Project to Collect and Analyze Pharmaceutical Near-Miss Event Information

2009 Annual Report

October 5, 2010

Japan Council for Quality Health Care
Division of Adverse Event Prevention

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Foreword

Tetsuo Ihara
President
Japan Council for Quality Health Care

In Japan, what is expected of health care has become more advanced and diversified with changes in common disease prevalence and advances in medical technologies. Public interest in and demand for health care has been increasing in recent years due to the changing social structure. In this context, quality assurance in the health care system is more emphasized than quantity maintenance, making it an important task to provide accurate health care information to the general public as well as to promote and ensure the provision of quality health care. The Japan Council for Quality Health Care (JCQHC) should therefore play an important role in improving the quality of health care in Japan.

Regarding quality health care services, public expectations and interest in promotion of medical safety and prevention of medical accidents have especially grown. As a neutral third-party organization, the JCQHC evaluates the care process to ensure the quality and safety of health care services at hospitals based on the predetermined criteria in a third-party hospital evaluation and accreditation project. As of now, about 30% of Japanese hospitals (over 40% of total hospital beds in the country) are JCQHC-accredited.

The five-year-old Project to Collect and Analyze Pharmaceutical Near-Miss/Adverse Event Information is another project of the JCQHC. Pharmaceutical near-miss/adverse event information is collected from the participating medical institutions in the Project since 2004 to prevent medical accidents and to promote medical safety. Since about 30% of reported events are related to drugs, indicating that a considerable number of medical near-miss events may be occurring at pharmacies.

According to the recently revised Health Service Act, pharmacies are now defined as health care facilities like hospitals and clinics. Now that promotion of medical safety is an important responsibility of pharmacies, we should learn from medical near-miss information reported by pharmacies and share the lessons nationwide.

After the Project to Collect and Analyze Pharmaceutical Near-Miss/Adverse Event Information and other activities of the JCQHC had been recognized by organizations and agencies involved in safety management at pharmacies, the JCQHC inaugurated the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information from Pharmacies in 2008. The registration of pharmacies to participate in the Project and collection of pharmaceutical near-miss information occurred or identified at pharmacies started in April 1, 2009.

Collected pharmaceutical near-miss information is widely available to health care facilities, the general public, relevant organizations and administrative organizations in forms of case database, periodic reports and near-miss information to be shared. The JCQHC deeply appreciates the participating pharmacies and those committed to the Projects for their cooperation in collection of pharmaceutical near-miss information.

The 2009 annual report was prepared herein based on past half-year reports. The annual report includes near-miss events reported from April to December 2009, analyses of individual themes and near-miss information to be shared that will be useful for medical safety promotion. The JCQHC hopes the annual report will be beneficial to pharmacies and help the general public understand current nationwide efforts to promote the medical safety in Japan. Your suggestions for improvement of the JCQHC's activities to provide useful information will be greatly appreciated.

The JCQHC is determined to maintain public trust in healthcare services and improve the quality of medical care and its safety through various projects, including the evaluation and accreditation of medical services provided at hospitals. The JCQHC appreciates your understanding and cooperation.

Issuing the 2009 Annual Report

Kikuo Nomoto
Director
Japan Council for Quality Health Care

The Division of Adverse Event Prevention inaugurated the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information in October 2008 to further promote medical safety measures by widely providing information useful for development of medical safety measures at pharmacies as well as by providing information to the general public. The Project has been carrying out based on over five years of our experience in the Project to Collect and Analyze Pharmaceutical Near-Miss/Adverse Event Information, in which pharmaceutical near-miss/adverse event information has been collected, analyzed and published in periodic reports and monthly medical safety information and workshops to improve the reporting quality. Since numerous events relating to drugs have been reported, we have particularly tabulated near-miss events involving drugs and prepared and provided multiple medical safety informations specifically related to drugs. Our experience is now used in the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information.

The objective of collecting and analyzing pharmaceutical near-miss information is to create a safety-oriented culture at pharmacies. It is important to collect a wide range of relevant information and use it to promote medical safety. In terms of creating a safety-oriented culture, it is not necessarily correct to view an increase in the number of reports as an actual increase in medical accidents or near-miss events, i.e., safety at pharmacies declined.

Medical near-miss events involving drug dispensing activities that may also occur at hospitals and clinics as well as near-miss events that particularly occurred at pharmacies such as those identified after making inquiries to hospitals and clinics and related to drug sales are subject to reporting in the Project. In addition medical errors with unknown consequences are also subject to reporting. The scope of reporting is thus determined to widely collect medical near-miss information from pharmacies. Since reports from pharmacies are the basis of the Project, the JCQHC deeply appreciates the cooperation of the pharmacies that have been reporting near-miss events. The participating pharmacies are encouraged to report near-miss events in accordance with the project outline and regulation in order to provide readers of the annual report with appropriate information on near-miss events occurring in Japan.

The Division of Adverse Event Prevention ensures anonymity of reported information to create an environment for safe reporting of pharmaceutical near-miss events by pharmacies. We hope pharmacies will understand the Project will not put reporting pharmacies at any disadvantages and actively participate in the Project, which is a nationwide effort to prevent medical accidents at pharmacies. We have received positive responses from the participating medical institutions to the Project to Collect and Analyze Medical Near-Miss/Adverse Event Information carried out in the same light, including an opinion that participation in the Project indicates proactive intension of the institute to promote medical safety.

The 2009 annual report includes medical near-miss events reported during the period from the launch of the Project in April 2009 to December of the same year. The report basically consists of the contents of published reports but also contains analyses based on five themes and near-miss event information on drugs listed in the National Health Insurance price list for less than one year. Figures and tables included in the annual report are mostly available on our website in different designs that can be easily posted at pharmacies or used in in-house workshops. We hope that pharmacy managers, those responsible for medical safety and pharmacy staff will share the information provided in the annual report for promotion of medical safety at individual pharmacies.

We will increase our efforts to enhance the content of project reports for prevention of medical adverse events and promotion of medical safety in Japan. Your understanding and cooperation is appreciated.

Project to Collect and Analyze Pharmaceutical Near-Miss Information

Focusing on the 2009 report

Shin Ushiro
Manager of Medical Adverse Event Prevention Division
Japan Council for Quality Health Care

1. Foreword

Thank you for your continuous understanding and cooperation in this project.

The 2009 Annual Report includes medical near-miss events that occurred or were identified at pharmacies and reported from April to December 2009. The 2009 Annual Report comprises the semiannually reports published so far and analyses of individual themes for prevention. I hope you will share the information contained in the 2009 Annual Report with the safety manager and the staff members at your pharmacy.

If you are reading the 2009 Annual Report or browsing our website as healthcare service users, I hope you will understand the types and details of the medical near-miss events that occurred at the pharmacies and those that occurred at the medical institutions and that are identified based on inquiries from pharmacists to physicians as well as the attempts of the pharmacies and the medical institutions to prevent recurrence of medical accidents.

The current statuses of the Project to Collect Pharmaceutical Near-Miss Information from Pharmacies and other relevant projects are introduced below.

2. About the 2009 Annual Report

1) Number of reports

Total of 1,460 pharmaceutical near-miss events were reported from April to December 2009 (page 16). The number of reported near-miss events included in the 2009 Annual Report is small since the project has just started. However, the number has been steadily increasing. Over 1,000 near-miss events are reported as of now monthly at one year after the launch of the project. I deeply appreciate your cooperation in this project and hope you review the scope of reporting provided in "I-2 Summary of the Project to Collect and Analyze Pharmaceutical Near-Miss Information" in the 2009 Annual Report (page 12) and report relevant near-miss events to promote medical safety in Japan.

It is not easy for the pharmacies to identify pharmaceutical near-miss events that fall into the scope of reporting, clarify the fact without lack of important information, summarize and report the near-miss events and continue reporting in high quality. JCQHC has experienced that the quality of medical adverse event reports had been improving through repeated reporting activities and medical adverse event analysis exercises provided at workshops in the Project to Collect Medical Near-miss Adverse Event Information. I encourage you to participate in this project to improve your skills to identify and report pharmaceutical near-miss events and promote medical safety at pharmacies.

2) Current reporting status

"II Current Reporting Status" includes the summary of reported cases, details of most frequently reported drugs, effects on prescription after inquiries, analyses of the reasons for inquiries and

information based on which inquiries were made and tabulations of causes of near-miss events. Drugs prescribed in the reported cases, wrong drugs used, replaced drugs, names of drugs identified as related products to near-miss event and number of reports and the tabulation specific to generics are also included. Since the number of reports may increase with the sales of the drug, the order of drugs on data presentation does not necessarily correspond with the extent of associated risks. We hope the information will be effectively used for further promotion of drug safety at dispensing pharmacies and drug manufacturing sites.

"Drugs newly listed for less than one year in the NHI price list but not considered as newly-listed drugs" (page 34), which is not available in our semiannual reports, is also included. Pharmaceutical near-miss events involving drugs newly listed in the NHI price list but not considered as newly-listed drugs (new drugs listed for less than one year) and drugs with changed names were reported and tabulated in the annual report. We hope the information will be used together with the tabulation of newly-listed drugs for prevention of medical accidents.

3) Analysis of pharmaceutical near-miss events

The 2009 annual report analyzed the reported near-miss events according to the following five themes.

(1) Pharmaceutical near-miss events related to similar drug names (page 39 to 43)

(2) Pharmaceutical near-miss events related to similar efficacies (page 44 to 48)

(3) Pharmaceutical near-miss events related to high-risk drugs (page 49 to 51)

(4) Pharmaceutical near-miss events related to inquiries about prescription (page 52 to 57)

(5) Pharmaceutical near-miss events related to particular drugs (page 58 to 68)

  (i) Warfarin potassium

  (ii) Insulin

In this first annual report of the Project, similar drug names and high-risk drugs were selected as themes by referring to those selected for the Project to Collect and Analyze Medical Near-Miss/Adverse Event Information. The analysis of near-miss events involving inquiries, which is unique to pharmacies, is also included to evaluate the cases involving hospital-pharmacy coordination. The analysis of near-miss events involving particular drugs focused on warfarin potassium and insulin. Details of the near-miss events are introduced according to release/no release of the drug, and pharmaceutical near-miss events occurred due to multiple drug strengths are analyzed.

4) Pharmaceutical near-miss information to be shared

Information that needs to be widely shared is selected by experts and posted on the website every month with the expert's opinion "the point of the case." Such information is included in the annual report (page 69 to 89). Details of individual near-miss events are available on the Project to Collect and Analyze Pharmaceutical Near-Miss Information website. Click the "public data search" button and enter the case number to browse. Three to four cases of pharmaceutical near-miss events to be shared are posted on the website every month. Posting of new information is notified to participating pharmacies through e-mail newsletters. The posted information is included in periodic semiannual reports as well as in the annual report. The selected near-miss events will provide important information to pharmacies. We hope they will be thoroughly reviewed and used for review and improvement of activities at pharmacies.

3. Pharmaceutical near-miss information analysis table

The 2009 annual report consists of over 100 pages. The data are analyzed according to the five themes and presented in detail in texts and tables. While deliverables from the Project to Collect and Analyze Medical Near-Miss/Adverse Event Information should generally contain a large volume of information as the 2009 annual report does since so much information has been reported, some deliverables should contain selected information so that busy healthcare professionals can use it in their daily practice. An example of the latter is medical safety information.
The budgetary scale of the Project to Collect and Analyze Pharmaceutical Near-Miss Information does not allow development of deliverables such as medical safety information. However, "pharmaceutical near-miss information to be shared" mentioned earlier consists of selected information as does medical safety information prepared in the Project to Collect and Analyze Medical Near-Miss/Adverse Event Information. The contents of the 2009 annual report shown in the figures and tables in the sections of the individual themes are also presented as "Pharmaceutical Near-Miss Information Analysis Table" [(i) to (v) below] in different designs and forms that can be easily posted at pharmacies or used in in-house workshops. A colored version is available on the website.

(i) Drug mix-ups due to similar drug names (page 97)

(ii) High-risk drugs reported in pharmaceutical near-miss events (page 98)

(iii) Prescription changes made after making inquiries and reasons for making inquiries (page 99)

(iv) Pharmaceutical near-miss events related to warfarin potassium (page 100)

(v) Pharmaceutical near-miss events related to insulin (page 101)

The analysis tables were prepared based on the concept of medical safety information in the Project to Collect and Analyze Medical Near-Miss/Adverse Event Information, which is to include selected information and be presented in colors and formats that appeal to the eye and draw attention. We hope the analysis tables will be printed out and posted at pharmacies or used for information sharing among pharmacy staff or practical training for pharmacy students.

4. Current status and challenges of the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information

The registration of pharmacies and information collection in the Project started in April 2009. The number of participating pharmacies has been increasing. More than 3,000 pharmacies are registered as of July 2010, nearing the target number of 5,000 to 10,000. However, the proportion of participating pharmacies is only 5.6% of 53,304 pharmacies in Japan (the 2008 Health Administration Activity Report). Unregistered pharmacies are encouraged to understand the objective of the Project to prevent medical accidents at pharmacies and participate in the Project activities. The cooperation of the participating pharmacies in recruiting unregistered pharmacies is appreciated.

The number of reported near-miss events has also been increasing. Currently 1,500 to 2,000 near-miss events are reported every month. While useful information that is later selected as pharmaceutical near-miss information to be shared has been reported, the sections of "Background and Causes" and "Improvement Measures" are blank in many of the reports. Improvement of reporting quality will be a future challenge as well as increasing the number of participating pharmacies and reported near-miss events. The participating pharmacies are encouraged to review "Case Report Data Entry Guidelines" on the Project to Collect and Analyze Pharmaceutical Near-Miss Information website (https://www.yakkyoku-hiyari.jcqhc.or.jp/pdf/text_report_guide.pdf) to ensure proper reporting. Common reporting errors are shown in "Reporting Precautions"

(http://www.yakkyoku-hiyari.jcqhc.or.jp/pdf/ask_report.pdf) sent to participating pharmacies in January 2010.

5. Information provision on the website

In parallel with the review of the Project to Collect and Analyze Medical Near-Miss/Adverse Event Information in 2008, the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information was developed based on the knowledge and experience gained through the operation of the former. Publication of near-miss events reported in the Project to Collect and Analyze Pharmaceutical Near-Miss Information on the website started last year, ahead of the new system for the Project to Collect and Analyze Pharmaceutical Near-Miss/Adverse Event Information started in January this year. Information provided on the website is a large volume as well as high transparency. Over 6,000 near-miss events have been published to date. The searchable website enables the users to pick out whatever near-miss events interest them.

Publication of a large number of near-miss events is just as important as providing information on individual near-miss events to be used to ensure medical safety at pharmacies. Provision of information on selected near-miss events with experts' comments and points to consider is described above in "2-4) Pharmaceutical near-miss information to be shared."

A list of participating pharmacies and published semiannual tabulation reports and annual reports are also included in the 2009 annual report.

6. Coordination with the Project to Collect and Analyze Medical Near-Miss/Adverse Event Information

The Division of Adverse Event Prevention launched the Project to Collect and Analyze Medical Near-Miss/Adverse Event Information in October 2004 to prevent occurrence and recurrence of medical accidents. The 21st report and the 2009 annual report were published in July and August 2010, respectively. In 2009, 2,064 medical adverse events and 241,939 near-miss events were reported by medical institutions. The situations of drug-related near-miss events, specifically, "drug dispensing," "drug prescription/administration" and "drug dispensing/management," took up 26.4% of the reported medical near-miss events. Many of the reports were similar to medical near-miss events that occurred at pharmacies. The 2009 annual report also contains individual drug-related themes such as "events related to drugs," "events related to chemotherapy" and "infarction and hemorrhage in patients treated with warfarin potassium for coagulability management" to provide useful information to medical institutions as well as to pharmacists working at pharmacies. In the section of "5. Medical near-miss events involving particular drugs: 1) Warfarin potassium," the near-miss events analyzed under the theme "Infarction and bleeding in patients treated with warfarin potassium for coagulability management" are presented as "(5) Cases reported by medical institutions." Medical safety information from the Project to Collect and Analyze Medical Near-Miss/Adverse Event Information is provided in the sections of other theme analyses to develop deliverables that can be shared by both Projects and help medical institutions and pharmacies share useful information. Near-miss/adverse events involving drugs should be analyzed in an integrated manner to develop proper medical safety measures rather than separately analyzed by medical institutions and pharmacies.

The Project to Collect and Analyze Medical Near-Miss Adverse Event Information started to prepare monthly medical safety information in 2006 to provide information through fax and on the website. Medical Safety Information No. 45 "Bone marrow suppression due to antirheumatic (methotrexate) overdose: the second report" was issued in August 2010. Other drug-related medical safety information such as "Drug mix-up," "Drug administered at a wrong dose level due to discrepancy in interpretation of the prescription" and "Drug administered at a wrong dose level due to discrepancy in interpretation of the prescription: the second report" had also been issued. We hope the medical safety information provided on the website will be used for recurrence prevention at pharmacies. Since the

contents of the 2009 annual report will be useful for in-house pharmacies and hospitals, the JCQHC will inform medical institutions of the issuance of the report.

Taking advantage of the integrated collection of medical near-miss/adverse event information from medical institutions and pharmacies, the JCQHC will provide especially valuable information for prevention of medical accidents involving drugs.

7. Postscript

The JCQHC will improve the contents of Project reports and effectively provide information to prevent medical accidents and promote medical safety in Japan. Your understanding and cooperation in the JCQHC's projects will be deeply appreciated.

I Outline of Project to Collect and Analyze Pharmaceutical Near-Miss Event Information

The objective of the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information from Pharmacies is to further promote the medical safety measures by collecting, analyzing and providing pharmaceutical near-miss information reported by pharmacies.

The outline of the information collection activities in the Project is described below.

1 Background of Pharmaceutical Near-Miss Event Information Collection

"The Law to Amend the Medical Service Law to Establish a System that Provides High Quality Medical Care" (Law No. 84, June 2006) positions pharmacies as "health care facilities" and stipulates they must establish a system to ensure medical safety by "appointing a manager" and "developing an operating procedure."

As the Law came into effect, a grant project (the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information) was started by the Ministry of Health, Labour and Welfare in 2008. Considering the importance of the Project to promote medical safety, the JCQHC decided to take over the project operation in June 2008.

Launched on October 1, 2008, the Project started recruiting pharmacies and collecting pharmaceutical near-miss information on April 1, 2009 after several months of preparation.

2 Outline of the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information

[1] Objective

The objective of the Project is to collect, analyze, and provide pharmaceutical near-miss information reported by pharmacies to widely share information useful to develop medical safety measures with pharmacies and to provide information to the general public to further promote medical safety measures.

[2] Collection of pharmaceutical near-miss event information

(1) Participating organizations

Pharmacies(Note) are recruited to participate in the Project.

(2) Pharmaceutical near-miss information to be reported

The following pharmaceutical near-miss event information is subject to reporting. In the Project, "health care service" is defined as any and all processes related to medical practice.

(i) A medical error occurred or identified before the health care service is provided to the patient

(ii) A medical error that did not affect the patient or required a minor procedure/treatment, which includes disinfection, poultice and administration of analgesics

(iii) A medical error whose consequence is unknown

The Project collects information on pharmaceutical near-miss events involving drugs or designated insured medical materials occurred or identified at pharmacies.

(3) Due date and reporting method

Participating pharmacies should report identified pharmaceutical near-miss events defined in the previous section on the exclusive reporting web page via Internet (SSL communication) within one month of identifying the near-miss event.

(4) Report form

See "Document 2: Information to be collected."

(Note) Pharmacies are defined as places where pharmacists perform drug preparation/dispensing activities for the purpose of sales or provision. However, dispensaries at hospitals, clinics and veterinary hospitals are not included. (See Article 2-11 of the Pharmaceutical Affairs Law)

[3] Publication of pharmaceutical near-miss event information

(1) Tabulation

Tabulation is performed by the JCQHC Medical Adverse Event Prevention Division.

(2) Publication of tabulation/analysis

The data is published in annual reports and on the JCQHC website(Note) to provide information to concerned parties and the general public.

(Note) See the JCQHC "Project to Collect and Analyze Medical Near-Miss Information from Pharmacies" website. (http://www.yakkyoku-hiyari.jcqhc.or.jp/)

II Current Reporting Status

[1] Participating pharmacies

Pharmacies participating in the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information are summarized in the tables below.

1. Number of participating pharmacies

	Number of pharmacies(Note)
Number of participating pharmacies	1,774

2. Changes in the number of registrations of participating pharmacies

	2009											
	Jan.	**Feb.**	**Mar.**	**Apr.**	**May.**	**Jun.**	**Jul.**	**Aug.**	**Sep.**	**Oct.**	**Nov.**	**Dec.**
Number of newly participating pharmacies	—	—	—	211	200	495	324	82	103	142	142	75
Number of pharmacies that withdrew	—	—	—	0	0	0	0	0	0	0	0	0
Accumulated total	—	—	—	211	411	906	1,230	1,312	1,415	1,557	1,699	1,774

3. Participating pharmacies in each prefecture

Prefecture	Number of pharmacies	Prefecture	Number of pharmacies	Prefecture	Number of pharmacies	Prefecture	Number of pharmacies
Hokkaido	339	Tokyo	128	Shiga	28	Kagawa	8
Aomori	44	Kanagawa	102	Kyoto	28	Ehime	45
Iwate	39	Niigata	53	Osaka	51	Kochi	40
Miyagi	33	Yamanashi	3	Hyogo	30	Fukuoka	30
Akita	49	Nagano	14	Nara	27	Saga	6
Yamagata	34	Toyama	4	Wakayama	21	Nagasaki	4
Fukushima	55	Ishikawa	5	Tottori	15	Kumamoto	12
Ibaragi	15	Fukui	2	Shimane	14	Oita	33
Tochigi	89	Gifu	10	Okayama	32	Miyazaki	3
Gunma	61	Shizuoka	21	Hiroshima	45	Kagoshima	24
Saitama	32	Aichi	35	Yamaguchi	34	Okinawa	5
Chiba	47	Mie	13	Tokushima	12	Total	1,774

(Note) Number of pharmacies as of December 31, 2009

[2] Number of reports

Pharmaceutical near-miss events reported by the pharmacies are summarized below.

1. Total number of reports

	Tabulation for 2009
Reporting month	From April to December
Number of participating pharmacies	1,774
Number of reporting pharmacies	159
Number of published near-miss events	1,460

2. Number of monthly reports

	2009											
	Jan.	**Feb.**	**Mar.**	**Apr.**	**May.**	**Jun.**	**Jul.**	**Aug.**	**Sep.**	**Oct.**	**Nov.**	**Dec.**
Number of participating pharmacies	—	—	—	211	411	906	1,230	1,312	1,415	1,557	1,699	1,774
Number of reports	—	—	—	18	66	91	155	206	204	181	245	294
Number of published near-miss events	—	—	—	18	66	91	155	206	204	181	245	294

3. Number of participating pharmacies and reports by number of pharmacists

Number of pharmacists (full-time basis)	Number of participating pharmacies	Number of reports
	April to December 2009	April to December 2009
1	272	66
2	569	207
3	386	150
4	215	524
5	121	66
6	69	137
7	46	148
8	35	132
9	18	9
10	15	0
11 or above	28	21
Total	1,774	1,460

4. Number of participating pharmacies and reports by number of prescription receipts

Number of prescription receipts (monthly)	Number of participating pharmacies	Number of reports
	April to December 2009	April to December 2009
0-500	212	14
501-1000	362	104
1001-1500	367	130
1501-2000	339	165
2001-2500	164	133
2501-3000	116	481
3001-3500	60	168
3501-4000	66	129
4001 or above	88	136
Total	1,774	1,460

5. Number of participating pharmacies and reports by number of prescription drugs stocked in pharmacy

Number of prescription drugs stocked in pharmacy	Number of participating pharmacies	Number of reports
	April to December 2009	April to December 2009
0	1	0
0-100	3	0
101-500	125	22
501-1000	855	449
1001-1500	523	791
1501-2000	206	173
2001-2500	42	19
2501-3000	15	0
3001 or above	4	6
Total	1,774	1,460

6. Number of participating pharmacies and reports by number of generics stocked in pharmacy

Number of generics stocked in pharmacy	Number of participating pharmacies	Number of reports
	April to December 2009	April to December 2009
0	1	0
0-100	604	215
101-500	962	1,236
501-1000	205	9
1001-1500	1	0
1501-2000	0	0
2001-2500	0	0
2501-3000	0	0
3001 or above	1	0
Total	1,774	1,460

7. Number of participating pharmacies and reports by over-the-counter (OTC) drugs stocked in pharmacy

Number of OTC drugs stocked in pharmacy	Number of participating pharmacies	Number of reports
	April to December 2009	April to December 2009
0	170	594
1-10	246	58
11-50	488	257
51-100	239	156
101-150	77	216
151-200	74	32
201-250	44	37
251-300	61	40
301-500	178	43
500-1000	135	20
1001 or above	62	7
Total	1,774	1,460

8. Number of participating pharmacies and reports by number of medical institutions issuing prescriptions

Number of medical institutions issuing prescriptions	Number of participating pharmacies	Number of reports
	April to December 2009	April to December 2009
0	1	0
1-10	377	201
11-20	415	546
21-30	286	241
31-40	185	86
41-50	179	169
51-60	84	20
61-70	64	45
71-80	53	119
81-90	23	0
91-100	32	0
101 or above	75	33
Total	1,774	1,460

9. Number of participating pharmacies and reports by proportion of dispensed generics

Proportion of dispensed generics	Number of participating pharmacies	Number of reports
	April to December 2009	April to December 2009
< 10%	19	1
10% to < 20%	43	20
20% to < 30%	153	153
30% to < 40%	566	444
40% to < 50%	464	556
50% to < 60%	258	56
60% to < 70%	171	200
70% to < 80%	70	28
80% to < 90%	25	2
90% or above	5	0
Total	1,774	1,460

10. Number of participating pharmacies and reports by administrative division

Administrative division	Number of participating pharmacies	Number of reports
	April to December 2009	April to December 2009
Hokkaido	339	113
Tohoku	254	121
Kanto/Koshinetsu	544	428
Tokai/Hokuriku	90	26
Kinki	185	175
Chugoku/Shikoku	245	554
Kyushu/Okinawa	117	43
Total	1,774	1,460

11. Number of participating pharmacies by number of reports

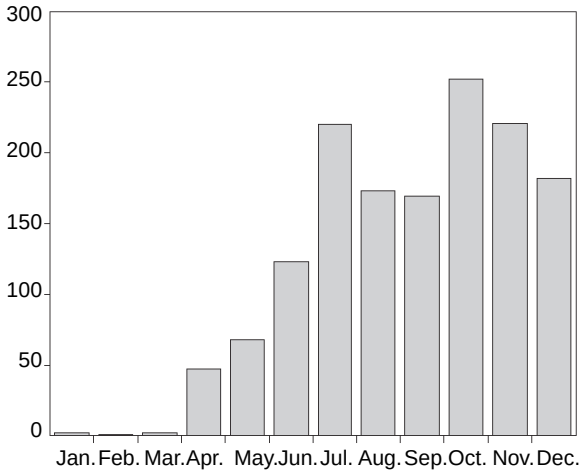
Number of reports	Number of participating pharmacies
April to December 2009	April to December 2009
0	1,615
1-5	121
6-10	17
11-20	10
21-30	5
31-40	1
41-50	1
51 -or above	4
Total	1,774

[3] Details of reports

One thousand four hundred and sixty medical near-miss events reported by pharmacies from April 1 to December 31, 2009 are tabulated below.

1. Month of occurrence

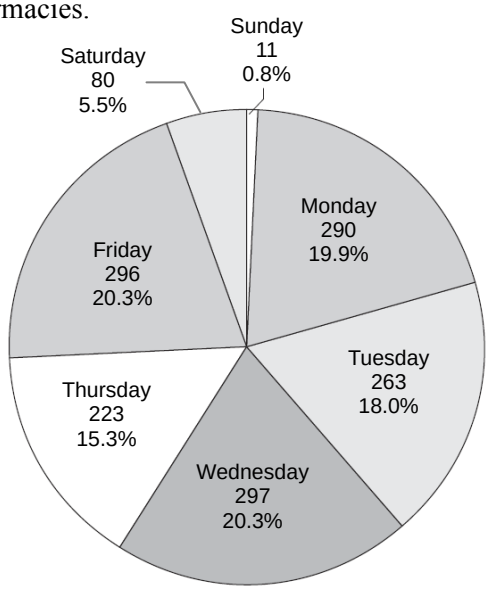
Month of occurrence	Number of reports
January	2
February	1
March	2
April	47
May	68
June	123
July	220
August	173
September	169
October	252
November	221
December	182
Total	1,460



The number of reports made in each month is shown. Since the start of pharmaceutical near-miss event information collection in April 2009, the number of reports has been increasing with the number of participating pharmacies.

2. Day of occurrence

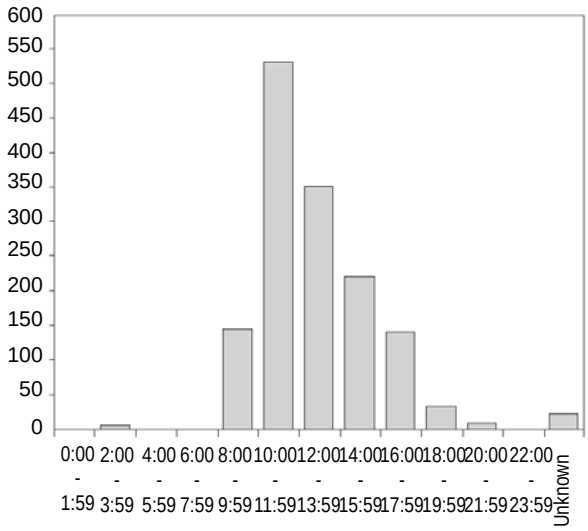
Day of occurrence	Number of reports
Sunday	11
Monday	290
Tuesday	263
Wednesday	297
Thursday	223
Friday	296
Saturday	80
Total	1,460



The number and proportion of reports made on each day of the week are presented. The number of reports is evenly distributed from Monday through Friday.

3. Time of occurrence

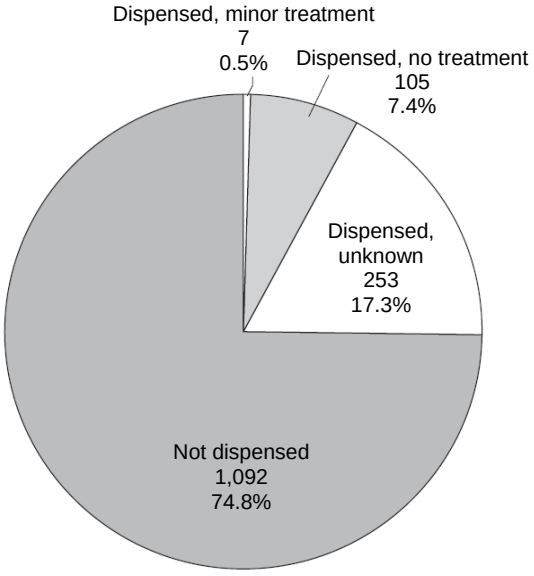
Time of occurrence	Number of reports
0:00-1:59	0
2:00-3:59	5
4:00-5:59	0
6:00-7:59	0
8:00-9:59	145
10:00-11:59	533
12:00-13:59	352
14:00-15:59	221
16:00-17:59	141
18:00-19:59	32
20:00-21:59	9
22:00-23:59	0
Unknown	22
Total	1,460



The number of reports made in each two-hour time frame is presented. Reports made in the 10:00-11:59 time frame were most frequent.

4. Whether the drug was dispensed and extent of treatment

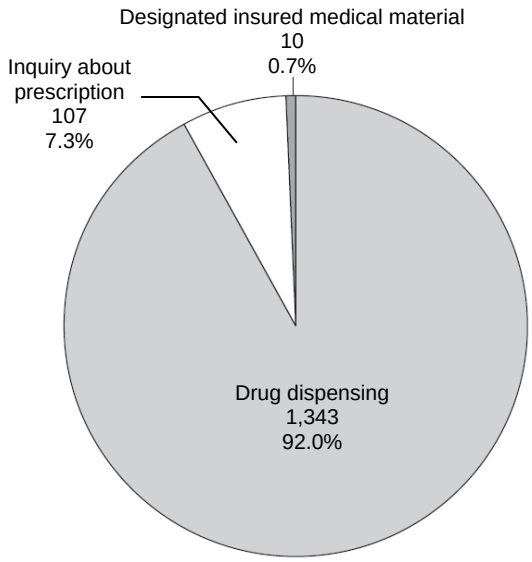
Drug dispensing Extent of treatment	Number of reports
Dispensed, minor treatment	7
Dispensed, no treatment	108
Dispensed, unknown	253
Not dispensed	1,092
Total	1,460



Drugs were dispensed in 25.2% of 1,460 near-miss events (368 near-miss events). Mild treatment was required in 0.5% (7 near-miss events).

5. Summary of near-miss events

Summary of near-miss events	Number of reports
Drug dispensing	1,343
Inquiry about prescription	107
Designated insured medical material	10
Drug sales	0
Total	1,460

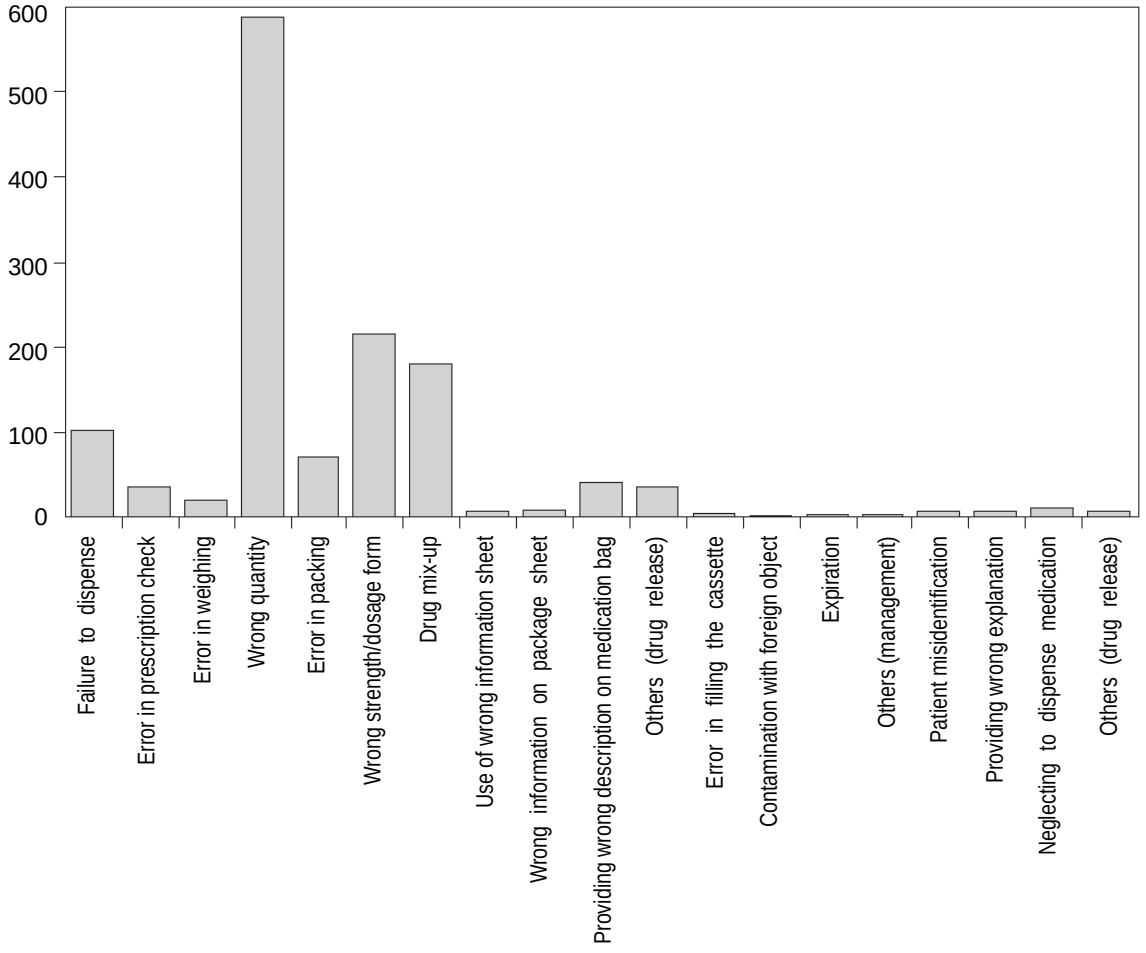


The number and proportion of reports are presented according to a summary of the near-miss event. “Drug dispensing” took up 92.0% (1,343 near-miss events), and “inquiry” made to physicians took up 7.3% (107 near-miss events). No near-miss event involved “drug sales.”

1) Drug dispensing

Situation	Specifics	Number of reports
Drug dispensing	Failure to dispense	102
	Error in prescription check	35
	Error in weighing	20
	Wrong quantity	590
	Error in packing	71
	Wrong strength/dosage form	216
	Drug mix-up	181
	Use of wrong information sheet	6
	Wrong information on package sheet	8
	Providing wrong description on medication bag	40
	Others (drug release)	35

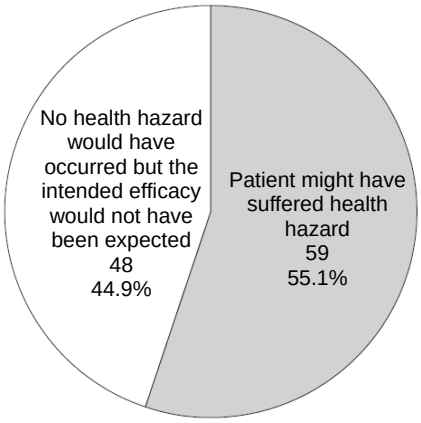
Situation	Specifics	Number of reports
Management	Error in filling the cassette	4
	Contamination with foreign object	1
	Expiration	2
	Others (management)	3
Drug release	Patient misidentification	7
	Providing wrong explanation	6
	Neglecting to release medication	10
	Others (drug release)	6
Total		1,343



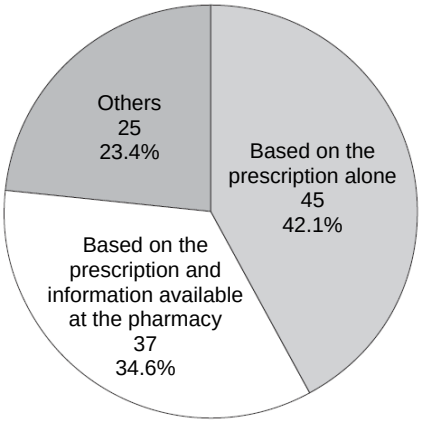
The number of reports related to drug dispensing is presented according to a summary of the near-miss event. “Wrong quantity” (590 near-miss events) was most frequent, followed by “wrong strength/dosage form” (216 near-miss events) and “drug mix-up” (181 near-miss events).

2) Inquiry about prescription

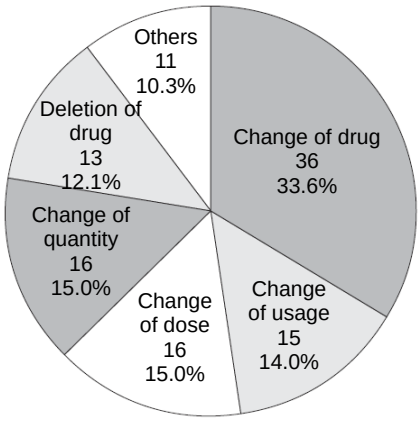
How the patient might have been affected if the drug was used according to the original prescription	Number of reports
Patient might have suffered health hazard	59
No health hazard would have occurred but the intended efficacy would not have been expected	48
Total	107



Reason for making inquiry	Number of reports
Based on the prescription alone	45
Based on the prescription and information available at the pharmacy	37
Others	25
Total	107



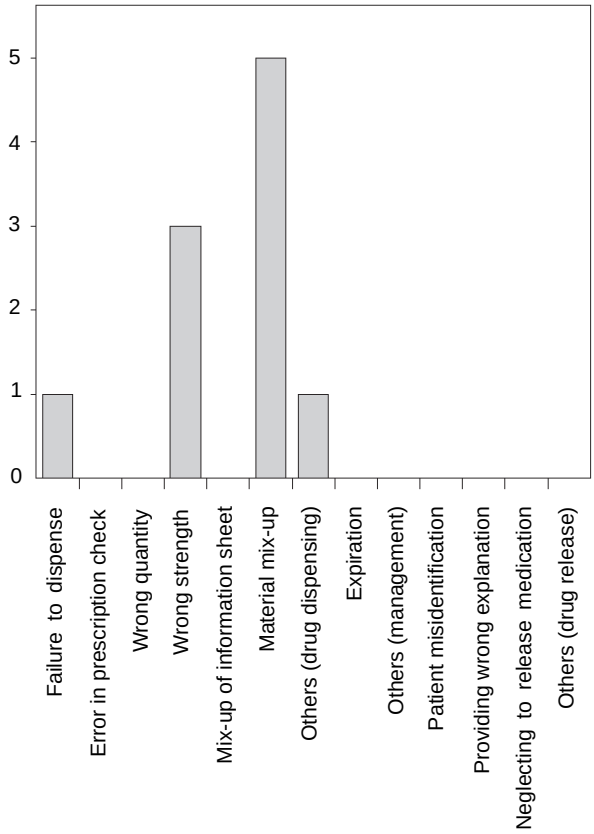
Specifics of change	Number of reports
Change of drug	36
Change of usage	15
Change of dose	16
Change of quantity	16
Deletion of drug	13
Others	11
Total	107



One hundred and seven near-miss events involving inquiries are sorted out by how the patient might have been affected if the drug was used according to the original prescription, the reason for making an inquiry and the specifics of a change, and the number and proportion of reports are presented. Near-miss events for which "the patient might have suffered a health hazard" took up 55.1% (59 near-miss events). Near-miss events for which inquiries were made "based on the prescription alone" took up 42.1% (45 near-miss events) while 57.9% (62 near-miss events) involved inquiries made based on information other than the prescription. Near-miss events involving "change of drug" were most frequent (33.6%; 36 near-miss events).

3) Designated insured medical material

Situation	Specifics of near-miss event	Number of reports
Drug dispensing	Failure to dispense	1
	Error in prescription check	0
	Wrong quantity	0
	Wrong strength	3
	Mix-up of information sheet	0
	Material mix-up	5
	Others (drug dispensing)	1
Management	Expiration	0
	Others (management)	0
Drug release	Patient misidentification	0
	Providing wrong explanations	0
	Neglecting to release medication	0
	Others (drug release)	0
Total		10



The number of reports on near-miss events involving designated insured medical materials is presented according to a summary of the near-miss event. “Material mix-up” (5 near-miss events) and “wrong strength” (3 near-miss events) were included.

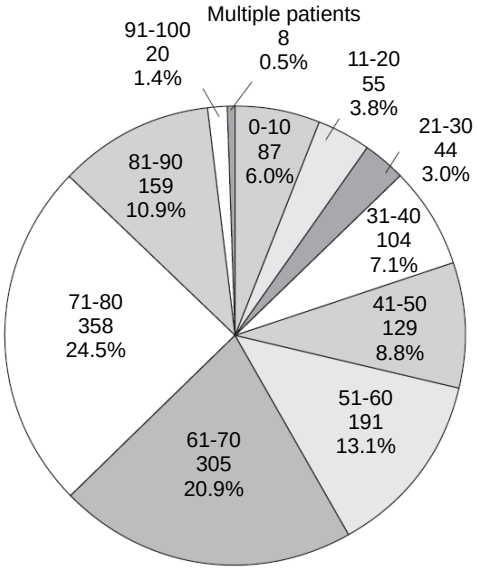
4) Drug sales

Wrong product	Number of reports
Providing wrong products	0
Providing wrong information	0
Expiration	0
Others	0
Total	0

The number of reports on near-miss events involving drug sales is presented. No report was made.

6. Age of patients

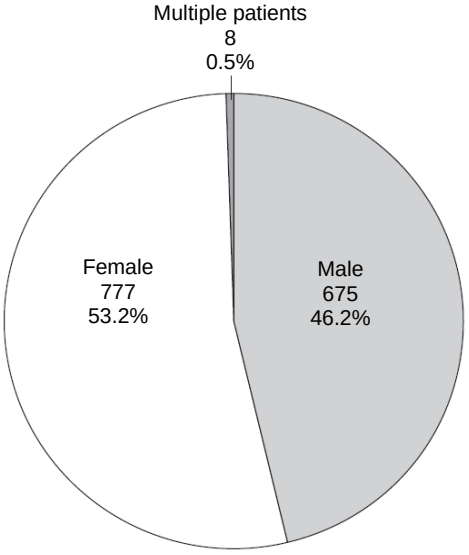
Age of patients	Number of reports
0-10	87
11-20	55
21-30	44
31-40	104
41-50	129
51-60	191
61-70	305
71-80	358
81-90	159
91-100	20
101-110	0
111-120	0
121-130	0
130 or above	0
Multiple patients	8
Total	1,460



The number and proportion of reports are presented by age of patients. “71-80” (24.5%; 358 reports) and “61-70” (20.9%; 305 reports) were most frequent.

7. Sex of patients

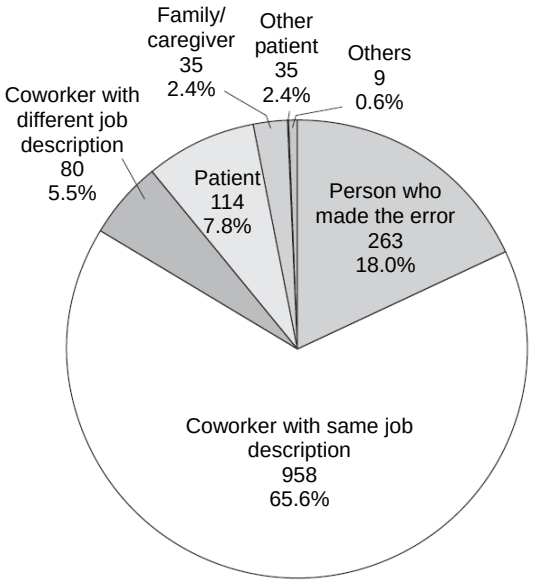
Sex of patients	Number of reports
Male	675
Female	777
Multiple patients	8
Total	1,460



The number and proportion of reports are presented by sex of patients. “Male” patients were involved in 46.2% (675 reports) while “female” patients were involved in 53.2% (777 reports).

8. First person to find

First person to find the error	Number of reports
Person who made the error	263
Coworker with same job description	958
Coworker with different job description	80
Patient	114
Family/caregiver	35
Other patient	1
Others	9
Total	1,460

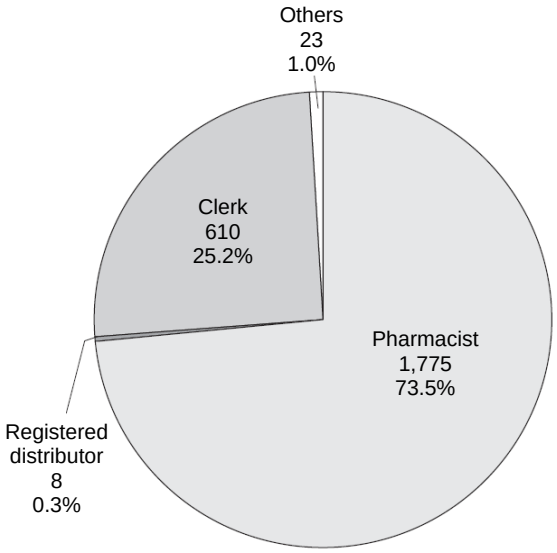


The number and proportion of reports are presented by first person to find the error. "Coworker with same job description" was the most frequent first person to find the error (65.6%; 958 reports).

9. Person who made the error

Person who made the error	Number of reports
Pharmacist	1,775
Registered distributor	8
Clerk	610
Others	23
	2,416

Note: "Person who made the error" may be more than one.

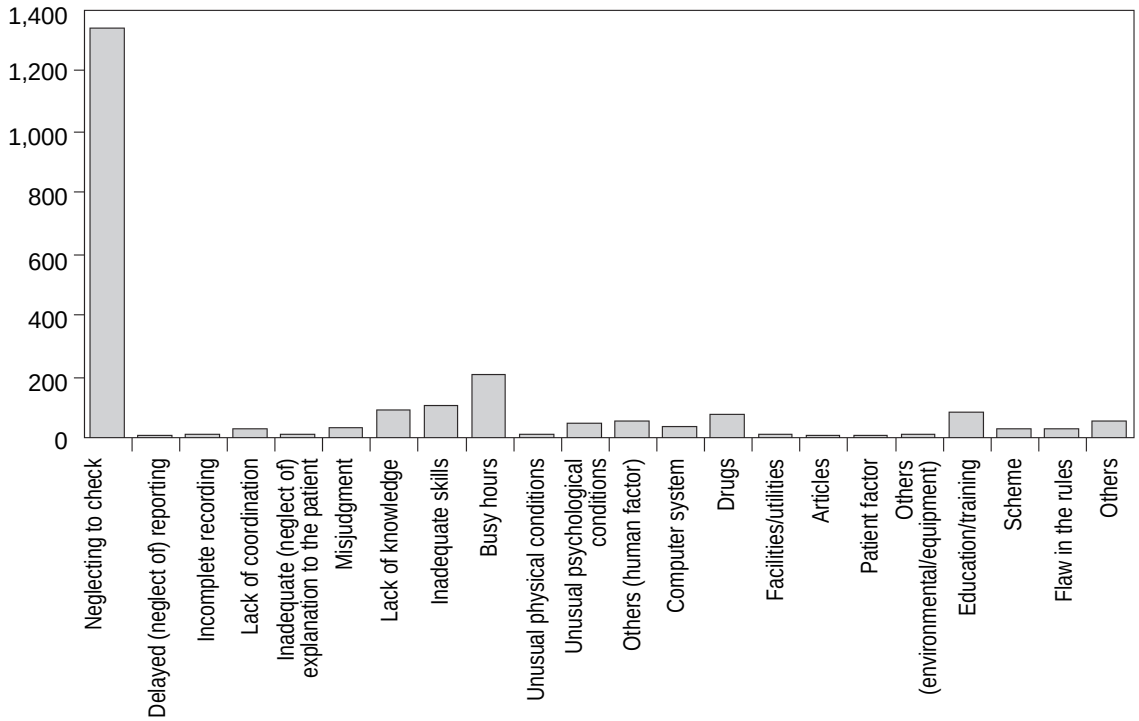


The number and proportion of reports are presented by person who made the error. "Pharmacist" was the most frequently reported person who made the error (73.5%; 1,775 reports).

10. Cause of near-miss event

Items			Number of reports
Behavior of the person who made the error		Neglecting to check	1,335
		Delayed (neglect of) reporting	3
		Incomplete recording	15
		Lack of coordination	32
		Inadequate (neglect of) explanation to the patient	20
		Misjudgment	39
Background/system/ environmental factor	Human factor	Lack of knowledge	92
		Inadequate skills	118
		Busy hours	210
		Unusual physical conditions	9
		Unusual psychological conditions	55
		Others (human factor)	69
	Environmental /equipment	Computer system	49
		Drugs	78
		Facilities/utilities	14
		Articles	5
		Patient factor	8
		Others (environmental/equipment)	14
	Others	Education/training	81
		Scheme	31
		Flaw in the rules	35
		Others	59
		Total	2,371

Note: "Cause of near-miss event" may be more than one.



The number of reports is presented by cause of near-miss event. "Neglecting to check" (1,335 reports) was most frequent, followed by "busy hours" (210 reports) and "inadequate skills" (118 reports).

11. Specifics of near-miss event × cause of near-miss event

Specifics of near-miss event × cause of near-miss event	Drug dispensing	Inquiry	Designated insured medical material	Drug sales	Total
Neglecting to check	1,293	32	10	0	1,335
Delayed (neglect of) reporting	2	1	0	0	3
Incomplete recording	9	6	0	0	15
Lack of coordination	23	9	0	0	32
Inadequate (neglect of) explanation to the patient	20	0	0	0	20
Misjudgment	36	3	0	0	39
Lack of knowledge	74	17	1	0	92
Inadequate skills	112	4	2	0	118
Busy hours	201	6	3	0	210
Unusual physical conditions	8	0	1	0	9
Unusual psychological conditions	54	1	0	0	55
Others (human factor)	52	16	1	0	69
Computer system	35	14	0	0	49
Drugs	63	14	1	0	78
Facilities/utilities	11	3	0	0	14
Articles	5	0	0	0	5
Patient factor	6	2	0	0	8
Others (environmental/equipment)	9	4	1	0	14
Education/training	63	15	3	0	81
Scheme	27	4	0	0	31
Flaw in the rules	33	2	0	0	35
Others	18	41	0	0	59
Total	2,154	194	23	0	2,371

Note: “Cause of near-miss event” may be more than one.

“Neglecting to check” was most frequent regardless of the specifics of the incident. Other causes of incidents included “busy hours” for incidents involving drug dispensing and “lack of knowledge” and “education/training” for incidents involving inquiries.

12. Person who made the error × cause of near-miss event

Person who made the error × cause of incident	Pharmacist	Registered distributor	Clerk	Others	Total
Neglecting to check	1,617	8	569	16	2,210
Delayed (neglect of) reporting	6	0	3	0	9
Incomplete recording	25	0	16	2	43
Lack of coordination	67	1	34	2	104
Inadequate (neglect of) explanation to the patient	28	0	8	2	38
Misjudgment	61	0	18	2	81
Lack of knowledge	145	1	60	6	212
Inadequate skills	189	1	53	1	244
Busy hours	313	1	73	3	390
Unusual physical conditions	13	0	5	0	18
Unusual psychological conditions	71	2	17	3	93
Others (human factor)	109	1	41	9	160
Computer system	81	2	37	1	121
Drugs	112	1	25	2	140
Facilities/utilities	18	0	1	3	22
Articles	8	0	3	0	11
Patient factor	9	0	2	1	12
Others (environmental/equipment)	26	0	7	1	34
Education/training	136	1	43	6	186
Scheme	46	2	12	0	60
Flaw in the rules	52	1	23	4	80
Others	79	0	24	4	107
Total	3,211	22	1,074	68	4,375

Note: “Person who made the error” and “cause of near-miss event” may be more than one.

“Neglecting to check” was most frequent regardless of the person who made the error. “Busy hours” was the second most frequent cause of near-miss events for pharmacists.

13. Specifics of near-miss event × drug dispensing, extent of treatment

Specifics of near-miss event × drug dispensing, extent of treatment	Drug dispensed			Drug not dispensed	Total
	Minor treatment	No treatment	Unknown		
Drug dispensing	7	108	248	980	1,343
Inquiry	0	0	0	107	107
Designated insured medical material	0	0	5	5	10
Drug sales	0	0	0	0	0
Total	7	108	253	1,092	1,460

Of near-miss events in which drugs were dispensed, 108 resulted in "no treatment" while 7 required "minor treatment."

14. Day of occurrence × time of occurrence

Day of occurrence × time of occurrence	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Total
0:00-1:59	0	0	0	0	0	0	0	0
2:00-3:59	0	0	3	1	0	1	0	5
4: 00-5:59	0	0	0	0	0	0	0	0
6:00-7:59	0	0	0	0	0	0	0	0
8:00-9:59	1	33	23	26	25	23	14	145
10:00-11:59	3	111	99	97	77	107	39	533
12:00-13:59	3	76	59	79	49	71	15	352
14:00-15:59	2	44	40	45	33	50	7	221
16:00-17:59	0	16	25	34	28	35	3	141
18:00-19:59	2	3	7	8	6	6	0	32
20:00-21:59	0	1	3	1	3	0	1	9
22:00-23:59	0	0	0	0	0	0	0	0
Unknown	0	6	4	6	2	3	1	22
Total	11	290	263	297	223	296	80	1,460

Pharmaceutical near-miss events were most frequently reported in the 10:00-11:59 time frame regardless of the day of the week.

[4] Tabulation according to product name

1. Near-miss events involving ethical drugs (1,964 reports)(Note 1)

(Most frequently reported products)

Product name	Number of reports
Loxonin Tablets	18
Warfarin Tablets 1 mg	17
Norvasc Tablets 5 mg	16
Mohrus Pap 30 mg	15
Micardis Tablets 40 mg Mucosta Tablets 100	14

Product name	Number of reports
Amaryl 1 mg Diovan Tablets 40 mg Mohrus Tape 20 mg	13
Alosenn Olmetec Tablets 20 mg	12

The 10 most frequently reported products are presented.

1) Near-miss events involving generics (301 reports)(Note 2)

(Most frequently reported products)

Product name	Number of reports
Gasport Tablets 20 mg Kentan Tablets 60 mg Methycobal Tablets 500 μg	11
Bayaspirin Tablets 100 mg	10
Kary Uni Ophthalmic Suspension 0.005%	8
Magmitt Tablets 330 mg	7
Magmitt Tablets 500 mg	9

Product name	Number of reports
Magmitt Tablets 250 mg	5
MS Onshippu "TAIHO", SP Troches "MEIJI", Azunol Gargle Liquid 4%, Calonal Tablets 200, Sorentmin Tablets 0.25 mg, Telgin G Dry Syrup 0.1%, Nelurolen Tablets "5", Voglibose Tablets 0.3 mg "SW", U-Pan Tablets 0.5 mg	4

The 10 most frequently reported generics are presented.

2) Near-miss events involving newly listed drugs(Note 3) (15 reports)

Product name	Number of reports
Co-DIO Combination Tablets MD	3
Cravit Tablets 250 mg Co-DIO Combination Tablets EX Tapros Ophthalmic Solution 0.0015%	2
Apidra Inj. SoloStar Cravit Tablets 500 mg	1

Product name	Number of reports
Pirespa Tablets 200 mg Micombi Combination Tablets AP Micombi Combination Tablets BP Lumigan Ophthalmic Solution 0.03%	1

New drugs listed in the NHI price list for less than one year are presented.

(Note 1) The number of reports refers to the number of entries made for each product name reported as "prescribed drug," "mixed-up drug," "changed drug" or "related drug" in incidents involving "drug preparation" or "inquiry."
(Note 2) The reports on "generics" or "newly listed drugs" were included in the reports on "ethical drugs."
(Note 3) Newly listed drugs are defined as new drugs listed in the NHI price list for less than one year.

3) Drugs newly listed in the NHI price list but not considered as newly-listed drugs

Only new drugs listed in the NHI price list for less than one year are considered as newly-listed drugs in the Project. However, other drugs listed for less than one year are also tabulated.

(1) Near-miss events involving generics (12 reports)

Product name	Number of reports
Amlodipine Tablets 2.5 mg "CH" **Galantase Powder 50%** **Gesin Tablets 25 mg** **Ketoten Nasal Solution 0.05%** **Threenofen Tablets 60 mg** **Cefcapene pivoxil hydrochloride Tablets 100 mg "SAWAI"**	1

Product name	Number of reports
Felnabion Pap 70 **Brotizolam OD Tablets 0.25 mg "TAIYO"** **Lansoprazole OD Tablets 15 mg "TOWA"** **Levemir FlexPen** **Levofloxacin Tablets 100 mg "YD"** **Lobu Tablets 60 mg**	1

(2) Near-miss events involving change of dosage form (13 reports)

Product name	Number of reports
Urief Tablets 4 mg	9
Norvasc OD Tablets 5 mg	3
Urief Tablets 2 mg	1

(3) Near-miss events involving pharmacopoeial dispensing (3 reports)

Product name	Number of reports
Magnesium oxide MARUISHI	2
Lactose hydrate YOSHIDA	1

(4) Near-miss events involving change of product name (96 reports)

Product name	Number of reports
Mucosta Tablets 100 mg	7
Isodine Gargle Solution 7%	6
NovoRapid FlexPen	5
Alosenn Granule Telgin G Dry Syrup 0.1% Nu-Lotan Tablets 50 mg Pursennid Tablets 12 mg U-Pan Tablets 0.5 mg	4
Nu-Lotan Tablets 25 mg Hirudoid Lotion 0.3% Mucosal Dry Syrup 1.5% Melbin Tablets 250 mg Loxonin Tablets 60 mg	3
Antebate Ointment 0.05% Xalatan Eye Drops 0.005% Hirudoid Cream 0.3% Hirudoid Soft Ointment 0.3% Mucosolvan Tablets 15 mg Mohrus Tape 20 mg	2
PL Combination Granule Asthphyllin Tablets Adoair 100 Diskus Adoair 500 Diskus Adoair 500 Diskus 60 for Inhalation Alimezine Syrup 0.05%	1

Product name	Number of reports
Antebate Cream 0.05% Kremezin Capsules 200 mg Gentacin Ointment 0.1% Sawadol L Tablets 20 mg Cephadol Tablets 25 mg Sofratulle Pap 10 cm Tarivid Otic Solution 0.3% Toledomin Tablets 25 mg Neuer Capsules 200 mg NovoRapid 30 Mix PenFill Banan Tablets 100 mg Bisolvon Tablets 4 mg Humulin R Cartridge Humulin R Kit Humalog Mix 25 MirioPen Humalog MirioPen Farom Dry Syrup for Pediatric 10% Proranon Ophthalmic Solution 0.1% Penfill 30 R Myser Ointment 0.05% Madopar Combination Tablet Meiact MS Fine Granule 10% U-Pan Tablets 1.0 mg Locoid Cream 0.1% Locoid Ointment 0.1%	1

2. Near-miss events involving designated insured medical materials (12 reports)(Note)

(Most frequently reported products)

Product name	Number of reports
NanoPass Needle	4
PenNeedle 32G Taper	
PenNeedle	3
PenNeedle 30G 8 mm	

Product name	Number of reports
Micro Fine Plus	1
Micro Fine Plus 31G	1
Micro Fine Plus 31G × 5 mm	1
Micro Fine Plus 31G × 8 mm	1

The designated insured medical materials involved in the reported near-miss events are presented.

3. Near-miss events involving drug sales (0 report)

(Most frequently reported products)

Product name	Number of reports
N/A	0

Classification of related drug	Number of reports
Ethical drug	0
First-class OTC drug	0
Designated second-class OTC drug	0
Second-class OTC drug	0
Third-class OTC drug	0

Products reported in near-miss events involving drug sales are presented. No near-miss event involving drug sales was reported.

(Note) The number of reports refers to the number of entries made for each product name reported as "designated insured medical material," "mixed-up designated insured medical material," "related designated insured medical material" or "related drug" in incidents involving "designated insured medical material" or "drug sales."

4. Product names by outline of near-miss event

1) Drug dispensing

- ○ Prescribed drug (418 reports)(Note 1)
- ○ Mixed-up drug (418 reports)
- ○ Related drug (961 reports)

(Most frequently reported products)

Product name	Number of reports		
	Prescribed drug	Mixed-up drug	Related drug
Warfarin Tablets 1 mg	0	3	13
Mohrus Pap 30 mg	3	7	5
Micardis Tablets 40 mg	5	5	4
Norvasc Tablets 5 mg	1	4	9
Loxonin Tablets	3	1	9
Mohrus Tape 20 mg	0	2	11
Diovan Tablets 40 mg	2	6	5

The top five products reported in the near-miss events involving “drug dispensing” are tabulated as prescribed drugs, mixed-up drugs or related drugs.

2) Inquiry

- ○ Prescribed drug (117 reports)(Note 2)
- ○ Changed drug (50 reports)

(Most frequently reported products)

Product name	Number of reports	
	Prescribed drug	Changed drug
Loxonin Tablets	4	1
Mucosta Tablets 100	4	1
Blopress Tablets 8	2	1
Blopress Tablets 4	2	1
Casodex Tablet 80 mg	1	2
Amaryl 1 mg Tablet	2	1

The top five products reported in the near-miss events involving “inquiry” are tabulated as prescribed drugs or changed drugs.

(Note 1) In the “drug preparation” category, the number of reports on “prescribed drug” and “mixed-up drug” may not be consistent since “the prescribed drugs” did not correspond to “the mixed-up drugs”.
(Note 2) In the “inquiry” category, the number of reports on “prescribed drug” and “changed drug” may not be consistent since only “prescribed drug” was reported if “change of usage,” “change of dosage,” “change of quantity” or “deletion of drug” was selected.

3) Designated insured medical material

- ○ Prescribed designated insured medical material (8 reports)
- ○ Mixed-up designated insured medical material (8 reports)
- ○ Related designated insured medical material (2 reports)

(Most frequently reported products)

Product name	Number of reports		
	Prescribed designated insured medical material	Mixed-up designated insured medical material	Related designated insured medical material
NanoPass Needle	1	2	1
PenNeedle 32G Taper	2	2	0
PenNeedle	0	2	1
PenNeedle 30G 8 mm	2	1	0
Micro Fine Plus	1	0	0
Micro Fine Plus 31G	1	0	0
Micro Fine Plus 31G × 5 mm	1	0	0
Micro Fine Plus 31G × 8 mm	0	1	0

The top five products reported in the near-miss events involving “designated insured medical material” are tabulated as prescribed designated insured medical material, mixed-up designated insured medical material or related designated insured medical material.

III Analysis of Pharmaceutical Near-Miss Event Information

[1] Pharmaceutical near-miss events related to similar drug names

Of the pharmaceutical near-miss events reported from April 1 to December 31, 2009, 181 near-miss events involved "drug mix-up." After excluding 10 near-miss events that apparently did not involve "drug mix-up," 171 near-miss events were analyzed.

The reported drugs with names with similar first letters were tabulated. Forty-one near-miss events involved drugs with names for which at least the first two letters were identical, and 28 near-miss events involved drugs with names for which at least the first three letters were identical.

The names of the reported drugs and their efficacies are shown below.

1) Drugs with names for which at least the first two letters were identical (not including those with at least three identical first letters)

Prescribed drug	Major efficacy	Mixed-up drug	Major efficacy
MS Reishippu「TAIHO」	Analgesic, antipruritic, astringent, antiphlogistic	MS Onshippu「TAIHO」	Analgesic, antipruritic, astringent, antiphlogistic
Asverin Tablets 20	Anti-tussive/expectorant	Astomin Tablets 10 mg	Anti-tussive
Cravit Tablets	Synthetic antibacterial	Klaricid Tablets 200 mg	Having a primary action against gram-positive bacteria and mycoplasma
Primobolan Tablets 5 mg	Anabolic steroid	Primperan Tablets 5	Other agent for digestive organs
Preran 1 mg Tablet	Hypotensive	Prelon Tablets 1 mg	Adrenal hormone
Bezatate SR Tablets 200	Hypolipidemic	Bezatol SR Tablets 200 mg	Hypolipidemic
Magmitt Tablets 330 mg	Antacid	Maglax Tablets 330 mg	Antacid
Mucodyne Tablets 500 mg	Expectorant	Mucosta Tablets 100 mg	Peptic ulcer treatment
Mevalotin Tablets 5	Hypolipidemic	Mevan Tablets 5	Hypolipidemic
Urinorm Tablets 25 mg	Gout treatment	Urief Tablets 4 mg	Other agent for urogenital and anal organs

* Near-miss events searched by identical first letters (two or three) of drug names were categorized as "similar drug names" while those searched by identical first four digits of YJ codes were categorized as "similar efficacies." Therefore, some near-miss events may be included in both categories.

2) Drugs with names for which at least the first three letters were identical

(1) Drug names and major efficaciesNote:

Prescribed drug	Major efficacy	Mixed-up drug	Major efficacy
Amlodin OD Tablets 5 mg	Vasodilator	Amlodipine Tablets 5 mg "SANDOZ"	Vasodilator
Amlodin Tablets 2.5 mg	Vasodilator	Amlodipine Tablets 2.5 mg CH	Vasodilator
Omepral Tablets 10	Peptic ulcer treatment	Omeprazole Tablets 10 mg "AMEL"	Peptic ulcer treatment
Clarith Tablets 200	Having a primary action against gram-positive bacteria and mycoplasma	Klaricid Tablets 200 mg	Having a primary action against gram-positive bacteria and mycoplasma
Slow-K Tablets 600 mg	Mineral preparation (other mineral preparation)	Slow-Fe Tablets 50 mg	Mineral preparation (iron compound including organic iron oxide)
Tarivid Ophthalmic Ointment 0.3%	Ophthalmic agent	Tarivid Otic Solution 0.3%	Agent for otic and nasal use
Tsumura Kamishoyosan Extract Granules for Ethical Use	Herbal medicine	Tsumura Yokukansan Extract Granules for Ethical Use	Herbal medicine
Tsumura Keishikashakuyakuto Extract Granules for Ethical Use	Herbal medicine	Tsumura Shikokeishito Extract Granules for Ethical Use	Herbal medicine
Tsumura Goreisan Extract Granules for Ethical Use	Herbal medicine	Tsumura Gorinsan Extract Granules for Ethical Use	Herbal medicine
Tsumura Shikokeishito Extract Granules for Ethical Use	Herbal medicine	Tsumura Shikokeishikanyoto Extract Granules for Ethical Use	Herbal medicine
Tsumura Shouseiryuto Extract Granules for Ethical Use	Herbal medicine	Tsumura Bakumonto Extract Granules for Ethical Use	Herbal medicine
Tsumura Daikenchuto Extract Granules for Ethical Use	Herbal medicine	Tsumura Choreito Extract Fi Granules for Ethical Use	Herbal medicine
Tsumura Hachimijiogan Extract Granules for Ethical Use	Herbal medicine	Tsumura Mashiningan Extract Granules for Ethical Use	Herbal medicine
Tsumura Hangekobokuto Extract Granules for Ethical Use	Herbal medicine	Tsumura Orengedokuto Extract Granules for Ethical Use	Herbal medicine
Tsumura Boiogito Extract Granules for Ethical Use	Herbal medicine	Tsumura Makyoyokukanto Extract Granules for Ethical Use	Herbal medicine
Tsumura Maobushisaishinto Extract Granules for Ethical Use	Herbal medicine	Tsumura Maoto Extract Granules for Ethical Use	Herbal medicine
Tsumura Shakuyakukanzoto Extract Granules for Ethical Use	Herbal medicine	Tsumura Keishikashakuyakuto Extract Granules for Ethical Use	Herbal medicine
Neurotropin Tablets 4 Units	Antipyretic / analgesic / antiphlogistic	Neurovitan Tablets	Multiple vitamins (not including vitamin A/D combination)
Prednisolone Tablets TAKEDA 5 mg	Adrenal hormone	Predonin Tablets 5 mg	Adrenal hormone
Prednisolone Tablets 1 mg (Asahi Kasei)	Adrenal hormone	Predonin Tablets 5 mg	Adrenal hormone
Lansoprazole-OD Tablets 15 mg "TOWA"	Peptic ulcer treatment	Lansoprazol-OD 15 mg TAIYO	Peptic ulcer treatment
Rinderon-V Cream 0.12%	Analgesic, antipruritic, astringent, antiphlogistic (Corticosteroid)	Rinderon-VG Lotion	Analgesic, antipruritic, astringent, antiphlogistic (Antibiotic and corticosteroid combination)
Rinderon-V Ointment 0.12%	Analgesic, antipruritic, astringent, antiphlogistic (Corticosteroid)	Rinderon-VG Ointment 0.12%	Analgesic, antipruritic, astringent, antiphlogistic (Antibiotic and corticosteroid combination)
1% Dihydrocodein Phosphate Powder "FUSO"	Anti-tussive/expectorant	1% Codein Phosphate Powder "FUSO"	Anti-tussive/expectorant
Zinc Oxide Ointment "YOSHIDA"	Analgesic, antipruritic, astringent, antiphlogistic	Zinc Oxide (10%) Simple Ointment "NIKKO"	Analgesic, antipruritic, astringent, antiphlogistic

* Near-miss events searched by identical first letters (two or three) of drug names were categorized as "similar drug names" while those searched by identical first four digits of YJ codes were categorized as "similar efficacies." Therefore, some near-miss events may be included in both categories.

Note: "Major efficacy" refers to the drug classification indicated by the first three digits of the YJ code.

(2) Twelve of 28 reported drugs with names that had at least three identical first letters were herbal medicines. The herbal medicines and their product number were compared between the prescribed drugs and the mixed-up drugs. The remarks sections for the drugs with the same last digit of the product code and similar package color have a remark "same color."

Prescribed drug	Product number	Mixed-up drug	Product number	Remarks
Tsumura Kamishoyosan Extract Granules for Ethical Use	24	Tsumura Yokukansan Extract Granules for Ethical Use	54	Same color
Tsumura Keishikashakuyakuto Extract Granules for Ethical Use	60	Tsumura Shikokeishito Extract Granules for Ethical Use	10	Same color
Tsumura Goreisan Extract Granules for Ethical Use	17	Tsumura Gorinsan Extract Granules for Ethical Use	56	
Tsumura Shikokeishito Extract Granules for Ethical Use	10	Tsumura Shikokeishikanyoto Extract Granules for Ethical Use	11	
Tsumura Shouseiryuto Extract Granules for Ethical Use	19	Tsumura Bakumonto Extract Granules for Ethical Use	29	Same color
Tsumura Daikenchuto Extract Granules for Ethical Use	100	Tsumura Choreito Extract Granules for Ethical Use	40	Same color
Tsumura Hachimijiogan Extract Granules for Ethical Use	7	Tsumura Mashiningan Extract Granules for Ethical Use	126	
Tsumura Hangekobokuto Extract Granules for Ethical Use	16	Tsumura Orengedokuto Extract Granules for Ethical Use	15	
Tsumura Boiogito Extract Granules for Ethical Use	20	Tsumura Makyoyokukanto Extract Granules for Ethical Use	78	
Tsumura Maobushisaishinto Extract Granules for Ethical Use	127	Tsumura Maoto Extract Granules for Ethical Use	27	Same color
Tsumura Shakuyakukanzoto Extract Granules for Ethical Use	68	Tsumura Keishikashakuyakuto Extract Granules for Ethical Use	60	

3) Improvement measures reported from the pharmacies

(1) Review of the procedure

- The person who dispenses the drug should say the drug name aloud to the patient. Instead of saying, "This is an herbal medicine," he/she should say, "This is an herbal medicine No. XX called YYY" to clearly communicate the product number and name.
- The product name should be included in the heading of the medication record so that errors made during drug dispensing can be detected during verifications.
- A warning "Currently taking YYY" should be included in the medication record in a clearly visible manner.
- Document the current medications in the patient's medication notebook so that the patient can check his medications.
- Ensure cross-checking of the dispensed drugs and the prescription.
- If an alternative drug was included in the previous prescription, notify the dispensary and document the product name in a copy of the current prescription when entering the medication data.

(2) Review of the checking system

- Drugs should be checked three times, specifically, at the time of dispensing, verification and giving instructions to the patient, even if only a few drugs are dispensed.
- Product names should be thoroughly read. The sheet number and the drug name should be cross-checked with the prescription when dispensing an herbal medicine.
- These who are in charge of verification should perform parallel verifications of prescriptions and dispensed drugs in accordance with the procedure. Drug names should be thoroughly read and marked to indicate the completion of checking especially when herbal medicines are dispensed.
- When switching to a generic, the prescription should be carefully read aloud by tracing the drug names with a finger.
- Drugs should always be checked by reading their names aloud and pointing to them with a finger.

(3) Review of the drug placement

- Drugs that can be easily mixed-up should be placed separately.
- Warning labels should be placed on similar drugs.
- Strengths and drug names should be double-checked. Frequently used drugs should be stored at eye level.

4) Discussion

One hundred and seventy-one of 181 reported near-miss events involving drug mix-up were analyzed. Forty-one near-miss events involved drugs with at least two identical first letters of the names, and 28 near-miss events involved drugs with at least three identical first letters of the names.

Nine of 13 near-miss events (69.2%) involved drugs with different efficacy with names that had only two identical first letters. The proportion was larger compared with seven of 16 near-miss events (43.8%) involving drugs with names that had at least three identical first letters, excluding herbal medications. Some drugs, e.g., a gout treatment Urinorm and an agent for urogenital and anal organs Urief, were reported in multiple near-miss events (three times).

Twelve of 28 near-miss events (42.9%) involved mix-up of herbal drugs with names that had at least three identical first letters. The product names of herbal medicines include the name of the manufacturer so that the first three letters of the product names are frequently identical. One half of the near-miss events involved the same package color due to the identical last digit of the product codes in addition to similar drug names.

Some drug names sound similar rather than having identical first letters. “Almarl Tablets 10” and “Acemail Tablets 10” are confusing just as “Anafranil Tablets 10 mg” and “Tofranil Tablets 10 mg” are.

5) Summary

One hundred and seventy-one of 181 reported near-miss events involving “drug mix-up” were analyzed, and 41 near-miss events (24.0%) involved similar drug names. As reported by the pharmacies, possible improvement measures include accurate checking of drug names as well as multiple checking at the time of drug dispensing, verification and giving instructions to the patient. Placement of drugs should be changed as necessary. Separate storage shelves may be used, for example.

The Drug Compounding Guidelines of the Japan Pharmaceutical Association provides a checking procedure for dispensed drugs, such as “First, thoroughly read the three essential elements of the prescribed drug, i.e., the product name, the dosage form and the strength (content) unit, to identify the drug and cross-check with the prepared drug.” (Excerpted from page 267, the Drug Compounding Guidelines [the 12th revision]) The recommended procedure may be integrated in the operating procedure at the pharmacy.

6) References

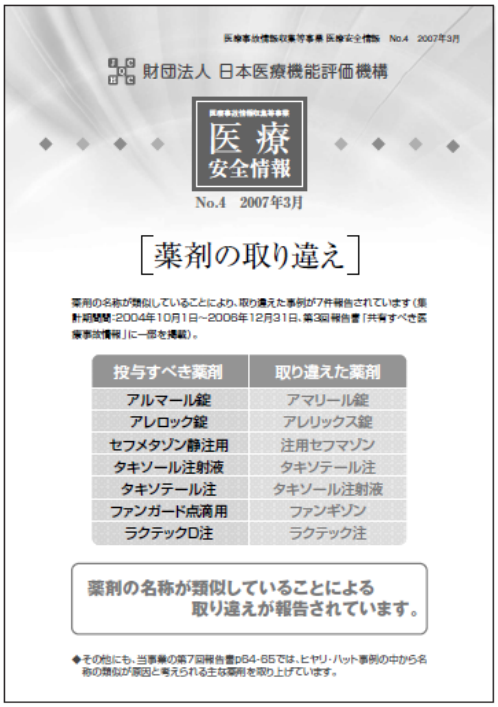
1. Japan Council for Quality Health Care Project to Collect and Analyze Medical Near-Miss/Adverse Event Information 2006 Annual Report

○ Medical adverse events involving drugs are analyzed. Misuse of drugs due to similar product names is reported.

2. Medical Safety Information No. 4 “Drug Mix-Up”

○ Medical safety information (see below for an example) is available on the Japan Council for Quality Health Care Project to Collect and Analyze Medical Near-Miss/Adverse Event Information website (http://www.med-safe.jp/).

<Reference: Medical Safety Information No. 4 “Drug Mix-Up”>



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財団法人 日本医療機能評価機構

医療事故情報収集等事業
医療安全情報
No.4 2007年3月

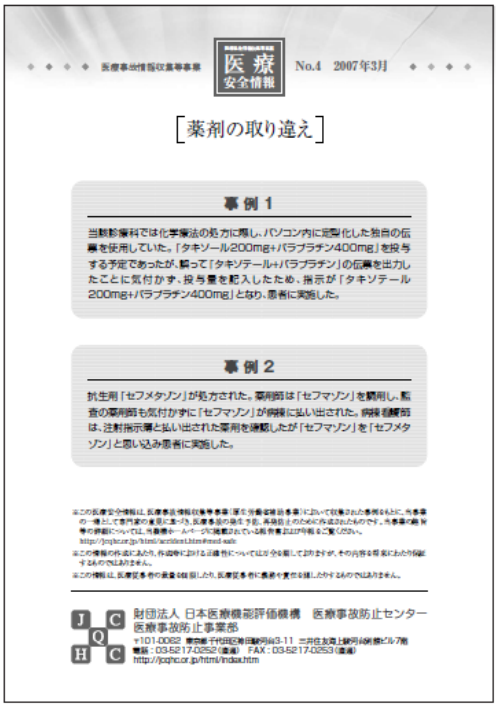
［薬剤の取り違え］

薬剤の名称が類似していることにより、取り違えた事例が7件報告されています（集計期間：2004年10月1日～2006年12月31日、第3回報告書「共有すべき医療事故情報」に一部を掲載）。

投与すべき薬剤	取り違えた薬剤
アルマール錠	アマリール錠
アレロック錠	アレリックス錠
セフメタゾン静注用	注用セフマゾン
タキソール注射液	タキソテール注
タキソテール注	タキソール注射液
ファンガード点滴用	ファンギゾン
ラクテックD注	ラクテック注

薬剤の名称が類似していることによる
取り違えが報告されています。

◆その他にも、当事業の第7回報告書p64-65では、ヒヤリ・ハット事例の中から名称の類似が原因と考えられる主な薬剤を取り上げています。



医療事故情報収集等事業 医療安全情報 No.4 2007年3月

［薬剤の取り違え］

事例1

当院診療科では化学療法の処方に際し、パソコン内に定型化した独自の伝票を使用していた。「タキソール200mg+パラプラチン400mg」を投与する予定であったが、誤って「タキソテール+パラプラチン」の伝票を出力したことに気付かず、投与量を記入したため、指示が「タキソテール200mg+パラプラチン400mg」となり、患者に実施した。

事例2

抗生剤「セフメタゾン」が処方された。薬剤部は「セフマゾン」を調剤し、監査の薬剤師も気付かずに「セフマゾン」が病棟に払い出された。病棟看護師は、注射指示簿と払い出された薬剤を確認したが「セフマゾン」を「セフメタゾン」と思い込み患者に実施した。

※この医療安全情報は、医療事故情報収集等事業（第1年分準備組織事業）において収集された事例をもとに、当事業の一環として専門家の意見に基づき、医療事故の発生予防、再発防止のために作成されたものです。当事業の概要等の詳細については、当事業ホームページに掲載されている報告書および手順をご覧ください。
http://jcqhc.or.jp/html/activities.htm#med-safe

※この情報の作成にあたり、作成時における正確性について以下を留意しておりますが、その内容を将来にわたり保証するものではありません。
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[2] Pharmaceutical near-miss events related to similar efficacies

Of the pharmaceutical near-miss events reported from April 1 to December 31, 2009, 181 near-miss events involved "drug mix-up." After excluding 10 near-miss events that apparently did not involve "drug mix-up," 171 near-miss events were analyzed.

The reported drugs with similar efficacies were tabulated. The tabulation of drugs with at least four identical first digits of the YJ codes included 103 drugs.

The names of the reported drugs and their efficacies(Note) are shown below.

1) Drugs with identical first four to six digits of the YJ code (not including drugs with identical first seven digits)

Prescribed drug	Mixed-up drug
Benzodiazepine	
Alprazolam Tablets 0.4 mg TOWA	Sukarnase Tablets 1 mg
Other hypnosedative and anxiolytic	
Zopicool Tablets 10	Myslee Tablets 10 mg
Other antipyretic/analgesic/antiphlogistic	
Loxonin Tablets	Soleton Tablets 80
Imipramine	
Anafranil Tablets 10 mg (high-risk drug)	Tofranil Tablets 10 mg (high-risk drug)
Other psychoneurotic agent	
Tetramide Tablets 10 mg (high-risk drug)	Depas Tablets 0.5 mg (high-risk drug)
Jzoloft Tablets 25 mg (high-risk drug)	Toledomin Tablets 25 mg (high-risk drug)
Other ophthalmic agent	
Kary Uni Ophthalmic suspention 0.005%	Hyalein Ophthalmic Solution 0.1%
Hyalein Ophthalmic Solution 0.1%	Proranon Ophthalmic Solution 0.1%
Hyalein Ophthalmic Solution 0.1%	Kary Uni Ophthalmic Solution 0.005%
Tarivid Ophthalmic Ointment 0.3%	Cravit Ophthalmic Solution 0.5%
Niflan Ophthalmic Solution 0.1%	Kary Uni Ophthalmic Solution 0.005%
Tapros Ophthalmic Solution 0.0015%	Lumigan Ophthalmic Solution 0.03%
Other agent for otic and nasal use	
Livostin Nasal Solution 0.025 mg 112 metered sprays	Alroyer Nasal
Other diuretic	
Luprac Tablets 4 mg	Diart Tablets 30 mg

(Note) "Major efficacy" refers to the drug classification indicated by the first four digits of the YJ code.

Prescribed drug	Mixed-up drug
Other hypotensive	
Atelec Tablets 10	Artist Tablets 10 mg
Diovan Tablets 40 mg	Micardis Tablets 40 mg
Micardis Tablets 40 mg	Nu-LOTAN Tablets 50 mg
Micardis Tablets 40 mg	Diovan Tablets 40 mg
Other hypolipidemic	
Lipitor Tablets 5 mg	Lochol Tablets 20 mg
Lipitor Tablets 10 mg	Pravatin Tablets 10
Codein (exempt narcotic)	
1% Dihydricodein phosphate powder ”FUSO”	1% Codeine Phosphate Powder ”FUSO”
H2 blocker	
Stogar Tablets 10	Gasport Tablets 20 mg
Miscellaneous agent for digestive organs	
Nauzelin Tablets 10	Primperan Tablets 5
Oradol S Lozenge 0.5 mg	SP Troches “MEIJI”
Pancreatic hormone	
Lantus SoloStar (high-risk drug)	Apidra Inj. SoloStar (high-risk drug)
Other hemorrhoid treatment	
Proctosedyl Ointment	Posterisan Forte (ointment)
Borraza-G Ointment	Posterisan Forte (ointment)
Corticosteroid	
Dermovate Scalp Lotion 0.05%	Methaderm Lotion 0.1%
Locoid Ointment 0.1%	Antebate Ointment 0.05%
Methaderm Cream 0.1%	Ledercort Cream 0.1%
Antebate Ointment	Dermovate Ointment 0.05%
Other analgesic, antipruritic, astringent, antiphlogic	
Zinc Oxide Ointment “YOSHIDA”	Zinc Oxide (10%) Simple Ointment「NIKKO」
Inteban Solution 1%	Napageln Lotion 3%
Mohrus Pap 30 mg	Seltouch Pap 70
Felnabion Pap 70	Adofeed Pap 40 mg
MS Reishippu “TAIHO”	MS Onshippu「TAIHO」
Miscellaneous blood/body fluid pharmaceutical product	
Prorenal Tablets 5 μg	Dornalin Tablets 20 μg

Prescribed drug	Mixed-up drug
Other diabetes treatment	
Starsis Tablets 90 mg (high-risk drug)	Voglibose Tablets 0.3 mg SW (high-risk drug)
Seibule Tablets 50 mg (high-risk drug)	Voglibose OD Tablets 0.3 mg SAWAI (high-risk drug)
Miscellaneous other metabolic drug	
Benet Tablets 2.5 mg	Bonalon Tablets 5 mg
Other allergy treatment	
Aplatin Tablets 20 mg	Azeptin Tablets 1 mg
Talion Tablets 10 mg	Claritin Tablets 10 mg
Herbal medicine	
Tsumura Kamishoyosan Extract Granules for Ethical Use	Tsumura Yokukansan Extract Granules for Ethical Use
Tsumura Keishikashakuyakuto Extract Granules for Ethical Use	Tsumura Shikokeishito Extract Granules for Ethical Use
Tsumura Goreisan Extract Granules for Ethical Use	Tsumura Gorinsan Extract Granules for Ethical Use
Tsumura Shikokeishito Extract Granules for Ethical Use	Tsumura Shikokeishikanyoto Extract Granules for Ethical Use
Tsumura Shakuyakukanzoto Extract Granules for Ethical Use	Tsumura Keishikashakuyakuto Extract Granules for Ethical Use
Tsumura Shouseiryuto Extract Granules for Ethical Use	Tsumura Bakumonto Extract Granules for Ethical Use
Tsumura Daikenchuto Extract Granules for Ethical Use	Tsumura Choreito Extract Granules for Ethical Use
Tsumura Hachimijiogan Extract Granules for Ethical Use	Tsumura Mashiningan Extract Granules for Ethical Use
Tsumura Hangekobokuto Extract Granules for Ethical Use	Tsumura Orengedokuto Extract Granules for Ethical Use
Tsumura Boiogito Extract Granules for Ethical Use	Tsumura Makyoyokukanto Extract Granules for Ethical Use
Tsumura Maobushisaishinto Extract Fine Granule (ethical drug)	Tsumura Maoto Extract Granules for Ethical Use

* The product names of the listed drugs were tabulated based on their YJ codes and may not be consistent with the drug names used in the "text information."
* Unlike other drugs, "herbal medicines" may have the same first four digits of the YJ codes even if they have different efficacies.
* Near-miss events involving "drug mix-up" searched by identical first letters (two or three) of drug names were categorized as "similar drug names" while those searched by identical first four digits of YJ codes were categorized as "similar efficacies." Therefore, some near-miss events may be included in both categories.
* "High-risk drug" refers to a drug requiring safety management, e.g., medication management and assistance appropriate for the patient's living environment and recuperation status. Drugs listed in "II. Drugs in the following therapeutic areas that may require special cautions when administered" in the "Operation Guidelines for Pharmacological Management of High Risk Drugs (version 1)" issued by the Japan Pharmaceutical Association in November 2009 were used as a reference for defining high-risk drugs.

3) Improvement measures reported by the pharmacies

(1) Review of the procedure

- The product name should be included in the heading of the medication record so that errors made during drug dispensing can be detected during verification.
- Instead of saying, "This is an herbal medicine," he/she should say, "This is an herbal medicine No. XX called YYY" to clearly communicate the product number and name.
- Document the current medications in the patient's medication notebook so that the patient can check his medications.
- Multi-tasking should be avoided. What can be completed now should be completed.
- The original drug should be kept in mind when preparing a generic.
- The post-treatment check system should be strengthened.

(2) Review of the check system

- Picking should be performed, or the drug should be pointed at with a finger and its name should be read aloud before packaging.
- Prescriptions received via fax should be thoroughly checked with the originals when they are filed.
- Drugs should be prepared after checking them with other staff members.
- Pharmacists should keep in mind that patients may check their medication differently from how pharmacists do at the time of drug release.
- Drugs should be repeatedly checked, even if they have been checked during verification.
- Drugs should be checked during verification and checked again before handing them to patients.

(3) Review of the placement

- Warning labels should be placed on similar drugs.

4) Discussion

One hundred and seventy-one of 181 reported near-miss events involving drug mix-up were analyzed. One hundred and three near-miss events involved drugs with YJ codes for which the first four or more digits were identical.

Drug mix-ups were evenly reported among a wide variety of efficacies, including "herbal medicine," "corticosteroid" and "other analgesic, antipruritic, astringent, antiinflammatory." Some drugs were high-risk drugs that require careful management for safety.

5) Summary

One hundred and seventy-one of 181 reported near-miss events involving "drug mix-up" were analyzed, and 103 near-miss events involved similar efficacies. The number of near-miss events was larger compared with the 41 near-miss events involving drugs with names whose first two or more letters were identical.

As the Drug Compounding Guidelines of the Japan Pharmaceutical Association point out, pharmacists with little experience in drug dispensing as well as experienced pharmacists have made errors reported in the medial near-miss events involving drugs with similar efficacies. As reported by the pharmacies, review of the procedure to ensure detection of errors by other staff members will be necessary. Checking the drugs with the patient and documenting the dispensed drugs in the patient's medication notebook may be effective.

6) References

1. Japan Council for Quality Health Care Project to Collect and Analyze Medical Near-Miss/Adverse Event Information 2006 Annual Report

○ Medical adverse events involving drugs are analyzed. Misuse of drugs due to similar efficacies is reported.

[3] Pharmaceutical near-miss events related to high-risk drugs

1) The definition of high-risk drug

In this analysis, a "high-risk drug" is defined as a drug requiring safety management, e.g., medication management and assistance appropriate for the patient's living environment and recuperation status. The following drugs listed in "II. Drugs in the following therapeutic areas that may require special cautions when administered" in the "Operation Guidelines for Pharmacological Management of High Risk Drugs (version 1)" issued by the Japan Pharmaceutical Association in November 2009 were used as a reference for defining high-risk drugs.

(i) Anti-cancer drug	(ii) Anti-arrhythmic	(iii) Anti-epileptic
(iv) Anti-coagulant	(v) Digitalis	(vi) Theophylline
(vii) Psychoneurotic agent	(viii) Diabetes treatment	(ix) Pancreatic hormone
(x) Immunosuppressant	(xi) Anti-HIV drug	

2) Reported high-risk drugs and number of reports

The reported drugs were searched for using the first three or four digits of the YJ codes for the same therapeutic areas of the high-risk drugs listed in 1). For the drugs for which no YJ code for the therapeutic area was available, the first three or four digits of the YJ codes for similar therapeutic areas were used for the search.

Therapeutic area of high-risk drug	Corresponding therapeutic area and YJ code	Similar therapeutic area and YJ code
(i) Anti-cancer drug	Anti-cancer drug (N/A)	Anti-tumor drug (42)
(ii) Anti-arrhythmic	Anti-arrhythmic (212)	
(iii) Anti-epileptic	Anti-epileptic (113)	
(iv) Anti-coagulant	Anti-coagulant (333)	
(v) Digitalis	Digitalis (2113)	
(vi) Theophylline	Xanthine (2251)	
(vii) Psychoneurotic agent	Psychoneurotic agent (117)	
(viii) Diabetes treatment	Diabetes treatment (396)	
(ix) Pancreatic hormone	Pancreatic hormone (2492)	
(x) Immunosuppressant	Immunosuppressant (N/A)	Adrenal hormone (245)
(xi) Anti-HIV drug	Antiviral drug (625)[Note]	

Note: Antiviral drugs with HIV infection as one of the target diseases listed in the section of "Indications" in the package insert

Of the pharmaceutical near-miss events reported from April 1 to December 31, 2009, 153 drugs were high-risk drugs according to the definition used for this analysis. The following table presents the frequently reported drugs.

(Most frequently reported drugs)

Product name	Major efficacy(Note)	Number of reports
Warfarin Tablets 1 mg	Anticoagulant	16
Amaryl Tablet 1 mg	Diabetes treatment	10
Depas Tablets 0.5 mg	Psychoneurotic agent	8
Zyprexa Tablets 5 mg	Psychoneurotic agent	7
Predonin Tablets 5 mg	Immunosuppressant	7
Paxil Tablets 10 mg	Psychoneurotic agent	6
Depakene-R Tablets 200	Anti-epileptic	5
Paxil Tablets 20 mg	Psychoneurotic agent	5
Lanirapid Tablets 0.05 mg	Digitalis	5
Theodur Tablets 100 mg	Xanthine	5
NovoRapid FlexPen	Pancreatic hormone	5
NovoRapid 30 Mix FlexPen	Pancreatic hormone	5
Seroquel Tablets 25 mg	Psychoneurotic agent	4
Jzoloft Tablets 25 mg	Psychoneurotic agent	4
Mexitil Capsules 50 mg	Anti-arrhythmic	4
Novolin 30 R FlexPen	Pancreatic hormone	4
Voglibose Tablets 0.3 mg ″SW″	Diabetes treatment	4
Basen OD Tablets 0.2	Diabetes treatment	4
Basen OD Tablets 0.3	Diabetes treatment	4
Actos Tablets 15	Diabetes treatment	4
Actos Tablets 30	Diabetes treatment	4
Contomin Sugar-Coated Tablets 12.5 mg	Psychoneurotic agent	3
Amoxan Capsules 10 mg	Psychoneurotic agent	3
Tetramide Tablets 10 mg	Psychoneurotic agent	3
Risperdal Tablets 2 mg	Psychoneurotic agent	3
Risperdal Oral Solution 1 mg/mL	Psychoneurotic agent	3
Seroquel 100 mg Tablets	Psychoneurotic agent	3
Zyprexa Tablets 10 mg	Psychoneurotic agent	3
Zyprexa Zydis Tablets 5 mg	Psychoneurotic agent	3
Lanirapid Tablets 0.1 mg	Digitalis	3
Mexitil Capsules 100 mg	Anti-arrhythmic	3
Celestamine combination Syrup	Immunosuppressant	3
Novolin R FlexPen	Pancreatic hormone	3
Humalog Mix 25 MirioPen	Pancreatic hormone	3
Warfarin Tablets 0.5 mg	Anticoagulant	3
Hirudoid Lotion 0.3%	Anticoagulant	3
Amaryl Tablets 3 mg	Diabetes treatment	3
Medet Tablets 250 mg	Diabetes treatment	3
Starsis Tablets 90 mg	Diabetes treatment	3
Seibule Tablets 50 mg	Diabetes treatment	3
UFT combination Capsules 100 mg	Anti-cancer drug	3

Note: “Major efficacy” refers to the therapeutic area of the reported high-risk drug.

3) Discussion

One hundred and fifty-three pharmaceutical near-miss events involved high-risk drugs with a variety of therapeutic areas. According to the product name-based tabulation of "ethical drugs," the most frequently reported high-risk ethical drugs included Warfarin Tablets 1 mg (most frequent), Amaryl Tablets 1 mg (13th), Depas Tablets 0.5 mg (22nd), Zyprexa Tablets 5 mg (27th) and Predonin Tablets 5 mg (27th).

4) Summary

The high-risk drugs defined for this analysis are identical to those listed in the "Operation Guidelines for Pharmacological Management of High Risk Drugs (version 1)" issued by the Japan Pharmaceutical Association as drugs especially requiring precautions concerning use. Special cautions should be exercised when preparing and dispensing these drugs, including pharmacological management and giving instructions to patients. These drugs should be "checked" and "watched" as well as stored separately from other drugs. Review of the audit procedure and collection of information from patients will also be necessary.

[4] Pharmaceutical near-miss events related to inquiries about prescription

Of the pharmaceutical near-miss events reported from April 1 to December 31, 2009, 107 near-miss events involved "inquiries."

1) Analysis of reasons for making inquiries

Reason for making the inquiry	Number and proportion of near-miss events (%)
Based on the prescription alone	45 (42.0%)
Based on the prescription and the information available at the pharmacy	37 (34.6%)
Others	25 (23.4%)
Total	107 (100.0%)

The reported 107 near-miss events were categorized by "reason for making the inquiry." Inquiries were made based on the prescription alone in 45 near-miss events, based on the prescription and the information available at the pharmacy in 37 near-miss events, and based on other reasons in 25 near-miss events.

<Reference: 2000 Analysis and Evaluation in "Survey on Inquiries Made by Pharmacies"(Note) >

Detection of potential error	1987	1998	2000
Based on the prescription alone	72.4%	51.9%	46.6%
Based on the medication record	15.8%	19.3%	17.3%
Based on the patient interview	7.5%	27.9%	32.0%
Others	4.3%	0.9%	4.1%

2) Analysis of specifics of changes

Specifics of change	Number of near-miss events
Change of drug	36
Change of usage	15
Change of dose	16
Change of quantity	16
Deletion of drug	13
Others	11
Total	107

The reported 107 near-miss events were categorized by "specifics of change." Drugs were changed in 36 near-miss events, and the dose or the quantity was changed in 16 near-miss events each. Nine of 11 near-miss events categorized as "others" involved additional medications.

(Note) See Nakamura K. 2000 Analysis and Evaluation in "Survey on Inquiries Made by Pharmacies". Journal of the Japan Pharmaceutical Association 54(4).

(1) The near-miss events involving "inquiries" are shown with "specifics of change" in the left column and "reason for making the inquiry" in the top row of the following table.

Reason for making the inquiry / Specifics of change	Based on the prescription alone	Based on the prescription and the information available at the pharmacy	Others	Number of near-miss events
Change of drug	13	14	9	36
Change of usage	8	4	3	15
Change of dose	8	4	4	16
Change of quantity	13	3	0	16
Deletion of drug	2	9	2	13
Others	1	3	7	11
Total	45	37	25	107

Drugs or quantities were frequently changed after making inquiries based on "the prescription alone." Drugs were frequently changed or deleted after making inquiries based on "the prescription and the information available at the pharmacy." Drugs were changed or other actions were taken after making inquiries based on "others" including interviewing the patient.

(2) The following tabulations i) to iii) were performed for the category "change of drug," which was most frequent in the reported near-miss events involving "inquiries."

i) The reported near-miss events involving inquiries were tabulated by type of change based on product names reported in "near-miss events involving drugs." Specifically, changes of strengths/dosage forms were categorized as "changed to different strength/dosage form," and changes of product names (not including changes of strengths/dosage forms) were categorized as "changed to different product name."

Type of change	Number of near-miss events
Changed to different strength/dosage form	12
Changed to different product name	24
Total	36

Twelve near-miss events were categorized as "changed to different strength/dosage form," and 24 near-miss events were categorized as "changed to different product name" (not including changes of strengths/dosage forms).

ii) The reported near-miss events involving "inquiries" were shown with "type of change" in the left column and "reason for making the inquiry" in the top row in the following table.

Reason for making the inquiry / Type of change	Based on the prescription alone	Based on the prescription and the information available at the pharmacy	Others	Number of near-miss events
Change to different strength/dosage form	7	5	0	12
Change to different product name	6	9	9	24
Total	13	14	9	36

Of 12 reported pharmaceutical near-miss events involving "change of drug," inquiries were made based on information other than the prescription in five near-miss events (41.7%) categorized as "changed to different strength/dosage form." Inquiries were made based on information other than the prescription in 18 of 24 (75.0%) near-miss events categorized as "changed to different product name."

iii) Twenty-four near-miss events categorized as "changed to different product name" were further categorized into "similar efficacy" and "different efficacy." Similar efficacy refers to YJ codes whose first four or more digits are identical.

Similarity of efficacy	Number of near-miss events
Similar efficacy	9
Different efficacy	15
Total	24

The originally prescribed drug was changed to other drug with a similar efficacy in nine near-miss events and to other drug with a different efficacy in
15 near-miss events. The reason for making the inquiry, the product name (efficacy) and the details of the near-miss events are shown below for the 15 near-miss events in which the prescribed drug was changed to a drug with a different efficacy.

Reason for making the inquiry	Product name (efficacy)	Details
Contraindication for coadministration (1 near-miss event)		
Based on the prescription and the information available at the pharmacy	○ **Prescribed drug** Unipron Suppository 100 (Other antipyretic/analgesic/antiphlogic) ○ **Changed to** Anhiba pediatric Suppository 200 mg (Aniline)	Baccidal Tablets for Children and Unipron Suppository were prescribed for the patient at the same time. The pharmacist casually read the package insert of Baccidal since it was the first time to dispense the drug at the pharmacy and found concurrent use of Baccidal and Unipron was contraindicated. An inquiry was made, and the prescription of Baccidal was changed to Anhiba Suppository.

Reason for making the inquiry	Product name (efficacy)	Details
Multiple prescriptions (3 near-miss events)		
Based on the prescription alone	○ **Prescribed drug** Seibule Tablets 25 mg (Other diabetes treatment) ○ **Changed to** Melbin Tablets 250 mg (Biguanide)	Seibule Tablets 25 mg was additionally prescribed to the patient using Voglibose OD Film 0.2 QQ. Both drugs have the same α-glucosidase inhibitory action. An inquiry was made to the physician, and he replied he had forgotten the patient had been using Voglibose. Seibule was changed to Melbin Tablets.
Based on the prescription and the information available at the pharmacy	○ **Prescribed drug** Carnaculin Tablets 50 (Circulating hormone) ○ **Changed to** Merislon (Other motion sickness medication)	The concomitant drugs prescribed to the new patient included Kallikrein. An inquiry was made because Carnaculin Tablets 50 with the same efficacy was prescribed. Carnaculin Tablets 50 was deleted, and Merislon was added to the prescription.
Others	○ **Prescribed drug** Cefcapene pivoxil hydrochloride 100 mg "SAWAI" (Cephem antibiotic) ○ **Changed to** Levofloxacin Tablets 100 mg "YD" (Pyridone carboxylic acids)	Cefcapene pivoxil hydrochloride had been prescribed. During the treatment, the pharmacy found the original drug Flomox had also been prescribed at other medical institution. An inquiry was made to the prescribing physician, and cefcapene pivoxil hydrochloride was changed to Levofloxacin Tablets YD. The prescribing physician gave an order to discontinue Flomox.
Adverse drug reaction (4 near-miss events)		
Based on the prescription and the information available at the pharmacy	○ **Prescribed drug** Meiact MS Tablets 100 mg (Cephem antibiotic) ○ **Changed to** Cravit Tablets (Pyridone carboxylic acids)	The patient sought treatment for recurrent cystitis and received a prescription. Meiact had been prescribed before but switched to Cravit due to drug eruption. The medication record was overlooked, and Meiact was prescribed again. An inquiry was made, and Meiact was changed to Cravit.
Based on the prescription and the information available at the pharmacy	○ **Prescribed drug** Tannalbin "WHEY" (Tannic acid) ○ **Changed to** Lopemin Capsules 1 mg (Other antidiarrhetic, antiflatulent)	The patient was allergic to milk according to a comment in the medication record. An inquiry was made because the prescription included Tannalbin, which was later changed to Lopemin Capsules 1 mg.
Others	○ **Prescribed drug** Etodolac Tablets 200 "KN" (Other antipyretic/analgesic/antiphlogic) ○ **Changed to** Voltaren Gel 1% (Other antipyretic, antipruritic, astringent, antiphlogic)	Etodolac Tablets 200 KN was prescribed to the patient treated for cancer at another medical institution. According to the medication record brought by the patient, the current medication included TS1 Capsules 25, Leucon Tablets 10 mg, Azunol Gargle Solution 4% and Mohrus Tape 20 mg. An inquiry was made to the prescribing physician because of potential leukocytopenia. Etodolac Tablets were discontinued and switched to Voltaren Gel.
Others	○ **Prescribed drug** Loxonin Tablets (Other antipyretic/analgesic/antiphlogic) ○ **Changed to** Voltaren Tablets 25 mg (Phenylacetic acid)	The patient complained he had difficulty urinating because of Loxonin Tablets. An inquiry was made regarding the prescription of Loxonin, which was later switched to Voltaren Tablets 25 mg.

Reason for making the inquiry	Product name (efficacy)	Details
Data entry error (6 near-miss events)		
Based on the prescription alone	○ **Prescribed drug** Mevan Tablets 5 (Other hypolipidemic) ○ **Changed to** Banan Tablets 100 mg (Cephem antibiotic)	The prescription for cold medication included a hypolipidemic. The product name was Meban, and no titer information was available. The pharmacist suspected it should have been Banan Tablets and made an inquiry. It turned out the drug should have been an antibiotic Banan Tablets.
Based on the prescription alone	○ **Prescribed drug** Asverin Tablets 10 (Other anti-tussive/expectorant) ○ **Changed to** Asthphyllin Combination Tablets (Other anti-tussive)	The prescribed dose of Asverin was only 10 mg while other drugs were prescribed in adult doses. An inquiry was made to the hospital, and a data entry error of a clerk was identified. Asverin should have been Asthphyllin Combination Tablets.
Based on the prescription and the information available at the pharmacy	○ **Prescribed drug** Urief Tablets 4 mg (Other agent for urogenital and anal organ) ○ **Changed to** Urinorm Tablets 50 mg (Other gout treatment)	The prescription for the female patient included Urief (4). An inquiry was made to the physician since the drug was not intended for female patients. Urief should have been Urinorm (50). The physician wrote "Urinorm (50)" in the patient's medical chart. There must have been a data entry error when the prescription was prepared.
Others	○ **Prescribed drug** Aspara-CA Tablets 200 (Organic calcium) ○ **Changed to** Aspara Potassium Tablets 300 mg (Other mineral preparation)	The patient came to the pharmacy with the prescription, which included Aspara-CA (prescribed for the first time). Asked how the physician described the newly prescribed drug, the patient said, "He did not say calcium would be added to my prescription." An inquiry was made. Aspara-CA should have been Aspara Potassium Tablets.
Others	○ **Prescribed drug** Loxonin Tablets (Other antipyretic/analgesic/antiphlogic) Mucosta Tablets 100 (Other peptic ulcer treatment) ○ **Changed to** Medicon Tablets 15 mg (Dextromethorphan) Dasen 5 mg tablets (Other enzyme preparation)	The patient requested the physician to prescribe the same cold medications he used last year. Loxonin × 1 tablet and Mucosta × 1 tablet for 20 days to be used when having fever or pain were prescribed. When the medications were about to be dispensed, the patient said, "These are not what I wanted." An inquiry was made, and the prescription was changed to Medicon × 3 tablets and Dasen 5 mg × 3 tablets t.i.d. for seven days.
Others	○ **Prescribed drug** Amaryl tablets 1mg (Sulfonylurea) ○ **Changed to** Almarl Tablets 10 (β-blocker)	Amaryl Tablets 1 mg was prescribed instead of Almarl Tablets 10. The prescription error was found both by the patient and the pharmacy. An inquiry was made, and the prescription was changed.
Prescription of off-label drug (1 near-miss event)		
Based on the prescription alone	○ **Prescribed drug** Kenacort-AG Ointment (Antibiotic/corticosteroid combination) ○ **Changed to** Kenalog in orabase 0.1% (Unclassifiable gastrointestinal treatment)	The dermatologist prescribed Kenacort-AG Ointment (to be used orally). Oral use of the drug was found off-label after checking the package insert and making an inquiry to the manufacturer. An inquiry was made, and Kenacort was changed to Kenalog.

3) Summary

Of 107 near-miss events involving inquiries about prescription, inquiries were made based on comprehensive information including that from sources other than the prescription in 62 near-miss events (58.0%). Of 15 near-miss events involving change of the prescribed drug to another drug with different product name and efficacy, inquiries were made based on information other than the prescription in 11 near-miss events (73.3%). Use of the prescribed drug may have resulted in health hazards in the patients in many of the near-miss events, in which inquiries were made due to contraindication for coadministration or to prevent adverse drug reactions. Potential health hazards were avoided because the pharmacies checked the medication records and patient information when they prepared the drugs. Information from prescriptions and other sources should be comprehensively used when verifying prescriptions.

[5] Pharmaceutical near-miss events related to 2 specific drugs

1) Warfarin potassium

(1) Occurrence of near-miss events

Of the pharmaceutical near-miss events reported from April 1 to December 31, 2009, 19 near-miss events involved warfarin potassium according to the YJ codes of the drugs.

The 19 near-miss events are tabulated according to "outline of near-miss events," "situation," "specifics of near-miss events or change" and "whether the drug was dispensed."

The prescribed drugs were dispensed in four near-miss events and not dispensed in 15 near-miss events. The tabulation according to "specifics of near-miss event or change" showed "wrong quantity" was most frequent (10 near-miss events) followed by "drug mix-up" (3 near-miss events).

Outline of near-miss event	Situation	Specifics of near-miss event or change	Whether the drug was dispensed		Total (near-miss event)
			Dispensed	Not dispensed	
Drug dispensing	Drug dispensing	Wrong quantity	3	7	10
		Wrong packaging	0	1	1
		Wrong strength/dosage form	1	0	1
		Drug mix-up	0	3	3
	Management	Error in filling the cassette	0	1	1
	Drug release	Patient misidentification	0	1	1
Inquiry about prescription		Change of dose	0	1	1
		Change of quantity	0	1	1
Total			4	15	19

(2) Details of the near-miss events

(i) Four near-miss events in which the drug was dispensed

The extent of treatment is shown in the following table, and the dose of dispensed warfarin potassium compared with the dose intended by the physician was categorized into low, moderate and high for the four near-miss events in which the drug was "dispensed."

The extent of treatment was "minor" in one near-miss event, "no treatment" in 0 near-miss events and "unknown" in three near-miss events. The warfarin potassium dose compared to the intended dose was low in three near-miss events and high in one near-miss event.

The details of the near-miss events are shown below.

Extent of treatment	**Comparison with the warfarin potassium dose intended by the physician**	**Details of the near-miss event**
[Details of the near-miss event, wrong quantity; 3 near-miss events]		
Unknown	Low	Forty-five warfarin tablets (1.5 tablets × 30 days) were dispensed instead of 75 warfarin tablets (2.5 tablets × 30 days). The pharmacist did the arithmetic in her head. The prepared drugs were not checked.
Unknown	Low	When packing warfarin 1 mg and warfarin 0.5 mg using a packaging machine, one packet worth of warfarin did not fall into the packet paper and remained in the machine. The pharmacy was busy with a lot of patients, and no thorough check was performed. The verification was performed by one pharmacist instead of two before release the drug.
Unknown	Low	Prepared packets contained one warfarin 1 mg tablet each instead of three tablets. The family of the patient found the error before the patient had taken the drug.
[Details of near-miss event, wrong strength/dosage form; 1 near-miss event]		
Minor treatment	High	The prescription was changed from warfarin 1 mg × 0.5 tablet to warfarin 0.5 mg × 1.5 tablet; however, warfarin 1 mg × 1.5 tablet was prepared. The warfarin dose increase was not thoroughly confirmed during the conversation with the patient, and the drug was prepared based on the pharmacist's assumption.

ii) Fifteen near-miss events in which the drug was not dispensed

The dose of dispensed warfarin potassium compared with the dose intended by the physician was categorized into low, moderate and high for 15 near-miss events in which the drug was "not dispensed."

The warfarin potassium dose compared to the intended dose was low in seven near-miss events, high in six near-miss events and the same in two near-miss events. In the latter two near-miss events the warfarin dose was unchanged but the generic was mixed up with the original drug.

The details of the near-miss events are shown below.

Comparison with the warfarin potassium dose intended by the physician	Details of the near-miss events
[Details of the near-miss event, wrong quantity; 7 near-miss events]	
High	Fifty-six packets of warfarin 0.5 tablets were prepared instead of 28 packets.
High	The prescribed warfarin 1 mg × 0.6 tablet × 21 days was prepared as a 0.5 tablet and a crushed 0.1 tablet. A 0.1 warfarin tablet × 21 days should have been crushed. However, 2.4 tablets were crushed instead of 2.1 tablets due to neglecting to check the quantity. The inspecting pharmacist started to perform other tasks, and neglected to check the quantity.
High	Warfarin 1 mg × 0.5 tablet × 28 packets were prepared instead of 14 packets.
Low	One tablet was prepared instead of 1.5 tablet.
Low	Due to an error in packaging machine operation, only one tablet of warfarin was put into the machine instead of four tablets. The machine operation was somewhat difficult, and the pharmacist did not completely know how to use it.
Low	Twenty-eight tablets were prepared instead of 56 tablets.
Low	Pre-packed 0.25 tablet was mixed up with 0.75 tablet.
[Details of near-miss event, drug mix-up; 3 near-miss events]	
High	When it should have been Onealfa × 1 tablet, warfarin 1 mg × 1 tablet was prepared because the pharmacist mistakenly assumed the drug was warfarin based on how the name sounded. The error was found during the verification.
Same	Warfarin Potassium Tablets 0.5 mg HD were prepared instead of Warfarin Tablets 0.5 mg. Checking was neglected.
Same	Warfarin Tablets 1 mg was prepared instead of Warfarin Potassium Tablets 1 mg HD.
[Details of near-miss event, wrong packaging; 1 near-miss event]	
Low	One and one-quarter tablet was packaged instead of 1.75 tablet.
[Details of near-miss event, error in filling the cassette; 1 near-miss event]	
Low	Lasix Tablets 40 mg were packed into the cassette of the tablet packaging machine for Warfarin Tablets 1 mg. One packet of Lasix was prepared by mistake. The pharmacist was confused because Lasix Tablets 40 mg was also prescribed.

Comparison with the warfarin potassium dose intended by the physician	Details of the near-miss event
[Details of near-miss event, patient misidentification; 1 near-miss event]	
Los	Drugs are usually placed in separate trays for each patient. However, the one dose packets for the patient were put into the tray of another patient. The wrong medications were almost dispensed because one dose packets had also been dispensed for the other patient. The error was found during the pre-release verification. There was a series of patients requiring long-term prescriptions and one dose packets of multiple drugs. The one dose packets for the patient were mistakenly put into the tray of the other patient after preparing and inspecting them. Multiple pharmacists prepared drugs for multiple patients at the same time because one dose packets of long-term prescription drugs (28 to 90 days) took time for packing and verification and simultaneous drug dispensing for multiple patients was unavoidable.
[Specifics of change, change of dose; 1 near-miss event]	
High	The patient received the prescription of one 5-mg tablet + two 1-mg tablets at the first visit after his discharge from the special hospital. The pre-admission prescription was 5 mg × 0.5 tablet. An inquiry was made because it was a sudden dose increase. The hospital replied through the reception that the prescription was unchanged from the one issued at the previous hospital and therefore correct. The drug was prepared but another pharmacist assumed 5 mg had been misread as 0.5 mg. Another inquiry was directly made to the physician. The prescribed 5 mg × 0.5 tablet had been prepared as 0.5 mg × 1 tablet and 1 mg × 2 tablets for the convenience of the hospital. 1) The pharmacist thought he/she was convinced because he/she had made an inquiry even though some doubts remained. 2) The rule to directly make inquiries to physicians was not thoroughly observed.
[Specifics of change, change of quantity; 1 near-miss event]	
High	Regarding the usage of Warfarin Tablets 1 mg, the intention of the physician to use Warfarin 8 mg on Day 1 and 2 mg on the following days was known after making an inquiry. Warfarin 8 mg was to be used on the following days according to the pre-inquiry prescription. It was an error of data entry on the electronic medical chart.

(3) Near-miss events involving errors due to multiple strengths

Of 19 reported near-miss events, two events involved errors due to multiple strengths of warfarin potassium.

The details of the near-miss events are shown below.

Details of near-miss event [specifics of near-miss event, inquiry]
The patient received the prescription of one 5-mg tablet + two 1-mg tablets at the first visit after his discharge from the special hospital. The pre-admission prescription was 5 mg × 0.5 tablet. An inquiry was made because it was a sudden dose increase. The hospital replied through the reception that the prescription was unchanged from the one issued at the previous hospital and therefore correct. The drug was prepared but another pharmacist assumed 5 mg had been misread as 0.5 mg. Another inquiry was directly made to the physician. The prescribed 5 mg × 0.5 tablet had been prepared as 0.5 mg × 1 tablet and 1 mg × 2 tablets for the convenience of the hospital.
Prescribed drug
Warfarin Tablets 5 mg

[Pre-admission]	**[During hospitalization]**	**[After discharge]**
Warfarin Tablets 5 mg × 0.5 tablet	Warfarin Tablets 0.5 mg × 1 tablet Warfarin Tablets 1 mg × 2 tablets	Warfarin Tablets 5 mg × 1 tablet Warfarin Tablets 1 mg × 2 tablets
Content of warfarin potassium **2.5 mg**	Content of warfarin potassium **2.5 mg**	Content of warfarin potassium **7 mg**

Details of near-miss event [specifics of near-miss event, drug dispensing]
The prescription was changed from Warfarin 1 mg Tablets × 0.5 tablet to Warfarin 0.5 mg Tablets × 1.5 tablet; however, Warfarin 1 mg Tablets ×1.5 tablet was prepared.

[Previous prescription]	**[Current prescription]**	**[Drug prepared by the pharmacist]**
Warfarin Tablet 1 mg × 0.5 tablet	Warfarin Tablet 0.5 mg × 1.5 tablet	Warfarin Tablet 1 mg × 1.5 tablet
Content of warfarin potassium **0.5 mg**	Content of warfarin potassium **0.75 mg**	Content of warfarin potassium **1.5 mg**

(4) Improvement measures reported by the pharmacies

Documentation of prescription information in medication notebooks should be thoroughly ensured to communicate the information to the past and present hospitals.

Observe the rules for drug dispensing and verification, and two pharmacists should always check the prepared drugs.

Place a reminder on the drawer for additional checking.

Ensure thorough checking of packed drugs.

Use a calculator to do even easy calculation for conversion.

(5) Near-miss events reported by medical institutions

The Japan Council for Quality Health Care Project to Collect and Analyze Medical Near-Miss/Adverse Event Information 2009 Annual Report includes analyses of near-miss events involving warfarin potassium.(Note)

Fifty-four near-miss events involving warfarin potassium were reported between October 2004 and December 2009. Patients had infarction or hemorrhage during an examination, a surgery or a treatment procedure in 22 near-miss events (see Reference). The use of warfarin potassium and the blood coagulability of the patient were not known in advance in five of the near-miss events. The improvement measures proposed by the reporting medical institutions included "thorough provision and exchange of information on patients using oral warfarin potassium." The Annual Report summarizes, "Management of patients using oral warfarin potassium and scheduled for an examination, a surgery or a treatment procedure needs to be determined based on the use of the drug and the blood coagulability to prevent infarction and hemorrhage associated with the medical procedures."

<Reference: Availability of information on use of oral warfarin potassium and blood coagulability of patients scheduled for examination, surgery or treatment procedure>

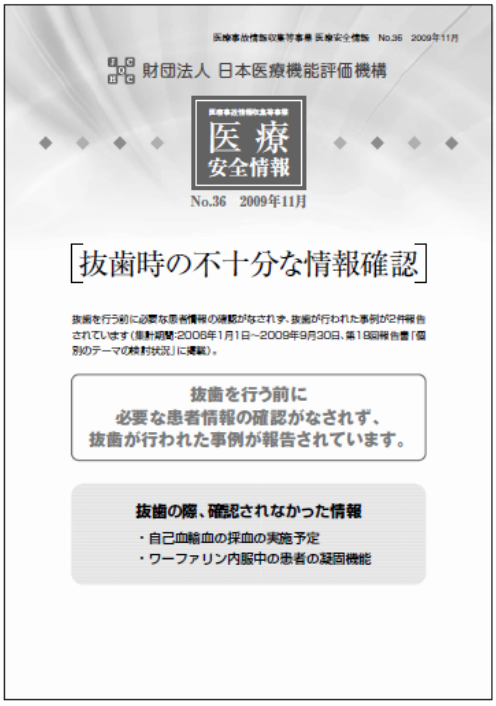
Availability of information	Infarction (incident)	Hemorrhage (incident)	Others (incident)	No disability (incident)	Unknown (incident)	Total (incident)
Available	2	3	0	0	1	6
Not available	8	9	1	0	0	18
Total	10	12	1	0	1	24

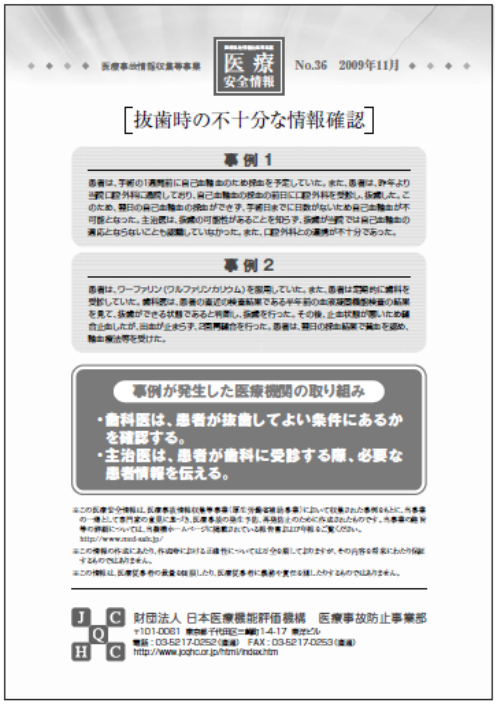
Excerpted from Figure III-2-45 (page 313) in the Japan Council for Quality Health Care Project to Collect and Analyze Medical Near-Miss/Adverse Event Information 2009 Annual Report

(Note) See the Japan Council for Quality Health Care Project to Collect and Analyze Medical Near-Miss/Adverse Event Information 2009 Annual Report for details of the reported medical adverse events.

In the Japan Council for Quality Health Care Medical Safety Information No. 36 “Insufficient Confirmation of relevant information at the time of dental extraction,” a tooth extraction procedure performed by a dentist who checked the blood coagulation test performed half a year ago and resulted in blood transfusion in a patient using oral warfarin potassium was reported. The improvement measures proposed by the reporting medical institution included, “the physician in charge of the patient should communicate necessary patient information when the patient receives dental treatment.”

（Medical Safety Information No. 36 “Insufficient Confirmation of relevant information at the time of dental extraction,”）





(6) Summary

Drugs were not dispensed in many of the near-miss events involving warfarin potassium. Most of these near-miss events involved “wrong quantity.” Some reported errors due to multiple strengths. If warfarin potassium is dispensed at doses higher than intended by the physician, health hazards may occur due to overdose. Being a high-risk drug, warfarin potassium should therefore be prepared more carefully compared with other drugs.

“(5) Near-miss events reported by medical institutions” excerpted from the analysis in the Project to Collect and Analyze Medical Near-Miss/Adverse Event Information 2009 Annual report introduces thorough provision and exchange of information on the patient’s condition as one of the improvement measures proposed by the reporting medical institution. Pharmacies should also ensure active coordination with medical institutions by providing information on the medication status and concomitant drugs of patients using oral warfarin potassium in their medication notebooks.

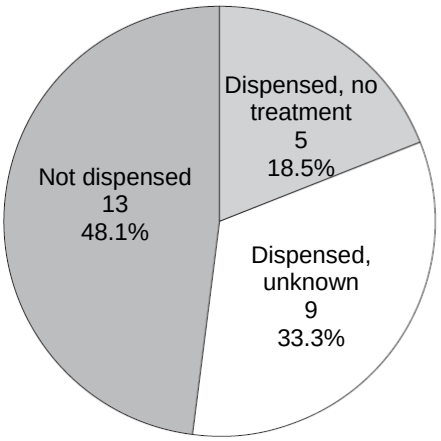
Also see “IV Pharmaceutical Near-Miss Event Information to Be Shared” in this Annual Report (page 69 to 89) for the reported near-miss events involving warfarin potassium.

2) Insulin

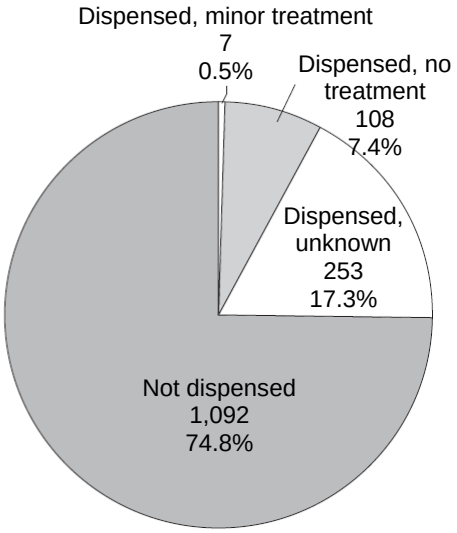
(1) Occurrence of near-miss events

Of the pharmaceutical near-miss events reported from April 1 to December 31, 2009, 27 near-miss events involved insulin according to the YJ codes of the drugs involved. The prescribed drugs were dispensed in 14 near-miss events. Compared with the data presented in "4. Whether the drug was dispensed and extent of treatment" (page 22), the proportion of dispensing/drug release errors was larger (14/27 near –miss events).

Whether the drug was dispensed and extent of treatment in the near-miss events involving insulin



Whether the drug was dispensed and extent of treatment in all the reported medical near-miss events



The reported 19 near-miss events are tabulated according to "specifics of near-miss event," "situation," "specifics of near-miss event or change" and "whether the drug was dispensed."

"Wrong strength/dosage form" (nine events) was most frequent followed by "drug mix-up" (five events) among "specifics of near-miss event or change."

Outline of near-miss event	Situation	Specifics of near-miss event or change	Whether the drug was dispensed		Total (near-miss event)
			Dispensed	Not dispensed	
Drug dispensing	Drug dispensing	Failure to dispense	0	3	3
		Wrong quantity	1	0	1
		Wrong strength/dosage form	5	4	9
		Drug mix-up	2	3	5
		Providing wrong description on medication bag	2	0	2
		Others	3	0	3
	Drug release	Neglect of drug release	1	0	1
Inquiry		Change of drug	0	2	2
		Change of dose	0	1	1
Total			14	13	27

(2) Summary of near-miss events

Details of 14 near-miss events in which the drug was dispensed are shown by extent of treatment in category and text.

The extent of treatment was “minor treatment” in 0 near-miss events, “no treatment” in five near-miss events and “unknown” in nine near-miss events.

Details of near-miss event	Details of near-miss event (text information)
[Extent of treatment, no treatment] 5 near-miss events	
Wrong quantity	“NovoRapid FlexPen × 1 and Lantus SoloStar × 3” were prescribed but “NovoRapid FlexPen × 2 and Lantus SoloStar × 6” were dispensed. The patient did not use the drugs.
Wrong strength/dosage form	Insulin 30R was prepared and dispensed instead of insulin R.
Wrong strength/dosage form	The patient had been using Humalog Mix 25 Kit, but the drug was switched to MirioPen. The change was overlooked, and Kit was dispensed. The error was found by another pharmacist during the inventory check on the next day. The patient was contacted immediately. He/she came to the pharmacy to exchange Kit to MirioPen. The pharmacy apologized and explained how to use MirioPen to the patient.
Drug mix-up	NovoRapid was dispensed by mistake instead of prescribed NovoRapid 30 Mix for the last time but one. The patient thought the drug must have been switched and used NovoRapid. The last time NovoRapid 30 Mix was dispensed according to the prescription, the patient used it. This time the patient talked to the physician who told him the medication had not been changed. The error was found when the hospital contacted the pharmacy.
Others (prescription error made by physician)	The prescription issued by the current hospital included NovoRapid 30 Mix FlexPen, which should have been NovoRapid 300 FlexPen. NovoRapid 30 Mix FlexPen was prepared and dispensed to the patient’s caregiver because the dosage and administration was not unusual. The patient found the prescription error before using the drug and contacted the pharmacy.
[Extent of treatment, unknown] 9 near-miss events	
Wrong strength/dosage form	Novolin 30R was dispensed instead of Novolin R. The patient later told the pharmacy he had used up the dispensed drug.
Wrong strength/dosage form	Humalog MirioPen was dispensed instead of prescribed Humalog Mix 25 MirioPen. The error was found when the patient later told the pharmacy the dispensed drug was different from what he usually used. The drug was not used, and no health hazard occurred.
Wrong strength/dosage form	InnoLet 30R was dispensed instead of InnoLet R.
Drug mix-up	The patient visited the pharmacy to exchange the drug because it was different from what he usually used. A prescription check found PenFill 30R was dispensed by mistake instead of PenFill R. Fortunately the patient found the error and did not use the drug.
Providing wrong documentation on medication bag	Wrong number of PenFill N 300 units, 20 units instead of 18 units in the morning, was documented on the medication bag. (The dose was switched in the current prescription)
Providing wrong documentation on medication bag	PenFill R was entered instead of PenFill 30R but the drug was correctly prepared according to the prescription.
Others (neglect of drug release)	The patient left his prescription for processing at the pharmacy around noon and went to have lunch. The pharmacy temporarily kept only the insulin in the refrigerator because the patient was not there when his name was called. The pharmacy forgot to dispense the insulin when the patient returned from lunch.
Others (data entry error)	The Levemir units were changed from previous 7 units to 6 units. When the changed units were entered into the system, the “7” was not deleted. The prescription said 67 units. The error was found during the prescription check. The pharmacy contacted the patient who knew the correct dose was 6 units.
Neglect of release	The medication bag was found in the refrigerator.

(3) Product names reported in the near-miss events involving wrong strength/dosage form or drug mix-up

Fourteen of 27 reported near-miss events involved “wrong strength/dosage form” or “drug mix-up.” The drug was dispensed in seven near-miss events and not dispensed in the other seven near-miss events.

Reported product names of insulin, whether the drug was dispensed and number of reports are shown below.

Prescribed drug	Mixed-up drug	Number of reports
[Dispensed] 7 near-miss events		
PenFill R 300	PenFill 30R 300	2
InnoLet R	InnoLet 30R	1
NovoRapid 30 Mix FlexPen	NovoRapid FlexPen	1
Novolin R FlexPen	Novolin 30R FlexPen	1
Humalog Mix 25 MirioPen	Humalog Mix 25 Kit	1
Humalog Mix 25 MirioPen	Humalog MirioPen	1
[Not dispensed] 7 near-miss events		
NovoRapid FlexPen	NovoRapid 30 Mix FlexPen	2
NovoRapid 30 Mix PenFill	NovoRapid 30 Mix FlexPen	1
NovoRapid 300 FlexPen	NovoRapid 30 Mix FlexPen	1
Novolin R FlexPen	InnoLet R	1
Novolin R Flexpen	Novolin 30R FlexPen	1
Lantus SoloStar	Apidra Inj SoloStar	1

(4) Improvement measures reported by the pharmacies

- Post a reminder for strength check.
- Check the type of injection together with the patient.
- Create labels for individual insulin and attach to the back of the prescription when dispensing, verifying and release the drug.
- Be sure to check the units when dispensing the drug. The units should also be checked together with the patient when released.
- The picture of the drug should also be checked before release to avoid overlooking when checking the drug dispensing record.

(5) Summary

The drug was “released” more frequently in the reported near-miss events involving insulin compared with all reported near-miss events. Errors in dispensing and release of the high risk drug insulin may result in serious accidents. The improvement measures reported by the pharmacies included posting of a reminder for strength check and checking of the type of injection together with the patient. “Comments on Precautions concerning Dispensing of Insulin and Explanation to be Given upon Release (Usage and Storage)”(Note) prepared and published by the Japan Pharmaceutical Association recommends, “the name of insulin should be thoroughly checked to the last letter.” Including the recommendation in the operating procedure at the pharmacy will be beneficial.

(Note) See Comments on Precautions concerning Preparation of Insulin and Explanation to be Given upon Dispensing (Usage and Storage) of the Japan Pharmaceutical Association (http://www.nichiyaku.or.jp/contents/kaiken/pdf/insulin_h21.pdf).

IV Pharmaceutical Near-Miss Event Information to Be Shared

Of the pharmaceutical near-miss events reported from April 1 to December 31, 2009, the incidents to be widely shared as useful information for medical safety management(Note 1) were selected in this section.

Case 1: a near-miss event involving wrong strength/dosage form of an injection (Case No. 000000000005)

Details of the incident
Novolin 30R was dispensed instead of Novolin R. The patient later told the pharmacy he had used up the dispensed drug.
Background/cause of the incident
(The incident occurred) probably because the drug was hastily handed to the patient who told the pharmacist he wanted his medication now, ready to go home after his dialysis treatment. The basics were neglected.
Improvement measures proposed by the pharmacy
Stick to the basics. Cross-check the drug with the prescription. Stay calm.

Other information
None

The point of the case
● Special cautions need to be exercised since errors involving insulin may result in serious accidents. ● Other incidents involving easily mixed up insulin injections were also reported. • NovoRapid 300 FlexPen and NovoRapid 30 Mix FlexPen (Case No. 000000000099 and 000000000107) • Humalog Mix 25 MirioPen and Humalog MirioPen (Case No. 000000000136) • PenFill 30R and PenFill R (Case No. 000000000141) ● Information on insulin is included in Medical Safety Information (No. 1 and No. 6) on the Japan Council for Quality Health Care Project to Collect and Analyze Medical Near-Miss/Adverse Event Information website.(Note 2)

(Note 1) Details of the individual incidents are available on the Project to Collect and Analyze Pharmaceutical Near-Miss Information website. Click the "public data search" button and enter the case number to browse.
(Note 2) See the Japan Council for Quality Health Care Project to Collect and Analyze Medical Near-Miss/Adverse Event Information website (http://www.med-safe.jp/).

Case 2: a near-miss event involving mix-up of oral medications (Case No. 000000000006)

Details of the incident
Instead of lactose, magnesium oxide was added as an excipient to Rise Granules 10%.
Background/cause of the incident
The weighed and pre-packed medication was not inspected for its contents.
Improvement measures proposed by the pharmacy
Drugs should be inspected by a person other than the one who prepared them. Verifications should be performed by two or more pharmacists. Dispensed drugs and dispensing processes should be checked for their correctness.

Other information
None

The point of the case
● Errors in dispensing of powder medications are difficult to find. ● A specific verification system for powder medications should be used. If such a system is not available, thorough checking at the time of dispensing should be ensured.

Case 3: a near-miss event involving an error in drug release and patient misidentification (Case No. 000000000041)

Details of the incident
The name of Patient A was called but Patient B came to the drug release counter. The drug was dispensed without checking the patient's name. Patient A and Patient B were on the same medications. The patient misidentification was found because Patient A was still in the waiting room.
Background/cause of the incident
The pharmacy was busy because it was before Golden Week. The pharmacist rushed to dispense drugs to the waiting patients. The error occurred probably because the pharmacist neglected to check the patient's name.
Improvement measures proposed by the pharmacy
Patients' names must be checked again at the drug release counter.

Other information
None

The point of the case
● Checking the patient's name at the pharmacy may be difficult because the family of the patient may come to pick up the medication. Distributing numbered tags to patients who come to fill their prescriptions to check their identifications later may be effective for prevention of patient misidentification.

Case 4: a near-miss event involving an inquiry about change of dose (Case No. 000000000147)

Details of the incident
The patient received the prescription of one 5-mg tablet + two 1-mg tablets at the first visit after his discharge from the special hospital. The pre-admission prescription was 5 mg × 0.5 tablet. An inquiry was made because it was a sudden dose increase. The hospital replied through the reception that the prescription was unchanged from the one issued at the previous hospital and therefore correct. The drug was prepared but other pharmacist assumed 5 mg had been misread as 0.5 mg. Another inquiry was directly made to the physician. The prescribed 5 mg × 0.5 tablet had been prepared as 0.5 mg × 1 tablet and 1 mg × 2 tablets for the convenience of the hospital.
Background/cause of the incident
1) The pharmacist was convinced because he/she had made an inquiry even though some doubts remained. 2) The rule to directly make inquiries to physicians was not thoroughly followed.
Improvement measures proposed by the pharmacy
Avoid making inquiries through hospital receptions as much as possible. Ensure documentation of medication records in medication notebooks. *The information on the patient's medication was not thoroughly communicated to the former and the current hospitals. (The patient was discharged with the medications prescribed during his hospitalization. The details of the medications were not provided in the patient information sheet given to the current hospital, however, and the pharmacy had to rely on the information provided by the patient alone.)

Other information
Prescribed drug: Warfarin Tablets 5 mg

The point of the case
● Special cautions need to be exercised since errors involving warfarin may result in serious accidents. ● Warfarin Tablets have multiple strengths, e.g., 0.5 mg, 1 mg and 5 mg, which may possibly result in prescription or dispensing of Warfarin with a wrong strength. Make specific inquiries, e.g., "the prescribed quantity seems to be too much."

Case 5: a near-miss event involving mix-up of oral medications (Case No. 000000000175)

Details of the incident
Adrenal hormone was almost dispensed by mistake instead of hypotensive.
Background/cause of the incident
The two types of drugs were stored on the same shelf side by side.
Improvement measures proposed by the pharmacy
The drugs are now stored separately

Other information
Prescribed drug: Preran 1 mg Tablets Mixed-up drug: Prelon Tablets 1 mg

The point of the case
● An ACE inhibitor Preran 1 mg Tablets were mixed up with a synthetic adrenal hormone Prelon Tablets 1 mg. The drug names were quite similar. ● Separate handling procedures for general drugs and high-risk drugs, storing drugs according to their efficacies and placing warning labels against similar drug names are desired.

Case 6: a near-miss event involving an inquiry on change of drug (Case No. 000000000293)

Details of the incident
The prescription for the female patient included Urief (4). An inquiry was made to the physician since the drug was not intended for female patients. Urief should have been Urinorm (50). The physician wrote "Urinorm (50)" in the patient's medical chart. There must have been a data entry error when the prescription was prepared.
Background/cause of the incident
Was the prescribing hospital busy? We don't know.
Improvement measures proposed by the pharmacy
Ensure a thorough checking system for prescription data entry and verifications, e.g., double-checking, at the medical institution as well as at the pharmacy.

Other information
None

The point of the case
● The prescription error made by the physician was found at the pharmacy. It was possibly an error in spelling of the drug name or in drug selection from the prescription drug master files due to the similar drug names. A checking system for in-house prescriptions at the time of issuing extramural prescriptions, a prescription system to select drugs from the prescription drug master files prepared separately for different efficacies and warning labels against similar drug names are desired.

Case 7: an inquiry involving mix-up of oral medications (Case No. 000000000308)

Details of the incident
Urief was prepared instead of Urinorm.
Background/cause of the incident
The drug was prepared based on the pharmacist's assumption.
Improvement measures proposed by the pharmacy
Drug names should be read to the last letter.

Other information
None

The point of the case
● The pharmacist mixed up the drugs at the time of dispensing. Urinorm Tablets 50 mg and Urief Tablets 4 mg are both powerful drugs. Storage of drugs according to their efficacies and warning labels against similar names are also desired for powerful drugs. Currently Urief 2 mg and 4 mg are being switched from capsules to tablets. Pharmacists should keep in mind Urief Capsules and Urief Tablets are both available now.

Case 8: a near-miss event involving a wrong strength/dosage form of oral medication (Case No. 000000000330)

Details of the incident
Mevalotin 10 mg was prepared instead of Mevalotin 5 mg. The error was overlooked during the verification, and Mevalotin 10 mg was dispensed. The error was found when the patient called the pharmacy. The dispensed drug was exchanged, and the pharmacy apologized to the patient.
Background/cause of the incident
The drug dispensing/verification error occurred because the pharmacy had almost always been releasing Mevalotin 10 mg. Mevalotin 10 mg and 5 mg were stored one above the other.
Improvement measures proposed by the pharmacy
A comment to use precautions was entered into the receipt processing computer and the medication record. The arrangement of the drug shelves was changed.

Other information
None

The point of the case
● People tend to be pulled toward usualness and frequentness. An “assumption” leads to errors because not all information is checked. Errors become frequent as we rush. Even experienced people can make errors. Verifications should be performed with these facts in mind.

Case 9: a near-miss event involving a wrong strength/dosage form of external medication (Case No. 000000000342)

Details of the incident
Dermovate Ointment was prepared instead of Dermovate Cream.
Background/cause of the incident
No data
Improvement measures proposed by the pharmacy
No data

Other information
None

The point of the case
● Drug mix-up may be caused due to similar appearances or names of drugs. Multiple strengths or dosage forms of the same drug may also cause a mix-up. Drug mix-up due to similar appearances can be prevented by storing the drugs on separate shelves. Other types of mix-up can be decreased by always reading prescriptions carefully.

Case 10: a near-miss event involving a wrong strength/dosage form of injection (Case No. 000000000377)

Details of the incident
The patient had been using Humalog Mix 25 Kit, but the drug was switched to MirioPen. The change was overlooked, and Kit was dispensed. The error was found by other pharmacist during the inventory check on the next day. The patient was contacted immediately. He came to the pharmacy to change the Kit to MirioPen. The pharmacy apologized and explained how to use MirioPen to the patient.
Background/cause of the incident
(The error was caused by) the pharmacist's assumption based on the long-term use of Kit by the patient. The hospital did not notify the pharmacy that Kit had been replaced with MirioPen in the formulary.
Improvement measures proposed by the pharmacy
Prescriptions should be checked without assumption.

Other information
None

The point of the case
● People tend to make assumptions based on what has been going on. Physicians should be reminded of the human nature and provide information clearly with emphasis when prescriptions are changed so that pharmacists will not have to make inquiries without knowing whether it is a prescription error or a prescription change.

Case 11: a near-miss event involving an error in verification of prescription of oral medication (Case No. 000000000569)

Details of the incident
The prescription for a patient with glaucoma had been changed but not all the staff at the pharmacy knew it.
Background/cause of the incident
The medication record had a tag indicating the patient had glaucoma; however, the tag was overlooked. The prescription change had not been properly recorded, and not all the pharmacists knew about the change.
Improvement measures proposed by the pharmacy
Ensure medication recording. Raise awareness.

Other information
Related drug: Myslee Tablets 10 mg

The point of the case
● Many drugs are contraindicated for treatment of glaucoma and prostate hypertrophy. Many patients do not know what type of glaucoma they have. Medication management based on patient interviews at the pharmacy is important. The condition of the patient may have to be checked with the physician in some cases. When checking the concomitant drugs the patient should be interviewed about his current oral medications as well as all other drugs he/she is using and all health foods he/she is eating.

Case 12: a near-miss event involving a wrong strength/dosage form of oral medication (Case No. 000000000645)

Details of the incident
The patient who had already filled his prescription came to the pharmacy and said, "This is not what I have been taking."
Background/cause of the incident
The product had a two-dimensional bar code, which is read to enter the prescription data. No one remembered the tablets had been switched to the combination tablets. Changed prescriptions are to be highlighted when the data are entered manually; however, the highlighted information was overlooked. The patient came to the pharmacy to receive medication guidance three days later. The pharmacist was distracted because he/she needed to contact the physician about the poultice prescribed to the patient, which was different from what the patient wanted.
Improvement measures proposed by the pharmacy
Manually entered data and data added after reading bar codes should be highlighted to raise caution. Strengths should be circled with a blue pen to raise caution about wrong strengths during data verification. If the current prescription is different from the previous one, enter an "S" for a newly prescribed drug and a "D" for an unchanged drug. Provide comments as well.

Other information
Prescribed drug: Eviprostat Combination Tablets DB Mixed-up drug: Eviprostat Tablets

The point of the case
● In July 2008, Eviprostat Combination Tablets DB went on sale and Eviprostat Tablets changed its name to Eviprostat Combination Tablets SG. Many drugs have lately changed their names to increase medical safety. However, not knowing about the change of drug names may result in drug dispensing errors. Pharmacies should make sure to obtain the latest information and share this among staff members.

Case 13: a near-miss event involving a wrong strength/dosage form of oral medication (Case No. 000000000646)

Details of the incident
The prescription was changed from warfarin 1 mg × 0.5 tablet to warfarin 0.5 mg × 1.5 tablet; however, warfarin 1 mg × 1.5 tablet was prepared.
Background/cause of the incident
The warfarin dose increase was not thoroughly confirmed during the conversation with the patient, and the drug was prepared based on the pharmacist's assumption.
Improvement measures proposed by the pharmacy
Place a reminder for repeated checking on the warfarin drawer.

Other information
None

The point of the case
● Prescriptions of Warfarin need special precautions since warfarin overdose may result in death. Warfarin dose may be changed frequently, and the strength or the dosage form may also be changed. Warfarin potassium, the nonproprietary name of Warfarin, has multiple strengths such as 0.5 mg tablets, 1 mg tablets, 2 mg tablets, 5 mg tablets and fine granule 0.2%. Which strength to use is at the discretion of individual medical institutions? Prescriptions should be carefully read when dispensing warfarin. Drug mix-up can be prevented by changing the shelf arrangement or by placing reminders. Early detection of errors based on frequent inventory checking is also necessary.

Case 14: a near-miss event involving an inquiry about a change of drug (Case No. 000000000689)

Details of the incident
The patient came to the pharmacy with the prescription, which included Aspara-CA (prescribed for the first time). Asked how the physician described the newly prescribed drug, the patient said, "He did not say calcium would be added to my prescription." An inquiry was made. Aspara-CA should have been Aspara Potassium Tablets.
Background/cause of the incident
The patient had been taking Slow-K. Aspara Potassium was to be added to his prescription. The pharmacist should have guessed Aspara CA may have been mixed up with Aspara Potassium during the verification and checked with the patient. Although additional Aspara CA was unexpected based on the patient's medication record, the pharmacist casually thought the drug was prescribed for a newly diagnosed disorder.
Improvement measures proposed by the pharmacy
When a prescription is changed and questions arise, the pharmacist should always check with the patient to see if the explanation he received from the physician is consistent with the prescription. Inquiries should be made when any inconsistency is found.

Other information
None

The point of the case
● Physicians may confuse drug names when writing prescriptions because some drugs have similar names or efficacies. The intention of the physician, which is unclear based on the prescription, may be understood after talking to the patient. Potential health hazards may be prevented by making inquiries if any questions arise while talking to the patient or checking the medication record.

Case 15: a near-miss event involving drug release (categorized as "Others") (Case No. 000000000788)

Details of the incident
A clerk entered Biofermin R (powder) instead of Biofermin R Tablets into the receipt processing computer by mistake. The pharmacist dispensed Biofermin R Tablets as prescribed. However, the medication bag said Biofermin R (powder), which was given to the patient together with the information sheet for Biofermin R (powder) because the pharmacist did not know about the data entry error.
Background/cause of the incident
The new clerk had been in the office for less than a month. The pharmacist dispensed the drug without checking the drug dispensing record, the information sheet or the medication bag. The clerk did not know there were two types of Biofermin R and different dosage forms for children and adults. The name Biofermin R is confusing. It should be changed to Biofermin R Powder or Biofermin R Fine Granule.
Improvement measures proposed by the pharmacy
Thorough pre-release check of drug dispensing records will be ensured. The clerk received information on the strengths of Biofermin.

Other information
None

The point of the case
● It was an error in entering the dosage form into the computer. In the Japan Council for Quality Health Care Hospital Accreditation(Note) process, availability of a system in which physicians check data entered by non-physicians is evaluated. Pharmacies should also have a similar system in which pharmacists check data entered by clerks to ensure consistencies of entered data and contents of prescriptions. ● Other incidents involving errors in entering a drug strength or a patient's name in the computer were reported. • The prescription for Patient A was entered into the receipt processing computer as that for Patient B who has the same family name. (Case No, 000000000766) • The quantity of the drug substance (5 mg, or 1 g as the quantity in the prepared medication) was entered as the quantity of prepared medication, and the drug information sheet containing the wrong information was given to the patient. (Case No. 000000000770)

(Note) See the Japan Council for Quality Health Care website (http://www.jcqhc.or.jp/).

Case 16: a near-miss event involving mix-up of oral medications (Case No. 000000000820)

Details of the incident
In October a prescription was received through fax. Acarbose Tablets had been switched from Glucobay Tablets and dispensed until the previous prescription; however, a clerk found the current prescription said, "No generics" when he/she entered the data into the computer. The clerk asked the pharmacist if the current prescription was correct. The pharmacist thought the current prescription had some error because the patient had been requesting generics. However, he/she checked the past prescriptions to make sure. The past prescriptions had allowed generics until July but disallowed generics after that. Glucobay Tablets were prescribed in July and September; however, Acarbose Tablets (generic) were dispensed both times because the instruction not to use generics was overlooked. Since the patient had been requesting generics, the pharmacy made an inquiry to the medical institution, asking if there had been an error in the instructions. The medical institution replied the prescription had been changed to disallow generics since July because the patient's condition had been aggravated.
Background/cause of the incident
Calculation, drug dispensing and verification had been performed without checking the instructions not to use generics in the prescription because the generic had been dispensed for months upon the request of the patient.
Improvement measures proposed by the pharmacy
Once an original drug is switched to a generic, pharmacists tend to assume generics are also allowed in later prescriptions and neglect to check the prescriptions. When preparing generics, the prescriptions should be checked by both a clerk and a pharmacist to see if generics are allowed.

Other information
None

The point of the case
● A generic was prepared because the pharmacy did not realize the prescription allowing generics had been changed to one disallowing generics. In most cases original drugs are switched to generics. Pharmacists should keep in mind that switching back to the original drug (disallowing generics) is rare but possible in some cases depending on the patient's condition. The name of the physician is usually printed in the section indicating generics are disallowed but his/her seal may be missing. The signature section is in the bottom of the prescription, which should be considered as one of the important check items during prescription verifications.

Case 17: a near-miss event involving an inquiry about a change of drug (Case No. 000000000911)

Details of the incident
The prescription for cold medication included a hypolipidemic. The product name was Meban, and no titer information was available. The pharmacist suspected it should have been Banan Tablets and made an inquiry. It turned out the drug should have been antibiotic Banan Tablets.
Background/cause of the incident
The prescription was handwritten by the physician who made an error based on his assumption. Errors such as drug mix-up due to similar names and omission of drug strengths have occurred, and there was no checking procedure for prescriptions prepared by physicians.
Improvement measures proposed by the pharmacy
A computer system should be introduced. Review the in-house procedure and include a checking procedure. If a computer system cannot be introduced, the physician should memorize drug strengths as part of drug names.

Other information
None

The point of the case
● It was a drug selection error due to similar drug names, which was caused by the absence of the efficacies and strength of the concomitant drugs in the prescription. While ordering systems usually have a function to prevent errors in selection of prescribed drugs (e.g., requirement to enter at least the first three letters of the drug name), receipt processing computers may not have such a function. Data are entered into the computer by clerks at some hospitals. Whether the traditional warning system for physicians is adequate is now being discussed. Pharmacists should keep in mind that errors in selection of prescribed drugs may occur in prescriptions printed out from computer systems and make inquiries as necessary.

Case 18: a near-miss event involving an inquiry about change of drug (Case No. 000000001012)

Details of the incident
The patient sought treatment for recurrent cystitis and received a prescription. Meiact had been prescribed before but switched to Cravit due to drug eruption. The medication record was overlooked, and Meiact was prescribed again. An inquiry was made, and Meiact was changed to Cravit.
Background/cause of the incident
Meiact had been prescribed by one physician and switched to Cravit by other physician. The error occurred probably because the physicians had prepared the prescriptions in different manners.
Improvement measures proposed by the pharmacy
An environment to thoroughly share and use information should be reestablished, e.g., uniform requirements for prescription contents should be established.

Other information
None

The point of the case
● The medication record containing the patient information, which is one of the advantages of separation of drug release and prescribing functions, could have been used to prevent health hazards. Accumulation of incidents such as this reminds us it is important for patients to have their pharmacy and pharmacist.

Case 19: a near-miss event involving an inquiry about change of drug (Case No. 000000001044)

Details of the incident
The prescription brought by ShimoXX (male) was the prescription for ShimoYY (female). The prescription misidentification was found because the medication notebook submitted with the prescription was of ShimoXX. The hospital misidentified the patient and issued the prescription by mistake.
Background/cause of the incident
The family names of the patients both started with "Shimo." The patients were around the same age. Although patients see their physicians themselves, they may not go to hospital receptions, prescription counters or pharmacies. Often the family of the patient picks up medications, and the patient cannot be identified based on the sex alone.
Improvement measures proposed by the pharmacy
Prescriptions should always be cross-checked with medication notebooks or health insurance cards at pharmacies. Improvement measures that had been taken at the hospital were unknown; however, the error was notified to the hospital.

Other information
[Cause of the incident] The prescription check was neglected. The pharmacy was busy. The patient was partially responsible. Education, training and rules were inadequate.

The point of the case
● The incident is similar to the one reported last year in which the patient received and took the medication prepared for another patient at the insurance pharmacy, fell unconscious and was hospitalized. Inadequate education and training of hospital staff was included as one of the causes of the incident; however, the error should have been prevented at the pharmacy.

Case 20: a near-miss event involving an error in filling the cassette of oral medications and oral medication management (Case No. 000000001047)

Details of the incident
One dose packets were prepared using a tablet packaging machine. Amaryl Tablets 3 mg was being packed. During the process the cassette of Amaryl Tablets 3 mg was filled with Amaryl Tablets 1 mg, and the packing was continued. The packets were only checked for the quantity of contents, and the packing error was unnoticed. Next day Amaryl Tablets 1 mg were found in the cassette of Amaryl Tablets 3 mg. Amaryl Tablets 1 mg were packed in six of 42 packets.
Background/cause of the incident
The error occurred during the busy hours. The name of the drug, the quantity and the name of the pharmacist who filled the cassette are usually recorded but was neglected because the pharmacy was busy. The post-packing verification failed to identify the error although the inspecting pharmacist intended to check the packets for wrong contents.
Improvement measures proposed by the pharmacy
When filling the tablet packaging machine in the middle of the packing procedure, place the empty package sheet on the tray to make sure what drug is being packed.

Other information
None

The point of the case
● It was an incident involving a tablet packaging machine. Amaryl Tablets 1 mg and Amaryl Tablets 3 mg are quite different in size and color. The inadequate final verification of the drug requiring priority management is a considerable problem. Improvement measures should include correction of potential problems at the time of packing and final verifications. While tablet packaging machines shorten drug dispensing time, they are associated with certain packing errors and cassette defects. Medical near-miss incidents will continue to occur unless thorough final verifications are ensured.

Case 21: a near-miss event involving mix-up of oral medications (Case No. 000000001178)

Details of the incident
Claritin Tablets 10 mg × 2 tablets × 15 days were prepared instead of Talion Tablets 10 mg × 2 tablets b.i.d. × 15 days.
Background/cause of the incident
The pharmacist performed picking while talking on the phone. He/she read the drug name "Talion" aloud but had Claritin in her hand. He/she knew the two drugs could easily be confused but still made the error because he/she neglected to check the prepared drug.
Improvement measures proposed by the pharmacy
Always perform self-verifications.

Other information
None

The point of the case
● The pharmacist prepared the drug while talking on the phone. The incident shows multitasking can make people careless and lead to people easily making errors. When a drug dispensing process is interrupted by other activities, the pharmacist should start the process all over again. ● Talion Tablets 10 mg and Claritin Tablets 10 mg come in similar package sheets and have the same efficacy and strength. Caution should be exercised to avoid confusion at the time of picking as well as packing. ● Drug mix-up was reported in other incidents. Drug mix-up can be effectively prevented by "reading aloud the drug name written in the prescription and in the package sheet," "placing cassettes as far away from the drug shelves as possible" and "placing a warning against confusion with other strength/dosage form."

Case 22: a near-miss event involving a wrong quantity of oral medication (Case No. 000000001200)

Details of the incident
Altat Capsules 75 were prepared in the wrong quantity.
Background/cause of the incident
It was a drug dispensing error made by a pharmacist who was sick.
Improvement measures proposed by the pharmacy
Pharmacists should be careful when they are sick and have to prepare drugs. They should avoid preparing drugs when they are sick, if possible.

Other information
None

The point of the case
● The pharmacist was sick and made a calculation error when preparing capsules. In other reported incidents involving a wrong quantity of tablets, capsules, packets or solution, the pharmacist "thought he/she took out the right drug," "thought it was correct," "was multitasking" or "thought it was the right drug." Pharmacists should be more careful when preparing drugs or have other pharmacist take over their duty when they are sick. ● Errors can be prevented by "taking calculation memos of the quantity specified in the prescription and reading aloud the quantity during picking," "performing a verification after a certain interval if the pharmacist needs to prepare and inspect the drug alone" and "counting the number of package sheets to check the entire quantity." Keeping these things in mind will help pharmacists prevent errors in their daily practice.

Case 23: a near-miss event involving an inquiry about change of quantity (Case No. 000000001280)

Details of the incident
Regarding the usage of Warfarin Tablets 1 mg, the intention of the physician to use Warfarin 8 mg on Day 1 and 2 mg on the following days was known after making an inquiry. Warfarin 8 mg was to be used on the following days according to the pre-inquiry prescription.
Background/cause of the incident
It was an error in data entry into the electronic medical chart.
Improvement measures proposed by the pharmacy
Errors should be corrected after making inquiries.

Other information
None

The point of the case
● It was an error in data entry into the electronic medical chart. Overdose was prevented by the pharmacist who made an inquiry about the quantity. Warfarin is one of the "drugs especially requiring safety management" according to the "Operating Procedure for Safe Drug Use." Promptly making inquiries to prescribing physicians whenever pharmacists have any questions about Warfarin prescriptions to prevent an overdose is one of the measures to prevent accidents such as the one reported in this incident.

Case 24: a near-miss event involving an inquiry about deletion of a drug (Case No. 000000001399)

Details of the incident
PL Combination Granules was prescribed to the patient treated for glaucoma. The drug was deleted after making an inquiry.
Background/cause of the incident
The drug was prepared and inspected without checking the prescription and almost dispensed to the patient. The contraindicated drug check was inadequate. Checking of the medication record and the patient profile was neglected.
Improvement measures proposed by the pharmacy
Medication records and patient profiles should be thoroughly checked when preparing additional drugs, which should be dispensed after confirming they are safe to use in the patient.

Other information
None

The point of the case
● The medication record and the information on contraindicated drugs were used to prevent health hazards. The incident shows one of the advantages of separation of release and prescribing functions. Checking the "medication notebook" and interviewing the patient may help pharmacists confirm the contents of prescription, understand the medication history and current oral medications prescribed at other medical institutions and prevent possible health hazards as in this incident.

Document 2: Information to be collected

[I. Basic information]

Year of occurrence	(Numerical data: ☐ years)

Month of occurrence

☐ January ☐ February ☐ March ☐ April ☐ May ☐ June
☐ July ☐ August ☐ September ☐ October ☐ November ☐ December

Day of occurrence

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday ☐ Saturday

Time of occurrence

☐ 0:00 – 1:59 ☐ 2:00 – 3:59 ☐ 4:00 – 5:59
☐ 6:00 – 7:59 ☐ 8:00 – 9:59 ☐ 10:00 – 11:59
☐ 12:00 – 13:59 ☐ 14:00 – 15:59 ☐ 16:00 – 17:59
☐ 18:00 – 19:59 ☐ 20:00 – 21:59 ☐ 22:00 – 23:59
☐ Unknown

Whether the drug was dispensed and extent of treatment	
• Dispensed	☐ Not dispensed
☐ Minor treatment ☐ No treatment ☐ Unknown	

Summary of the incident

☐ Drug dispensing → Go to [1. Drug dispensing]
☐ Inquiry → Go to [2. Inquiry]
☐ Designated insured medical material → Go to [3. Designated insured medical material]
☐ Drug sales → Go to [4. Drug sales]

Number of patients

☐ One
Age ☐ years
Sex ☐ Male ☐ Female
☐ Two or more

First person to find the error

☐ Person who made the error ☐ Coworker with the same job description ☐ Coworker with a different job description ☐ Patient ☐ Family/caregiver
☐ Other patient ☐ Others ( )

Person who made the error (number of persons)

Pharmacist ( ) Registered distributor ( ) Clerk ( )
Others: job description ( ) ( )

[1. Drug dispensing]

Situation	Specifics of incident	
Drug dispensing	**Drug dispensing**	
☐ Dispensing of oral medication ☐ Dispensing of external medication ☐ Dispensing of injection ☐ Others	☐ Failure to dispense ☐ Error in weighing ☐ Error in filling the cassette ☐ Drug mix-up ☐ Wrong information on package sheet ☐ Others ( )	☐ Error in prescription check ☐ Wrong quantity ☐ Wrong strength/dosage form ☐ Mix-up of information sheet ☐ Providing wrong description on medication bag
Management	**Management**	
☐ Management of oral medication ☐ Management of external medication ☐ Management of injection ☐ Others	☐ Error in filling the cassette ☐ Expiration	☐ Contamination with foreign object ☐ Others ( )
Drug release	**Drug release**	
☐ Drug release	☐ Patient misidentification ☐ Neglecting to dispense medication	☐ Providing wrong explanation ☐ Others ( )

(Drug information)

(i) Fill out the following sections if "Error in weighing," "Wrong strength/dosage form" or "Drug mix-up" under "Drug dispensing" was selected in "Summary of the incident."

Number of drugs involved	**Change** * To change the number of drugs involved, enter the correct number and press the "Change" button.

Prescribed drug		**Mixed-up drug**	
MHLW code		MHLW code	
Product name		Product name	
Marketing approval holder		Marketing approval holder	

(ii) Fill out the following sections if an item other than "Error in weighing," "Wrong strength/dosage form" or "Drug mix-up" under "Drug dispensing" was selected in "Summary of the incident."

Number of drugs involved	**Change** * To change the number of drugs involved, enter the correct number and press the "Change" button.

Related drug	
MHLW code	
Product name	
Marketing approval holder	

[2. Inquiry about prescription]

Possible effect on the patient if the drug had been taken as instructed in the original prescription
☐ Health hazards may have occurred. ☐ No health hazards would have occurred but the efficacy intended by the physician would not be expected.

Reason for making the inquiry
☐ Based on the prescription alone ☐ Based on the prescription and the information available at the pharmacy ☐ Others (ex. a claim filed by the patient)

Specifics of change			
☐ Change of drug	☐ Change of usage	☐ Change of dose	☐ Change of quantity
☐ Deletion of drug	☐ Others (	)	

(Drug information)

Number of drugs involved	**Change** * To change the number of drugs involved, enter the correct number and press the "Change" button.

Prescribed drug		**Changed drug**	
MHLW code		MHLW code	
Product name		Product name	
Marketing approval holder		Marketing approval holder	

[3. Designated insured medical material]

Situation	Specifics of near-miss event	
Drug dispensing	**Drug dispensing**	
☐ Drug dispensing	☐ Failure to dispense ☐ Wrong quantity ☐ Mix-up of information sheet ☐ Others ( )	☐ Error in prescription check ☐ Wrong strength ☐ Material mix-up
Management	**Management**	
☐ Management	☐ Expiration	☐ Others ( )
Drug release	**Drug release**	
☐ Drug release	☐ Patient misidentification ☐ Neglecting to dispense medication	☐ Providing wrong explanation ☐ Others ( )

(Designated insured medical material)

(i) Fill out the following sections if "Wrong strength" or "Material mix-up" under "Drug dispensing" was selected in "Summary of the incident."

Designated insured medical materials involved	[ ] **Change** * To change the number of designated insured medical materials involved, enter the correct number and press the "Change" button.

Prescribed designated insured medical material		Mixed-up designated insured medical material	
MHLW code		MHLW code	
Product name		Product name	
Marketing approval holder		Marketing approval holder	

(ii) Fill out the following sections if the item other than "Wrong strength" or "Material mix-up" under "Drug dispensing" was selected in "Summary of the incident."

Designated insured medical materials involved	[ ] Change * To change the number of designated insured medical materials involved, enter the correct number and press the "Change" button.

Related designated insured medical material	
MHLW code	
Product name	
Marketing approval holder	

[4. Drug sales]

Specifics of the incident		
☐ Wrong product	☐ Providing wrong information	☐ Expiration
☐ Others ( )		

(Drug information)

Number of drugs involved	**Change** * To change the number of drugs involved, enter the correct number and press the "Change" button.

Related drug

MHLW code	
Product name	
Marketing approval holder	

○ Classification

☐ Ethical drug	☐ First-class OTC drug
☐ Designated second-class OTC drug	☐ Second-class OTC drug
☐ Third-class OTC drug	

[II. Information on cause of incident]

Cause of the incident (multiple answers acceptable)

[Related to the behavior of the person who made the error]

☐ Neglecting to check
☐ Delayed (neglect of) reporting(Note 1)
☐ Incomplete recording
☐ Lack of coordination(Note 2)
☐ Inadequate (neglect of) explanation to the patient
☐ Misjudgment

[Background/system/environmental factor]

Human factor

☐ Lack of knowledge
☐ Inadequate skills
☐ Busy hours
☐ Unusual physical conditions
☐ Unusual psychological conditions
☐ Others ( )

Environmental/equipment

☐ Computer system(Note 3)
☐ Drugs(Note 4)
☐ Facilities/utilities(Note 5)
☐ Articles
☐ Patient factor(Note 6)
☐ Others ( )

☐ Education/training
☐ Scheme(Note 7)
☐ Flaw in the rules
☐ Others ( )

Note 1: Reporting refers to communication within the institution.
Note 2: Coordination refers to communication between multiple institutions.
Note 3: Computer system refers to a receipt processing computer or an inventory management system.
Note 4: Drugs include similar drug names and appearances
Note 5: Facilities/utilities include placement of drugs on the shelves.
Note 6: Patient factor includes similar appearance and names of patients.
Note 7: Scheme refers to an operation-related scheme such as an operation flow.

[III. Text information]

Information on the medical near-miss incident (required)

Specifics of the incident

Information on the medical near-miss incident (optional)

Background/cause

Improvement measures

Document 3: Pharmaceutical near-miss event analysis table

Pharmaceutical near-miss event analysis tables can be seen in color at the Project to Collect and Analyze Pharmaceutical Near-Miss Information website.

Project to Collect and Analyze Pharmaceutical
Near-Miss Event Information 2009 Annual Report, No. 1

Drug mix-up due to similar product name

Of the reported pharmaceutical near-miss events occurred at pharmacies, 181 near-miss events involved "drug mix-up." (Data collected from April 1 to December 31, 2009)
Of 171 incidents analyzed, 41 near-miss events involved drugs with at least the first two letters of the names were identical.
The drugs reported in the near-miss events involving similar drug names and their efficacies are presented in the following table.

(Drug names)

Prescribed drug	Major efficacy	Mixed-up drug	Major efficacy
Asverin Tablets 20	Anti-tussive/ expectorant	Astomin Tablets 10 mg	Anti-tussive
Cravit Tablets	Synthetic antibacterial	Klaricid Tablets 200 mg	Having a primary action against gram-positive bacteria and mycoplasma
Primobolan Tablets 5 mg	Anabolic steroid	Primperan Tablets 5	Other agent for digestive organs
Preran Tablets 1 mg	Hypotensive	Prelon Tablets 1 mg	Adrenal hormone
Mucodyne Tablets 500 mg	Expectorant	Mucosta Tablets 100 mg	Peptic ulcer treatment
Urinorm Tablets 25 mg	Gout treatment	Urief Tablets 4 mg	Other agent for urogenital and anal organs
Slow-K Tablets 600 mg	Mineral preparation (other mineral preparation)	Slow-Fe Tablets 50 mg	Mineral preparation (iron compound including organic iron oxide)
Tarivid Ophthalmic Ointment 0.3%	Agent for ophthalmic use	Tarivid Otic Solution 0.3%	Agent for otic and nasal use
Neurotropin Tablets 4 Units	Antipyretic/ analgesic/ antiphlogistic	Neuropitan Tablets	Multiple vitamins (not including vitamin A/D combination)

*Excerpted from Project to Collect and Analyze Pharmaceutical Near-Miss Event Information 2009 Annual Report, page 39-40

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Project to Collect and Analyze Pharmaceutical
Near-Miss Event Information 2009 Annual Report, No. 2

Pharmaceutical near-miss events related to high-risk drugs

Of the pharmaceutical near-miss events occurred at pharmacies, 317 near-miss events (16.1% of all reported near-miss events involving ethical drugs) involved drugs requiring safety management (high-risk drugs). (Data collected from April 1 to December 31, 2009) The product names of reported high-risk drugs and their efficacies are presented in the following table.

(Most frequently reported drugs)

Product name	Major efficacy	Product name	Major efficacy
Actos Tablets	Antidiabetic	NovoRapid	Pancreatic hormone
Amaryl	Antidiabetic	Novolin 30R	Pancreatic hormone
Amoxan Capsules	Psychoneurotic agent	Novolin R	Pancreatic hormone
Contomin Sugar-Coated Tablets	Psychoneurotic agent	Paxil Tablets	Psychoneurotic agent
Jzoloft Tablets	Psychoneurotic agent	Humalog Mix 25	Pancreatic hormone
Zyprexa Zydis Tablets	Psychoneurotic agent	Hirudoid Lotion	Anticoagulant
Zyprexa Tablets	Psychoneurotic agent	Predonin Tablets	Immunosuppressant
Starsis Tablets	Antidiabetic	Basen OD	Antidiabetic
Seibule Tablets	Antidiabetic	Voglibose Tablets	Antidiabetic
Celestamine Syrup	Immunosuppressant	Mexitil Capsules	Antiarrhythmic
Seroquel Tablets	Psychoneurotic agent	Medet Tablets	Antidiabetic
Theodur Tablets	Theophylline	UFT Combination Capsules	Anticancer drug
Tetramide Tablets	Psychoneurotic agent	Lanirapid Tablets	Digitalis
Depakene-R Tablets	Antiepileptic	Risperdal Tablets	Psychoneurotic agent
Depas Tablets	Psychoneurotic agent	Risperdal Oral Solution	Psychoneurotic agent
NovoRapid 30 Mix	Pancreatic hormone	Warfarin Tablets	Anticoagulant

*Excerpted from Project to Collect and Analyze Pharmaceutical Near-Miss Information 2009 Annual Report, page 50

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Project to Collect and Analyze Pharmaceutical
Near-Miss Event Information 2009 Annual Report, No. 3

Pharmaceutical near-miss events related to inquiry by pharmacy

Of the pharmaceutical near-miss events occurred at pharmacies, 107 near-miss events involved "inquiries." (Data collected from April 1 to December 31, 2009)
"Specifics of change" made after inquiries are shown in the left column, and "reasons for making inquiries" are shown in the top row of the following table. Red cells indicate the most frequently reported specifics of changes under each of the "reasons for making inquiries."

Reason for making inquiry / Specifics of change	Based on the prescription alone	Based on the prescription and information available at the pharmacy	Others
Change of drug	13	14	9
Change of usage	8	4	3
Change of dose	8	4	4
Change of quantity	13	3	0
Deletion of drug	2	9	2
Others	1	3	7

*Excerpted from Project to Collect and Analyze Pharmaceutical Near-Miss Event Information 2009 Annual Report, page 53

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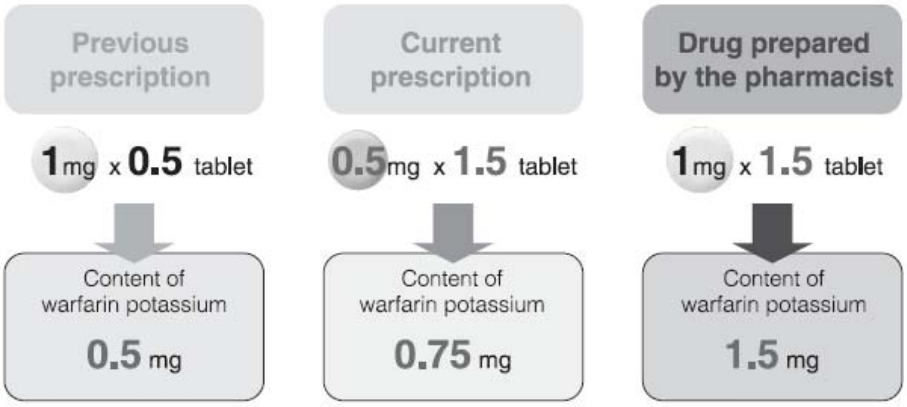
Project to Collect and Analyze Pharmaceutical
Near-Miss Event Information 2009 Annual Report, No. 4

Pharmaceutical near-miss events related to warfarin potassium

Of the pharmaceutical near-miss events occurred at pharmacies, 19 near-miss events involved a high-risk drug warfarin potassium. (Data collected from April 1 to December 31, 2009)
Two near-miss events involved errors due to multiple specifications.

Near miss event

The prescription was switched from Warfarin Tablet 1 mg x 0.5 tablet to Warfarin Tablets 0.5 mg x 1.5 tablet. However, Warfarin Tablets 1 mg x 1.5 tablet were prepared.



*Excerpted from Project to Collect and Analyze Pharmaceutical Near-Miss Event Information 2009 Annual Report, page 62

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Project to Collect and Analyze Pharmaceutical
Near-Miss Event Information 2009 Annual Report, No. 5

Pharmaceutical near-miss events related to insulin

Of the pharmaceutical near-miss events occurred at pharmacies, 27 near-miss events involved a high-risk drug insulin. (Data collected from April 1 to December 31, 2009)
Fourteen near-miss events (51.9% of all reported near-miss events involving insulin) involved errors due to "wrong strength/dosage form" or "drug mix-up."
The product names reported in the near-miss events involving "wrong strength/dosage form" or "drug mix-up," whether the drug was dispensed(Note) and number of reports are shown in the following table.

(Drug names)

Prescribed drug	Mixed-up drug	Number of reports
[Dispensed] 7 near-miss events		
PenFill R 300	PenFill 30R 300	2
InnoLet R	InnoLet 30R	1
NovoRapid 30 Mix FlexPen	NovoRapid FlexPen	1
Novolin R FlexPen	Novolin 30R FlexPen	1
Humalog Mix 25 MirioPen	Humalog Mix 25 Kit	1
Humalog Mix 25 MirioPen	Humalog MirioPen	1
[Not dispensed] 7 near-miss events		
NovoRapid FlexPen	NovoRapid 30 Mix FlexPen	2
NovoRapid 30 Mix PenFill	NovoRapid 30 Mix FlexPen	1
NovoRapid 300 FlexPen	NovoRapid 30 Mix FlexPen	1
Novolin R FlexPen	InnoLet R	1
Novolin R FlexPen	Novolin 30R FlexPen	1
Lantus SoloStar	Apidra Inj. SoloStar	1

Note: "Dispensed" means the drug was dispensed or sold.

*Excerpted from Project to Collect and Analyze Pharmaceutical Near-Miss Event Information 2009 Annual Report, page 67

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