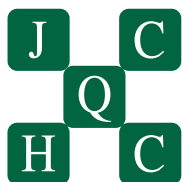
- Carry out treatment such as the administration of drugs via orders using a set menu format only after checking which diseases the patient has.
- The package insert for Visiclear Combination Tablets has been revised to add "Elderly people with hypertension" to the contraindications section (February 2012).
- Package inserts are revised from time to time, so check them periodically.

\* 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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