Project to Collect Medical Near-Miss/Adverse Event Information

2005 Annual Report

August 9, 2006

Center for Medical Adverse Event Prevention

Japan Council for Quality Healthcare

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Foreword

Eitaka Tsuboi
President
Japan Council for Quality Healthcare

Japan Council for Quality Healthcare (JCQHC) has been carrying out various activities such as evaluation of medical services provided at hospitals in order to maintain public confidence in the healthcare service and improve its quality. Public awareness of medical safety promotion and medical adverse event prevention has recently been rising.

The JCQHC Center for Medical Adverse Event Prevention has been carrying out Project to Collect Medical Near-Miss/Adverse Event Information to prevent medical adverse events and promote medical safety. Collected information and data tabulation/analysis are compiled in periodic reports and published and distributed to medical professionals, the public, and administrative organizations once every 3 months in principle. The project is based on voluntary reports from medical institutions. The JCQHC would like to thank all cooperating medical institutions and relevant parties.

The 2005 annual report was prepared based on past reports. Numerous responses including inquiries for and publicities of numbers of medical adverse events and their details appeared in past reports indicate elevated social awareness of medical safety promotion and medical adverse event prevention. The JCQHC will enhance its efforts to enrich the contents of future reports and establish an environment for convenient case reporting in order to provide useful information to parties concerned through publication of the current report and periodic reports. Your suggestions for our future activities will be appreciated.

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

Issuing the 2005 Annual Report

Kikuo Nomoto
Director
Center for Medical Adverse Event Prevention
Japan Council for Quality Healthcare

The Center for Medical Adverse Event Prevention has published 5 periodic reports on medical adverse events reported by medical institutions in Project to Collect Medical Near-Miss/Adverse Event Information, started in October 2004. The project intends to prevent medical adverse events and promote medical safety. As a project developed based on legal grounds, it is considered quite important for medical safety promotion in Japan. I described that encouraging development of medical safety measures at medical institutions throughout Japan was the basic concept of carrying out the project in the preface of the first report. In order to do so, information feedback has been ensured and workshops in which many medical institutions could participate have been held. An effort has been made to establish an environment for easy case reporting since some institutions are required to report medical adverse events by law. Let alone ensuring confidentiality of personal information, reports have been prepared to include unidentifiable cases that could provide useful information to medical institutions. In light of being a third-party organization in a neutral position in the healthcare community, the JCQHC has been providing information to outside parties by collecting and analyzing data with an unbiased point of view.

The 2005 Annual Report is based on previous reports. The current report basically consists of the contents of previous reports and includes tabulation based on previously published reporting dates. However, tabulation of medical adverse events by date on which an event occurred or the occurrence of an event was noticed and additional data of registered participating medical institutions that voluntarily participate in the project are also included. Previous reports have raised public awareness, and numerous suggestions have been made by relevant parties as well as by the general public. Some medical institutions are referring to our reports in their daily practice. The current report will be useful as basic data for discussion of future medical safety in Japan.

The JCQHC will enhance its efforts to enrich the contents of project reports for medical adverse event prevention and medical safety promotion in Japan. Your understanding and cooperation is appreciated.

I. Outline of Project to Collect Medical Near-Miss/Adverse Event Information

1. Background of Medical Near-Miss/Adverse Event Information Collection

Background of Near-Miss Information Collection

The Ministry of Health, Labour and Welfare (MHLW) started "Network for Medical Safety Measures (Project to Collect Medical Near-Miss Information)" in October 2001 to analyze collected near-miss information and provide medical safety information and proposed preventive measures to parties concerned. In the initial project scheme, Organization for Pharmaceutical Safety and Research [OPSR; present Pharmaceuticals and Medical Devices Agency (PMDA)] collected medical near-miss information from participating medical institutions and reported to the MHLW of which study group was responsible for data tabulation and analysis. Medical near-miss information was collected in 10 surveys in the previous scheme, and the MHLW published tabulated data to provide information to parties concerned based on the collected near-miss information[Note 1].

JCQHC took over Project to Collect Medical Near-Miss Information from Organization for Pharmaceutical Safety and Research [OPSR; present Pharmaceuticals and Medical Devices Agency (PMDA)] in 2004 and has conducted the 11th and subsequent surveys since. Tabulated data and analyses are posted on JCQHC website[Note 2].

Background on the collecting of medical adverse event information

A Report on the "Comprehensive Promotion Measures for Medical Treatment Safety" [Note 3] was compiled and published in April 2002 by the Investigation Committee for Medical Treatment Safety Measures, a body established by the Ministry of Health, Labour and Welfare. Commenting on the governmental network service for medical treatment safety (a project to collect medical near-miss information) which began in October 2001, the report stated, "In analyzing such cases, there is a need to study the building of a system to collect even more accurate analytical and study results, as well as the results of analyzing and studying the improvement measures, from an even greater number of institutions." The report also touched on medical adverse event cases and, while introducing opinions that called for utilizing the collecting and analysis of such case examples and establishing a system for enforcing surveys and reports, it pointed out the need to conduct further studies that include legal issues associated with the reporting of medical malpractice.

(Note 1) See "Medical Near-Miss Information Collection/Analysis (Network for Medical Safety Measures)" on the MHLW website (http://www.mhlw.go.jp/topics/bukyoku/isci/j-anzen/jiko/index.html).

(Note 2) See "Project to Collect, Analyze, and Provide Medical Near-Miss/Adverse Event Information" on the JCQHC website (http://jcqhc.or.jp/html/accident.htm#med-safe).

(Note 3) Issues such as "safety measures at medical institutions," "improving safety of pharmaceuticals and medical devices," "education and training to enhance medical safety," and "establishing an environment to promote medical safety" were included in the proposals for "Comprehensive Measures to Promote Medical Safety."
See "Reports" in "Medical Safety Measures" page on the MHLW website (http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/houkoku/index.html).

The MHLW subsequently issued a ministerial ordinance to partially revise the enforcement regulations for Health Servece Law(Note 1) on September 21, 2004 to require advanced treatment facilities to report medical adverse events. The JCQHC was registered at the MHLW on October 1, 2004 and became a Minister's recognized organization to analyze medical adverse event data in accordance with the said ordinance.

Background of JCQHC Project

The Center for Medical Adverse Event Prevention was established within the JCQHC on July 1, 2004, and collection of near-miss/medical adverse event information in accordance with the law started on October 7, 2004. The Center for Medical Adverse Event Prevention comprehensively analyzes medical near-miss/adverse event information and prepares reports under the organizational structure described in the following pages. The JCQHC has been providing reports prepared by the Center for Medical Adverse Event Prevention to participating medical institutions, relevant organizations, and administrative organizations as well as posting them on its website(Note 2) for public review.

(Note 1) MHLW Ordinance No. 133
(Note 2) See "Project to Collect, Analyze, and Provide Medical Near-Miss/Adverse Event Information" on the JCQHC website (http://jcqhc.or.jp/html/accident.htm#med-safe).

2. Outline of Project to Collect Medical Near-Miss/Adverse Event Information and Organizational Structure

The project consists of Project to Collect, Analyze, and Provide Medical Adverse Event Information(Note 1) and Project to Collect, Analyze, and Provide Medical Near-Miss Information.(Note 2) The outline of each project is described below.

[1] Outline of Project to Collect, Analyze, and Provide Medical Adverse Event Information

(1) Objective

To collect, analyze, and provide medical adverse event information reported by medical institutions subject to reporting requirement, and for registered participating medical institutions to widely share information useful to develop medical safety measures with medical institutions in general and to provide information to the general public in order to further promote medical safety measures.

(2) Collection of medical adverse event information

1. Medical institutions

Information is collected at the following medical institutions subject to reporting requirement, as well as registered participating medical institutions.

i) Medical institutions subject to reporting requirement(Note 3)

A. National Centers and National Sanatoriums for Hansen’s disease
B. Hospitals run by the National Hospital Organization
C. Hospitals affiliated with universities governed by the School Education Law (not including their branch hospitals)
D. Advanced treatment facilities

ii) Registered participating medical institutions

Medical institutions other than those subject to reporting requirement may participate in the project by providing their organizational information required by the JCQHC to register.

(Note 1) See Attachment 1.
(Note 2) See Attachment 2.
(Note 3) The MHLW issued a ministerial ordinance to partially revise the enforcement regulations for Health Service Law (MHLW Ordinance No. 133, 2004) on September 21, 2004 to require National Centers, National Sanatoriums for Hansen’s disease, hospitals run by National Hospital Organization, hospitals affiliated with universities (not including their branch hospitals) governed by the School Education LawLaw No. 22, 1947) (not including their branch hospitals), and advanced treatment facilities to report medical adverse events.
See Attachment 3 “Medical Institutions Subject to Reporting Requirement.”

2. Medical adverse event information to be reported

The following medical adverse event information is subject to reporting.

A. Apparent error in treatment or management that resulted in patient's death or mental or physical disability or required unexpected treatment, treatment to an unexpected extent, or other medical procedure

B. Unapparent error in treatment or management that resulted in patient's death or mental or physical disability or required unexpected treatment, treatment to an unexpected extent, or other medical procedure (including events possibly associated with treatment or management provided; limited to unexpected events)

C. Other than those described in A and B, information conducive to prevention of medical adverse events and their recurrence at medical institutions

3. Reporting method and due date

Medical adverse events should be reported on the exclusive reporting web page via Internet (SSL communication). As a general rule, a medical adverse event must be reported within 2 weeks of occurrence or within 2 weeks after identifying the occurrence.

4. Report form

Code choice reporting and descriptive reporting are available(Note 1). In code choice reporting, applicable codes are checked or selected from pull-down lists. In descriptive reporting, descriptions are provided in the relevant fields.

In this report, an answer with no chosen code is referred as "no choice" and a field with no description entry as "no description."

(3) Analysis and publication of medical adverse event information

1. Tabulation

Performed by the JCQHC Center for Medical Adverse Event Prevention.

2. Publication of tabulation/analysis

Information is provided to relevant parties and the public in published reports and on the JCQHC website(Note 2).

(Note 1) See Attachment 4 "Outline of Medical Adverse Event Report Form."
(Note 2) See "Project to Collect, Analyze, and Provide Medical Near-Miss/Adverse Event Information" on the JCQHC website (http://jcqhc.or.jp/html/accident.htm#med-safe).

[2] Outline of Project to Collect, Analyze, and Provide Medical Near-Miss Information

(1) Objective

To collect, analyze, and provide medical near-miss information reported by registered participating medical institutions to widely share information useful to develop medical safety measures with medical institutions in general and to provide information to the general public in order to further promote medical safety measures

(2) Collection of medical near-miss information

1. Medical institutions

Information is collected at registered participating medical institutions.

2. Medical near-miss information to be reported

i) Medical near-miss information subject to reporting

A. Potentially erroneous medical procedures identified before actually performed for patients

B. Erroneous medical procedures performed but did not affect patients' conditions

C. Erroneous medical procedures performed, and patients required minor procedure/treatment as the result

ii) Medical institutions where "general coded information" and/or "descriptive information" are collected

Medical near-miss information consists of "general coded information" and "descriptive information" that are collected separately at different medical institutions. The difference in the nature of information and medical institutions where such information is collected is described below.

A. General coded information

Information on any and all medical near-miss incidents (e.g. situation and details) occurred during a given collection period will be collected in the form of code table-based report[Note 1].

General coded information will be collected only at designated medical institutions[Note 2].

B. Descriptive information

Regarding near-miss incidents of which information should be provided to others in general in light of promoting medical safety measures, causes and proposed corrective measures will be reported in the form of a "descriptive information" report.

"Descriptive information" described in a) and b) below will be collected from all registered participating medical institutions.

(Note 1) See Attachment 6 "Medical Near-Miss Information Report Form."

(Note 2) Designated medical institutions are medical institutions participating in Project to Collect Medical Near-Miss Information and agreed to cooperate to provide "general coded information." As of December 31, 2005, 249 institutions have been designated by avoiding biases in institution size and location.
See Attachment 5 "Designated Medical Institutions for Collection of Medical Near-Miss Information."

a) Medical near-miss cases covered by themes specified for individual collection periods(Note 1) (Fig. I-1)

b) Medical near-miss cases to be collected regularly regardless of periodic themes described in a)

- Cases in which patients would have died or had serious conditions if actions in question had been done or occurrence of events in question had been unnoticed
- Cases involving names or dosage forms of newly introduced drugs; cases involving drugs, medical devices/equipment such as errors in medical device operation(Note 2)
- Other cases that persons responsible for safety management at medical institutions examined thoroughly and determined that reporting of such cases would be conducive to improvement of medical safety

Fig. I-1 Themes for Descriptive Information Specified for Individual Collection Periods

Collection period	Month of occurrence	Theme
15th	2005 January to March	❍ Cases involving mechanical ventilator (including those related to tube trouble, alarm or peripheral equipment of mechanical ventilator; not including self-removal of tracheal tube) ❍ Retained foreign objects (cases involving foreign objects retained during surgeries or procedures)
16th	April to June	❍ Cases involving mechanical ventilator (including those related to tube trouble, alarm or peripheral equipment of mechanical ventilator; not including self-removal of tracheal tube) ❍ Retained foreign objects (cases involving foreign objects retained during surgeries or procedures) ❍ Cases involving patient misidentification or wrong-site surgeries/procedures
17th	July to September	❍ Cases involving mechanical ventilator (including those related to tube trouble, alarm or peripheral equipment of mechanical ventilator; not including self-removal of tracheal tube) ❍ Cases involving patient misidentification or wrong-site surgeries/procedures ❍ Cases related to placement and/or management of feeding tube such as nasogastric tube and percutaneous endoscopic gastrostomy (PEG) (not including self-removal of tube) ❍ Errors or unexpected events occurred during enema procedure
18th	October to December	❍ Cases involving patient misidentification or wrong-site surgeries/procedures ❍ Cases related to placement and/or management of feeding tube such as nasogastric tube and percutaneous endoscopic gastrostomy (PEG) (not including self-removal of tube) ❍ Errors or unexpected events occurred during enema procedure

3. Reporting method

(1) Web reporting and (2) reporting in a designated format (CSV format) are available. The reporting method will be selected by individual registered participating medical institutions at the time of registration.

4. Report form

Code choice reporting and descriptive reporting are available(Note 3). In code choice reporting, applicable codes are checked or selected from pull-down lists. In descriptive reporting, descriptions are provided in relevant fields.

(Note 1) Certain themes are specified for medical near-miss cases to be collected in individual collection period in order to analyze medical adverse events covered by specific themes.
(Note 2) Information such as drug (product) names and units is also collected in events associated with drugs, medical devices or other items
(Note 3) See Attachment 6 "Medical Near-Miss Information Report Form."

(3) Analysis and provision of medical near-miss information

1. Tabulation

Performed by the JCQHC Center for Medical Adverse Event Prevention.

2. Publication of tabulation/analysis

Provided to relevant parties and general public in reports and on the JCQHC website(Note 1) (Note 2).

[3] Organizational Structure for Project to Collect Medical Near-Miss/Adverse Event Information

The following committees and divisions have been established in Center for Medical Adverse Event Prevention to maintain neutrality and fairness of a third-party organization to collect medical adverse event information and to promote smooth organizational operation.

(1) Management Committee

Consisting of 22 experts in general medicine or medical safety measures and general advisors (as of December 31, 2005)(Note 3), Management Committee develops operational policies of Center for Medical Adverse Event Prevention and evaluates its activities. Management Committee is established as a subcommittee specified in the JCQHC act of endowment.

(2) Expert divisions

A. Comprehensive Evaluation Panel

Consisting of 16 experts from various fields (as of December 31, 2005)(Note 4), Comprehensive Evaluation Panel reviews and evaluates reports (proposals) prepared by "Expert Analysis Groups" described below as well as provides technological advice for analytical methods.

B. Expert Analysis Groups

Consisting of medical experts involved in medical safety and safety management experts, Expert Analysis Groups review and analyze reported cases, develop corrective measures, and prepare reports (proposals). Expert Analysis Groups also collect necessary information for analysis and development of corrective measures and conduct on-site visit. Currently 20 members are participating in the activities of Expert Analysis Groups.

(Note 1) See "Project to Collect, Analyze, and Provide Medical Near-Miss Information" on the JCQHC website (http://jcqhc.or.jp/html/accident.htm#med-safe).
(Note 2) See Medical Near-Miss (Important Cases) Information Database Development/Publication Website (http://www2.hiyari-hatto.jp/hiyarihatto.index.jsp).
(Note 3) See Attachment 7 "Center for Medical Adverse Event Prevention Management Committee Members."
(Note 4) See Attachment 8 "Center for Medical Adverse Event Prevention Comprehensive Evaluation Panel Members."

(3) Medical Adverse Event Prevention Division

Planning and Coordination Department of Medical Adverse Event Prevention Division is in charge of Project to Collect Medical Near-Miss/Adverse Event Information.

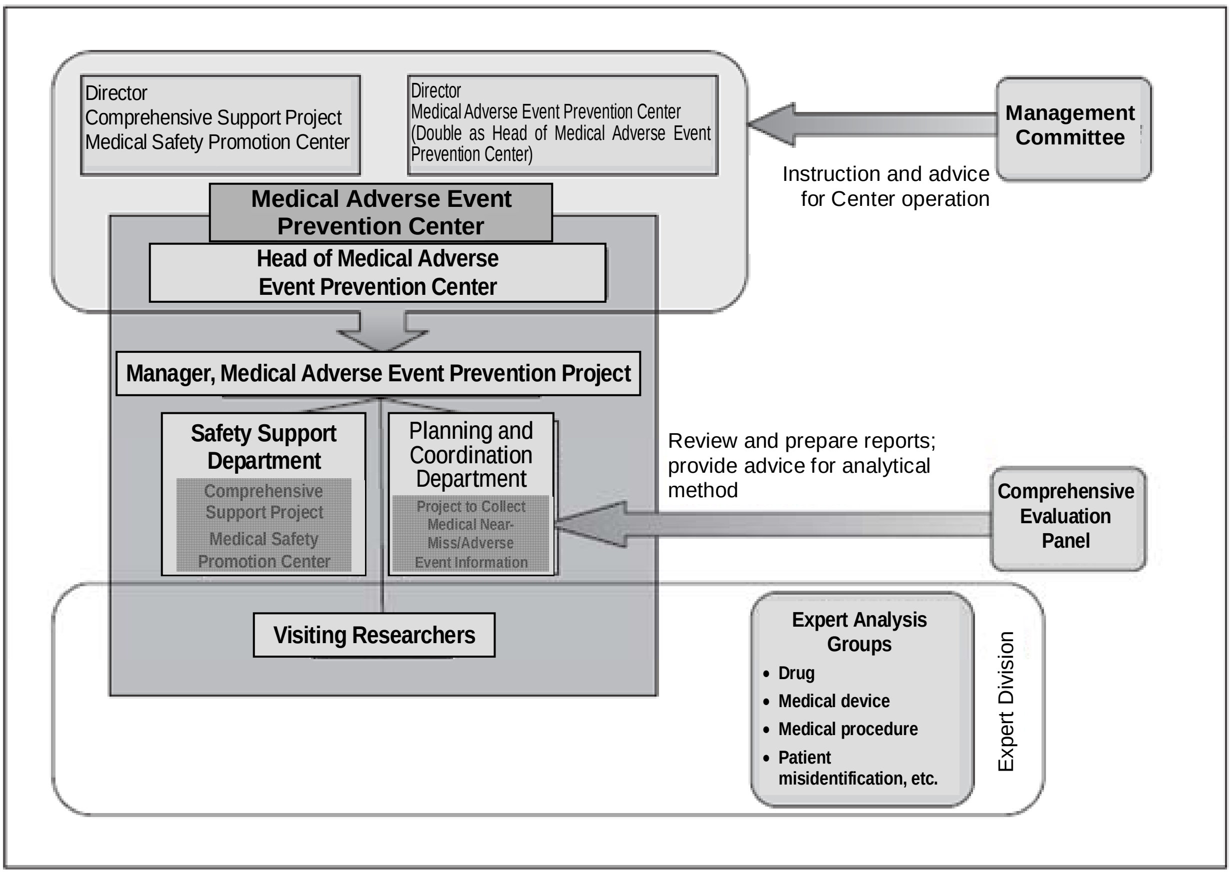
Consisting of staff with medical qualifications and visiting researchers, Planning and Coordination Department receives medical near-miss/adverse event reports and other useful information for medical safety as well as prepares and publishes project reports. The Department also visits medical institutions with members of Expert Analysis Groups to collect further information as necessary.

[4] Organization for Data Analysis and Information Provision

Initial reports are processed by staff, visiting researchers, and members of Expert Analysis Groups bound by the confidentiality clause of Center for Medical Adverse Event Prevention. Information contained in initial reports is anonymized by Center staff before being processed for analysis.

Expert Analysis Groups collect follow-up information, review published studies, and monitor activities of medical institutions making advanced efforts to prevent medical adverse events as necessary. Expert Analysis Groups prepare reports (proposals) containing results of comprehensive analysis of obtained information and submit them to Comprehensive Evaluation Panel. Comprehensive Evaluation Panel reviews submitted reports (proposals) from an expert point of view, prepares final reports, and publishes them as JCQHC reports.

Fig. I-2



II. Current Reporting Status

1. Report on Collection, Analysis, and Provision of Medical Adverse Event Information

This annual report contains three types of tabulated information.

A. Details of information provided by medical institutions subject to reporting requirement (by month of report)
Same tabulation as that published quarterly

B. Details of information provided by medical institutions subject to reporting requirement (by month of occurrence)

C. Details of information provided by registered participating medical institutions (by month of report)
Tabulation of information provided by all medical institutions participated in the project (medical institutions subject to reporting requirement and participating medical institutions)

[1] Registered Medical Institutions

Medical near-miss/adverse event information is provided by medical institutions subject to reporting requirement and registered participating medical institutions whose participations are voluntary.

(1) Number of medical institutions subject to reporting requirement and registered participating medical institutions

The number of medical institutions participating in Project to Collect, Analyze, and Provide Medical Near-Miss/Adverse Event Information as of December 31, 2005 is shown in Fig. II-1-1.

Fig. II-1-1 Number of Medical Institutions Subject to Reporting Requirement and Registered Participating Medical Institutions

Mother body		Medical institutions subject to reporting requirement	Registered participating medical institutions(Note)
Government	National University Corporation	46	1
	National Hospital Organization	146	
	Ministry of Health, Labour and Welfare (National Centers)	8	
	Ministry of Health, Labour and Welfare (Sanatoriums for Hansen's Disease)	13	
	Others	—	
Municipality	Prefecture	7	32
	City/village	2	
	Japan Association of Municipal and Prefectural Colleges and Universities	1	
Mother body of public medical institution other than municipality	Japan Red Cross	—	106
	Saiseikai Imperial Gift Foundation	—	
	National Welfare Federation of Agricultural Cooperatives	—	
	All Japan Federation of Social Insurance Associations	—	
	Employees' Pension Welfare Corporation	—	
	Seamen's Insurance Society	—	
	Mutual Aid Associations and their associations	—	
Corporation	School juridical organization	49	121
	Healthcare corporation	—	
	Charitable organization	—	
	Company	—	
	Other corporation	—	
Individual practitioner		—	23
Total		272	283

(Note) Registered participating medical institutions are those participating in the project other than medical institutions subject to reporting requirement.

(2) Changes in number of registration of registered participating medical institutions

Changes in the number of registration of registered participating medical institutions between January 1 and December 31, 2005 are shown below.

Fig. II-1-2 Number of Registrations of Registered Participating Medical Institutions

	2005											
	January	February	March	April	May	June	July	August	September	October	November	December
Number of registered participating medical institutions	22	10	10	8	1	3	4	4	1	1	1	4
Number of rejected registrations	0	0	0	0	0	0	0	0	0	0	1	0
Accumulated total	237	247	257	265	266	269	273	277	278	279	279	283

[2] Changes in Number of Reports

(1) Number of monthly reports

The number of monthly reports made by medical institutions subject to reporting requirement and registered participating medical institutions between January 1 and December 31, 2005 is shown below.

Fig. II-1-3 Number of Reports Made by Medical Institutions Subject to Reporting Requirement and Registered Participating Medical Institutions

	2005												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of reports made by medical institutions subject to reporting requirement	103	84	71	79	84	145	81	105	87	82	80	113	1,114
Number of reports made by registered participating medical institutions	7	17	10	12	23	13	7	12	11	14	10	15	151
Number of medical institutions subject to reporting requirement	277	277	276	275	275	275	272	272	272	272	272	272	—
Number of registered participating medical institutions	237	247	257	265	266	269	273	277	278	279	279	283	—

(2) Medical near-miss/adverse event reporting status

A. Reporting status of medical institutions subject to reporting requirement

The number of reporting medical institutions subject to reporting requirement and the number of reports made between January 1 and December 31, 2005 are shown below.

Fig. II-1-4 Number of Reporting Medical Institutions Subject to Reporting Requirement and Reports Made

Mother body		Number of registrations (As of December 31, 2005)	Number of reporting medical institutions	Number of reports
			January to December 2005	January to December 2005
Government	National University Corporation	46	40	238
	National Hospital Organization	146	81	335
	National Centers	8	8	55
	Sanatoriums for Hansen's Disease	13	6	14
Municipality	Prefecture	10	7	31
	City/village			
	Japan Association of Municipal and Prefectural Colleges and Universities			
Corporation	School juridical organization	49	34	441
Total		272	176	1,114

(Note) Total number of beds at medical institutions subject to reporting requirement as of December 31, 2005 is 147,627.

B. Number of medical institutions subject to reporting requirement by number of reports

The number of medical institutions subject to reporting requirement by number of reports made between January 1 and December 31, 2005 is shown below.

Fig. II-1-5 Number of Medical Institutions Subject to Reporting Requirement by Number of Reports

Number of reports	Number of medical institutions
0	96
1	50
2	25
3	17
4	16
5	12
6	5
7	8
8	7
9	3
10	5
11 to 20	18
21 to 30	5
31 to 40	3
41 or more	2
Total	272

C. Reporting status of registered participating medical institutions

The number of reporting registered participating medical institutions and the number of reports made between January 1 and December 31, 2005 are shown below.

Fig. II-1-6 Number of Reporting Registered Participating Medical Institutions and Number of Reports

Mother body	Number of registrations (As of December 31, 2005)	Number of reporting medical institutions	Number of reports
		January to December 2005	January to December 2005
Government	1	0	0
Municipality	32	10	10
Public medical institution	106	20	58
Corporation	121	26	83
Individual practitioner	23	0	0
Total	283	56	151

[3] Details of Reports Made by Medical Institutions Subject to Reporting Requirement (by Month of Report)

The quarterly tabulation of reports made by medical institutions subject to reporting requirement between January 1 and December 31, 2005 is shown below.

Fig. II-1-7 Month of Occurrence

Month of occurrence		Number of events
2004	November and therebefore	38
	December	75
2005	January	103
	February	78
	March	92
	April	101
	May	72
	June	85
	July	97
	August	88
	September	80
	October	89
	November	76
	December	37
	No choice(Note)	3
Total		1,114

(Note) “No choice” means no “month of occurrence” was selected.

Fig. II-1-8 Day of Occurrence and Weekday/Holiday Category

Day of occurrence	Weekday					Holiday					No choice(Note)					Aggregate total
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
Mon.	28	53	38	30	149	6	1	1	2	10	0	0	0	0	0	159
Tue.	41	53	46	45	185	1	0	0	0	1	1	1	1	2	5	191
Wed.	44	53	39	44	180	3	0	0	0	3	1	0	1	1	3	186
Thu.	41	48	60	57	206	3	1	0	1	5	2	1	2	0	5	216
Fri.	36	45	36	55	172	3	1	0	1	5	1	1	1	0	3	180
Sat.	11	11	5	6	33	13	21	23	16	73	0	1	1	2	4	110
Sun.	0	0	0	0	0	19	14	19	11	63	1	0	0	0	1	64
No choice(Note)	1	0	0	0	1	0	0	0	0	0	2	3	0	2	7	8
Total	202	263	224	237	926	48	38	43	31	160	8	7	6	7	28	1,114

(Note) “No choice” means no “day of occurrence” or “weekday/holiday category” was selected.

Fig. II-1-9 Time of Occurrence

Time of occurrence	Number of events				
	January to March	April to June	July to September	October to December	Total
0:00 – before 2:00	12	12	10	13	47
2:00 – before 4:00	16	6	14	11	47
4:00 – before 6:00	8	15	6	9	38
6:00 – before 8:00	10	10	23	8	51
8:00 – before 10:00	23	34	21	21	99
10:00 – before 12:00	42	36	40	37	155
12:00 – before 14:00	24	25	21	33	103
14:00 – before 16:00	37	47	41	46	171
16:00 – before 18:00	26	29	34	32	121
18:00 – before 20:00	17	14	17	23	71
20:00 – before 22:00	8	17	13	11	49
22:00 – before 24:00	18	14	10	13	55
Time unknown	9	40	15	12	76
No choice(Note)	8	9	8	6	31
Total	258	308	273	275	1,114

(Note) "No choice" means no "time of occurrence" was selected.

Fig. II-1-10 Patient Age

Patient age	Number of events					Inpatient				
	January to March	April to June	July to September	October to December	Aggregate total	January to March	April to June	July to September	October to December	Aggregate total
0 to 9	8	12	12	13	45	7	9	8	10	34
10s	2	8	4	2	16	2	6	4	2	14
20s	14	10	7	9	40	13	8	7	9	37
30s	9	12	12	8	41	8	8	8	8	32
40s	16	19	10	16	61	13	14	8	15	50
50s	21	29	19	25	94	18	26	16	22	82
60s	32	49	29	54	164	25	43	23	49	140
70s	63	57	69	63	252	59	51	61	55	226
80s	18	30	33	17	98	16	28	27	17	88
90 or above	4	9	5	6	24	3	7	4	6	20
No choice(Note)	71	73	73	62	279	22	32	22	29	105
Aggregate total	258	308	273	275	1,114	186	232	188	222	828

(Note) "No choice" means no "patient age" was selected.

Fig. II-1-11 Sex of Patients

Sex	Number of events				
	January to March	April to June	July to September	October to December	Total
Male	99	127	96	105	427
Female	83	105	95	94	377
No choice(Note)	76	76	82	76	310
Total	258	308	273	275	1,114

(Note) "No choice" means no "sex of patient" was selected.

Fig. II-1-12 Inpatient/Outpatient Status and Duration of Hospital Stay

Inpatient/outpatient status		Number of events				
		January to March	April to June	July to September	October to December	Total
Inpatient	Duration: 0 to 31 days	116	172	122	151	561
	Duration: 32 days or longer	66	54	61	66	247
	No choice(Note)	4	6	5	5	20
	Total	186	232	188	222	828
Outpatient	Initial visit	2	2	1	1	6
	Follow-up visit	13	31	14	9	67
	Total	15	33	15	10	73
No choice(Note)		57	43	70	43	213
Aggregate total		258	308	273	275	1,114

(Note) "No choice" means no "inpatient/outpatient status" or "duration of hospitalization" was selected.

Fig. II-1-13 Person Who Identified Event

Person who identified event	Number of events				
	January to March	April to June	July to September	October to December	Total
Medical staff	179	231	216	220	846
Patient himself/herself	8	15	8	8	39
Patient's family/caregiver	16	9	9	7	41
Other patient	11	10	12	6	39
Others	36	34	20	25	115
No choice(Note)	8	9	8	9	34
Total	258	308	273	275	1,114

(Note) "No choice" means no "person who identified event" was selected.

Fig. II-1-14 Job Title of Person Involved

Job title of person involved (Note 1)	Number of events				
	January to March	April to June	July to September	October to December	Total
Doctor	222	203	184	209	818
Dentist	1	9	6	4	20
Nurse	123	145	152	169	589
Assistant nurse	4	5	2	2	13
Pharmacist	0	3	6	2	11
Clinical engineer	2	1	1	0	4
Midwife	3	1	3	3	10
Nursing assistant	2	2	0	3	7
Radiological technologist	3	2	2	1	8
Clinical technologist	4	3	0	1	8
Physical therapist (PT)	3	1	4	2	10
Occupational therapist (OT)	0	1	0	0	1
Medical technologist	0	0	0	0	0
Dental hygienist	0	0	0	0	0
Others	10	20	12	10	52
No choice(Note 2)	30	34	26	25	115
Total	407	430	398	431	1,666

(Note 1) Person involved is a person determined by the medical institution to have been involved in the event occurred; more than 1 person may have been involved.

(Note 2) "No choice" means no "job title of person involved" was selected.

Fig. II-1-15 Summary of Event

Summary of event	January to March		April to June		July to September		October to December		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Ordering	0	0.0	1	0.3	4	1.5	1	0.4	6	0.5
Drug	15	5.8	13	4.2	14	5.1	15	5.5	57	5.1
Blood transfusion	1	0.4	3	1.0	1	0.4	1	0.4	6	0.5
Treatment/procedure	77	29.8	91	29.5	75	27.5	93	33.8	336	30.2
Medical equipment, etc.	31	12	36	11.7	31	11.4	44	16.0	142	12.7
Medical device	9	3.5	13	4.2	9	3.3	11	4.0	42	3.8
Drainage tube or other tube	22	8.5	23	7.5	22	8.1	31	11.3	98	8.8
Dental equipment	0	0.0	0	0.0	0	0.0	2	0.7	2	0.2
Examination/test	12	4.7	21	6.8	12	4.4	10	3.6	55	4.9
Nursing care	57	22.1	68	22.1	81	29.7	50	18.2	256	23.0
Others	50	19.4	64	20.8	42	15.4	52	18.9	208	18.7
No choice(Note)	15	5.8	11	3.6	13	4.8	9	3.3	48	4.3
Total	258	100	308	100	273	100	275	100	1,114	100

(Note) "No choice" means no "summary of event" was selected.

Fig. II-1-16 Severity of Event

Severity of event(Note 1)	January to March		April to June		July to September		October to December		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Death	41	15.9	32	10.4	41	15.0	29	10.5	143	12.8
Potential residual disability (likely)	36	14.0	47	15.3	41	15.0	35	12.7	159	14.3
Potential residual disability (unlikely)	127	49.2	163	52.9	148	54.2	156	56.7	594	53.3
Unknown(Note 2)	47	18.2	57	18.5	39	14.3	52	18.9	195	17.5
No choice(Note 3)	7	2.7	9	2.9	4	1.5	3	1.1	23	2.1
Total	258	100	308	100	273	100	275	100	1,114	100

(Note 1) "Severity of event" is not necessarily associated with occurrence of event or negligence.

(Note 2) "Unknown" includes indefinite outcome at the time of reporting (within 2 weeks) and events of warning that did not affect patients' conditions in any way.

(Note 3) "No choice" means no "severity of event" was selected.

Fig. II-1-17 Place of Occurrence

Place of Occurrence	January to March		April to June		July to September		October to December		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Outpatient examination room	5	1.9	4	1.3	7	2.6	6	2.2	22	2.0
Outpatient treatment room	1	0.4	5	1.6	1	0.4	4	1.5	11	1.0
Outpatient lobby	0	0.0	2	0.6	1	0.4	0	0.0	3	0.3
Emergency room	3	1.2	4	1.3	1	0.4	1	0.4	9	0.8
Critical care center	0	0.0	0	0.0	3	1.1	3	1.1	6	0.5
Patient room	118	45.7	128	41.6	121	44.3	110	40.0	477	42.8
Ward treatment room	6	2.3	0	0.0	3	1.1	5	1.8	14	1.3
Operation room	30	11.6	51	16.6	38	13.9	51	18.5	170	15.3
ICU	7	2.7	12	3.9	10	3.7	6	2.2	35	3.1
CCU	2	0.8	1	0.3	4	1.5	1	0.4	8	0.7
NICU	2	0.8	1	0.3	3	1.1	4	1.5	10	0.9
Examination room	2	0.8	8	2.6	4	1.5	5	1.8	19	1.7
Catheterization laboratory	15	5.8	12	3.9	10	3.7	10	3.6	47	4.2
Radiotherapy room	2	0.8	0	0.0	1	0.4	2	0.7	5	0.4
Radiography room	7	2.7	3	1.0	4	1.5	7	2.5	21	1.9
Radioactive scanning room	0	0.0	1	0.3	0	0.0	2	0.7	3	0.3
Dialysis room	3	1.2	1	0.3	1	0.4	0	0.0	5	0.4
Delivery room	1	0.4	0	0.0	0	0.0	2	0.7	3	0.3
Rehabilitation room	1	0.4	0	0.0	3	1.1	2	0.7	6	0.5
Restroom	12	4.7	4	1.3	9	3.3	7	2.5	32	2.9
Hallway	8	3.1	11	3.6	11	4.0	7	2.5	37	3.3
Bathroom	4	1.6	6	1.9	2	0.7	6	2.2	18	1.6
Stairway	0	0.0	1	0.3	1	0.4	1	0.4	3	0.3
Unknown	2	0.8	5	1.6	1	0.4	1	0.4	9	0.8
Others	24	9.3	45	14.6	32	11.7	32	11.6	133	11.9
No choice(Note)	3	1.2	3	1.0	2	0.7	0	0.0	8	0.7
Total	258	100	308	100	273	100	275	100	1,114	100

(Note) "No choice" means no "place of occurrence" was selected.

Fig. II-1-18 Cause of Event

Cause of Event (Note 1)	January to March		April to June		July to September		October to December		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Neglect to check	67	14.7	71	13.5	83	15.2	71	14.1	292	14.4
Neglect to observe	62	13.6	49	9.4	74	13.6	62	12.3	247	12.2
Misjudgment	47	10.3	62	11.8	67	12.3	62	12.3	238	11.7
Lack of knowledge	14	3.1	25	4.8	30	5.5	26	5.2	95	4.7
Deficiency of technique/skill	24	5.3	31	5.9	28	5.1	20	4.0	103	5.1
Delayed reporting	4	0.9	6	1.1	13	2.4	11	2.2	34	1.7
Under unusual physical condition	15	3.3	16	3.1	18	3.3	13	2.6	62	3.1
Under unusual psychological condition	12	2.6	5	1.0	10	1.8	8	1.6	35	1.7
System failure	7	1.5	17	3.2	10	1.8	14	2.8	48	2.4
Inadequate coordination	29	6.4	27	5.2	29	5.3	33	6.5	118	5.8
Inadequate documentation	5	1.1	2	0.4	4	0.7	4	0.8	15	0.7
Similarity in patient's appearance or name	0	0.0	0	0.0	1	0.2	1	0.2	2	0.1
Busy working condition	12	2.6	11	2.1	15	2.8	12	2.4	50	2.5
Problem in environment	12	2.6	12	2.3	10	1.8	11	2.2	45	2.2
Problem in the drug	3	0.7	6	1.1	3	0.6	4	0.8	16	0.8
Problem in medical device	4	0.9	13	2.5	9	1.7	11	2.2	37	1.8
Problem in other items	8	1.8	11	2.1	4	0.7	5	1.0	28	1.4
Problem in facility	14	3.1	14	2.7	9	1.7	9	1.8	46	2.3
Problem in education/training	7	1.5	10	1.9	16	2.9	19	3.8	52	2.6
Lack of explanation	17	3.7	17	3.2	23	4.2	17	3.4	74	3.6
Others	67	14.7	101	19.3	75	13.8	74	14.7	317	15.6
No choice (Note 2)	26	5.7	18	3.4	14	2.6	17	3.4	75	3.7
Total	456	100	524	100	545	100	504	100	2,029	100

(Note 1) "Cause of event" may be more than one.

(Note 2) "No choice" means no "cause of event" was selected.

Fig. II-1-19 Clinical Department

Clinical Department (Note 1)	January to March		April to June		July to September		October to December		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Internal medicine	32	9.7	36	8.9	34	9.9	26	8.0	128	9.1
Anesthesiology	14	4.3	18	4.5	10	2.9	11	3.4	53	3.8
Cardiovascular medicine	20	6.1	25	6.2	21	6.1	15	4.6	81	5.8
Neurology	15	4.6	11	2.7	7	2.0	6	1.8	39	2.8
Respiratory tract medicine	13	4.0	11	2.7	13	3.8	12	3.7	49	3.5
Gastrointestinal medicine	15	4.6	19	4.7	25	7.3	25	7.6	84	6.0
Hematology	4	1.2	5	1.2	5	1.5	8	2.4	22	1.6
Circulatory surgery	4	1.2	13	3.2	5	1.5	0	0.0	22	1.6
Allergy	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Rheumatism	1	0.3	2	0.5	0	0.0	1	0.3	4	0.3
Pediatrics	7	2.1	16	4.0	13	3.8	8	2.4	44	3.1
General surgery	30	9.1	34	8.4	30	8.8	38	11.6	132	9.4
Orthopedics	24	7.3	33	8.2	37	10.8	26	8.0	120	8.6
Plastic surgery	3	0.9	5	1.2	3	0.9	3	0.9	14	1.0
Cosmetic surgery	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Neurosurgery	21	6.4	20	5.0	15	4.4	18	5.5	74	5.3
Respiratory surgery	8	2.4	5	1.2	9	2.6	7	2.1	29	2.1
Cardiovascular surgery	13	4.0	14	3.5	17	5.0	20	6.1	64	4.6
Pediatric surgery	4	1.2	0	0.0	3	0.9	3	0.9	10	0.7
Pain clinic	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Dermatology	7	2.1	7	1.7	6	1.8	3	0.9	23	1.6
Urology	17	5.2	13	3.2	7	2.0	10	3.1	47	3.4
Venereology	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Proctology	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Gynecology/Obstetrics	3	0.9	5	1.2	7	2.0	0	0.0	15	1.1
Obstetrics	1	0.3	0	0.0	1	0.3	4	1.2	6	0.4
Gynecology	2	0.6	6	1.5	6	1.8	3	0.9	17	1.2
Ophthalmology	3	0.9	4	1.0	6	1.8	9	2.8	22	1.6
Otolaryngology	5	1.5	8	2.0	5	1.5	8	2.4	26	1.9
Psychosomatic medicine	2	0.6	0	0.0	1	0.3	0	0.0	3	0.2
Psychiatry	19	5.8	19	4.7	19	5.6	14	4.3	71	5.1
Rehabilitation	4	1.2	6	1.5	3	0.9	3	0.9	16	1.1
Radiology	5	1.5	8	2.0	7	2.0	9	2.8	29	2.1
Dentistry	0	0.0	3	0.7	1	0.3	1	0.3	5	0.4
Orthodontics	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pediatric dentistry	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Dental/oral surgery	2	0.6	4	1.0	3	0.9	8	2.4	17	1.2
Others	24	7.3	42	10.4	15	4.4	19	5.8	100	7.1
No choice (Note 2)	7	2.1	11	2.7	8	2.3	9	2.8	35	2.5
Total	329	100	403	100	342	100	327	100	1,401	100

(Note 1) More than one “clinical department” may have been involved in one event.

(Note 2) “No choice” means no “clinical department” was selected.

Fig. II-1-20 Years of Experience of Person Involved by Job Title (Doctor, Dentist, Nurse, Pharmacist)

Years of experience × Job title of person involved(Note 1)	Doctor					Dentist				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
0 year	7	4	4	7	22	0	0	0	1	1
1 year	18	6	3	4	31	0	1	2	0	3
2 years	13	6	5	14	38	0	0	0	1	1
3 years	12	15	5	13	45	0	0	0	0	0
4 years	14	5	13	10	42	0	0	0	1	1
5 years	8	11	11	6	36	0	2	0	0	2
6 years	6	5	11	6	28	0	1	1	0	2
7 years	6	7	11	9	33	0	2	0	1	3
8 years	14	6	4	6	30	1	0	0	0	1
9 years	10	15	6	11	42	0	0	0	0	0
10 years	9	6	9	12	36	0	0	1	0	1
11 to 20 years	65	67	57	64	253	0	2	1	0	3
21 to 30 years	17	15	25	20	77	0	0	1	0	1
30 years or longer	3	7	2	4	16	0	0	0	0	0
No choice(Note 2)	20	28	18	23	89	0	1	0	0	1
Total	222	203	184	209	818	1	9	6	4	20

(Note 1) Person involved is a person determined by the medical institution to have been involved in the event occurred; more than 1 person may have been involved.

(Note 2) “No choice” means no “years of experience” was selected.

Nurse					Pharmacist				
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
9	6	18	20	53	0	0	1	1	2
10	12	6	21	49	0	0	0	0	0
10	21	13	12	56	0	0	0	0	0
12	15	15	15	57	0	0	0	0	0
6	6	14	7	33	0	0	1	0	1
11	10	4	13	38	0	1	0	0	1
3	2	4	3	12	0	0	0	0	0
7	7	9	3	26	0	0	0	0	0
8	4	4	3	19	0	0	0	1	1
2	4	1	4	11	0	0	0	0	0
3	4	3	4	14	0	0	0	0	0
14	17	27	25	83	0	2	2	0	4
18	12	12	21	63	0	0	1	0	1
2	4	6	2	14	0	0	0	0	0
8	21	16	16	61	0	0	1	0	1
123	145	152	169	589	0	3	6	2	11

Fig. II-1-21 Number of Years Person Involved (Doctor, Dentist, Nurse, Pharmacist) Has Been Working at Current Department

Number of years at current department × Job title of person involved(Note 1)	Doctor					Dentist				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
0 year	52	31	29	31	143	0	0	2	1	3
1 year	28	22	21	32	103	0	1	1	1	3
2 years	20	16	20	23	79	0	0	1	1	2
3 years	18	20	11	23	72	0	1	0	0	1
4 years	7	9	14	8	38	0	0	0	1	1
5 years	9	7	17	6	39	0	1	0	0	1
6 years	3	10	5	9	27	0	0	0	0	0
7 years	5	6	2	6	19	0	0	0	0	0
8 years	5	4	4	3	16	0	0	0	0	0
9 years	7	3	3	6	19	0	0	0	0	0
10 years	4	1	1	3	9	0	0	0	0	0
11 to 20 years	23	26	24	24	97	0	0	1	0	1
21 to 30 years	2	1	8	5	16	0	0	1	0	1
30 years or longer	1	1	0	0	2	0	0	0	0	0
No choice(Note 2)	38	46	25	30	139	1	6	0	0	7
Total	222	203	184	209	818	1	9	6	4	20

(Note 1) Person involved is a person determined by the medical institution to have been involved in the event occurred; more than 1 person may have been involved.

(Note 2) "No choice" means no "number of years at current department" was selected.

Nurse					Pharmacist				
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
28	16	38	43	125	0	0	1	1	2
28	22	22	40	112	0	2	1	0	3
17	34	18	23	92	0	1	0	1	2
18	17	20	12	67	0	0	0	0	0
8	6	12	10	36	0	0	1	0	1
7	10	6	11	34	0	0	1	0	1
1	1	4	1	7	0	0	0	0	0
0	5	4	1	10	0	0	0	0	0
2	1	3	3	9	0	0	0	0	0
0	1	1	2	4	0	0	0	0	0
2	0	1	1	4	0	0	0	0	0
2	3	1	1	7	0	0	0	0	0
1	0	1	0	2	0	0	1	0	1
0	0	1	0	1	0	0	0	0	0
9	29	20	21	79	0	0	1	0	1
123	145	152	169	589	0	3	6	2	11

Fig. II-1-22 Cause of Event and Summary of Event

Cause of event (Note 1) × summary of event	Ordering					Drug					Blood transfusion					Treatment /procedure					Medical equipment, etc. Medical device				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Neglect to check	0	1	3	0	4	10	12	10	10	42	1	1	0	1	3	28	17	25	30	100	4	6	6	4	20
Neglect to observe	0	0	0	0	0	1	2	2	3	8	0	0	0	0	0	14	8	15	19	56	4	4	4	2	14
Misjudgment	0	0	2	0	2	3	6	2	3	14	1	1	1	0	3	17	20	20	21	78	0	1	2	1	4
Lack of knowledge	0	0	1	0	1	4	5	6	6	21	0	1	0	0	1	4	5	8	1	18	0	3	0	3	6
Deficiency of technique/skill	0	0	0	0	0	1	0	0	1	2	0	0	0	0	0	16	18	14	12	60	1	1	2	0	4
Delayed reporting	0	0	1	0	1	0	2	2	0	4	0	1	0	0	1	0	2	4	3	9	0	0	1	0	1
Under unusual physical condition	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	5	6	6	3	20	0	0	1	0	1
Under unusual psychological condition	0	0	0	0	0	1	0	1	0	2	0	0	1	0	1	4	1	4	5	14	0	0	1	0	1
System failure	0	0	1	0	1	2	1	4	3	10	0	0	0	1	1	1	4	0	3	8	2	1	2	1	6
Inadequate coordination	0	1	2	0	3	6	0	3	6	15	0	0	0	1	1	1	7	10	11	29	1	1	2	2	6
Inadequate documentation	0	0	0	0	0	2	1	0	1	4	0	0	0	1	1	1	0	1	1	3	0	0	0	0	0
Similarity in patient’s appearance or name	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0
Busy working condition	0	0	1	0	1	3	1	1	2	7	0	0	0	0	0	1	2	2	4	9	2	0	2	2	6
Problem in environment	0	0	0	0	0	2	0	0	0	2	0	0	0	0	0	3	0	0	3	6	0	0	1	0	1
Problem in the drug	0	0	0	0	0	2	3	3	2	10	0	0	0	0	0	1	1	0	0	2	0	0	0	1	1
Problem in medical device	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	2	3	1	7	0	5	3	5	13
Problem in other items	0	0	0	0	0	0	0	1	0	1	0	1	0	0	1	2	1	0	3	6	2	2	0	0	4
Problem in facility	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	4	1	6	1	0	0	1	2
Problem in education/training	0	0	1	0	1	1	0	2	2	5	0	0	0	0	0	0	2	3	7	12	0	2	2	1	5
Lack of explanation	0	0	0	0	0	2	1	1	3	7	0	0	0	0	0	0	3	8	1	12	1	1	0	1	3
Others	0	0	1	0	1	5	1	1	0	7	0	1	0	0	1	19	34	24	28	105	1	4	0	3	8
No choice (Note 2)	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	8	3	3	3	17	0	0	0	0	0
Total	0	2	13	1	16	45	36	39	42	162	2	7	2	4	15	127	136	155	160	578	19	31	29	27	106

(Note 1) “Cause of event” may have been more than one.

(Note 2) “No choice” means no “cause of event” or “summary of event” was selected.

Medical equipment, etc.										Examination					Nursing care					Others					No choice(Note 2)					Aggregate total
Drainage tube or other tube					Dental equipment																									
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
9	5	10	7	31	0	0	0	1	1	2	4	4	1	11	4	9	16	5	34	7	13	3	7	30	2	3	6	5	16	292
7	3	6	11	27	0	0	0	0	0	0	1	1	0	2	22	21	35	16	94	11	8	7	8	34	3	2	4	3	12	247
2	9	9	8	28	0	0	0	0	0	2	1	1	1	5	14	15	23	14	66	4	7	2	14	27	4	2	5	0	11	238
2	2	5	5	14	0	0	0	1	1	0	0	1	1	2	2	6	3	5	16	1	3	3	4	11	1	0	3	0	4	95
0	5	5	3	13	0	0	0	0	0	3	2	1	1	7	2	4	2	2	10	0	0	1	1	2	1	1	3	0	5	103
1	0	0	1	2	0	0	0	0	0	0	0	1	0	1	1	1	2	2	6	1	0	2	4	7	1	0	0	1	2	34
0	3	1	1	5	0	0	0	0	0	1	0	1	1	3	0	3	2	4	9	6	3	6	4	19	3	0	1	0	4	62
1	2	1	0	4	0	0	0	0	0	0	0	0	0	0	2	1	2	2	7	3	0	0	0	3	1	1	0	1	3	35
0	2	1	0	3	0	0	0	0	0	0	2	1	0	3	0	1	0	2	3	2	6	0	3	11	0	0	1	1	2	48
2	3	2	4	11	0	0	0	0	0	2	3	2	0	7	9	9	5	5	28	6	3	2	2	13	2	0	1	2	5	118
2	0	1	1	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	2	0	0	1	0	1	15
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2
1	1	2	2	6	0	0	0	0	0	0	0	0	0	0	3	5	6	2	16	2	1	1	0	4	0	1	0	0	1	50
0	1	1	0	2	0	0	0	0	0	0	1	0	0	1	3	7	6	3	19	4	2	1	4	11	0	1	1	1	3	45
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	0	0	1	16
2	1	1	2	6	0	0	0	1	1	0	2	1	0	3	0	0	0	0	0	1	2	0	1	4	0	0	1	1	2	37
0	3	2	0	5	0	0	0	0	0	0	1	0	1	2	1	3	1	0	5	2	0	0	1	3	1	0	0	0	1	28
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	5	5	1	16	6	8	0	6	20	1	1	0	0	2	46
2	1	2	1	6	0	0	0	0	0	0	0	2	0	2	1	2	2	4	9	1	3	1	3	8	2	0	1	1	4	52
1	1	0	0	2	0	0	0	0	0	0	4	0	1	5	4	4	12	8	28	8	3	2	3	16	1	0	0	0	1	74
6	8	4	7	25	0	0	0	0	0	6	7	5	3	21	13	17	20	14	64	16	27	17	18	78	1	2	3	1	7	317
2	0	0	2	4	0	0	0	0	0	0	0	0	1	1	6	5	5	2	18	6	9	6	7	28	4	1	0	1	6	75
40	51	53	55	199	0	0	0	3	3	16	28	21	11	76	92	118	147	92	449	87	99	55	90	331	28	16	31	19	94	2,029

Fig. II-1-23 Place of Occurrence and Severity of Event

Place of Occurrence × Severity of Event	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Outpatient examination room	0	0	0	0	0	1	0	1	0	2
Outpatient treatment room	0	0	0	0	0	0	0	0	0	0
Outpatient lobby	0	0	1	0	1	0	0	0	0	0
Emergency room	1	0	0	0	1	0	1	0	0	1
Critical care center	0	0	1	0	1	0	0	1	0	1
Patient room	19	17	17	9	62	16	21	21	13	71
Ward treatment room	0	0	0	0	0	1	0	1	0	2
Operation room	2	3	6	2	13	7	10	7	10	34
ICU	3	3	3	2	11	0	0	1	1	2
CCU	0	0	1	1	2	0	0	0	0	0
NICU	1	0	1	0	2	0	0	0	1	1
Examination room	0	0	1	0	1	0	1	0	1	2
Catheterization laboratory	1	1	2	2	6	3	3	1	2	9
Radiotherapy room	0	0	0	0	0	0	0	0	1	1
Radiography room	1	1	0	0	2	1	1	1	1	4
Radioactive scanning room	0	0	0	0	0	0	0	0	0	0
Dialysis room	0	1	0	0	1	0	0	0	0	0
Delivery room	0	0	0	0	0	0	0	0	0	0
Rehabilitation room	0	0	0	0	0	0	0	0	0	0
Restroom	1	0	1	0	2	3	1	1	0	5
Hallway	0	0	1	1	2	1	2	2	1	6
Bathroom	2	1	1	2	6	1	0	0	1	2
Stairway	0	0	0	1	1	0	0	0	0	0
Unknown	0	0	0	0	0	0	2	0	0	2
Others	10	4	5	9	28	2	5	4	3	14
No choice(Note)	0	1	0	0	1	0	0	0	0	0
Total	41	32	41	29	143	36	47	41	35	159

(Note) “No choice” means no “place of occurrence” or “severity of event” was selected.

Residual disability (unlikely)					Unknown					No choice(Note)					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
3	4	4	2	13	1	0	2	4	7	0	0	0	0	0	22
1	2	1	3	7	0	2	0	1	3	0	1	0	0	1	11
0	2	0	0	2	0	0	0	0	0	0	0	0	0	0	3
2	2	1	0	5	0	1	0	1	2	0	0	0	0	0	9
0	0	0	3	3	0	0	1	0	1	0	0	0	0	0	6
58	63	72	70	263	23	23	9	17	72	2	4	2	1	9	477
4	0	1	4	9	1	0	1	1	3	0	0	0	0	0	14
13	31	19	30	93	8	6	6	8	28	0	1	0	1	2	170
2	5	4	2	13	2	4	2	1	9	0	0	0	0	0	35
1	1	3	0	5	0	0	0	0	0	1	0	0	0	1	8
1	0	0	2	3	0	1	2	1	4	0	0	0	0	0	10
1	5	1	3	10	1	2	2	1	6	0	0	0	0	0	19
9	6	5	6	26	2	2	2	0	6	0	0	0	0	0	47
2	0	1	1	4	0	0	0	0	0	0	0	0	0	0	5
4	1	2	6	13	1	0	1	0	2	0	0	0	0	0	21
0	0	0	0	0	0	0	0	2	2	0	1	0	0	1	3
3	0	0	0	3	0	0	1	0	1	0	0	0	0	0	5
1	0	0	1	2	0	0	0	1	1	0	0	0	0	0	3
0	0	3	1	4	1	0	0	1	2	0	0	0	0	0	6
7	3	7	5	22	1	0	0	2	3	0	0	0	0	0	32
6	8	4	4	22	1	1	3	1	6	0	0	1	0	1	37
1	4	1	2	8	0	1	0	1	2	0	0	0	0	0	18
0	1	1	0	2	0	0	0	0	0	0	0	0	0	0	3
2	0	1	0	3	0	3	0	1	4	0	0	0	0	0	9
5	25	15	11	56	4	10	7	8	29	3	1	1	1	6	133
1	0	2	0	3	1	1	0	0	2	1	1	0	0	2	8
127	163	148	156	594	47	57	39	52	195	7	9	4	3	23	1,114

Fig. II-1-24 Place of Occurrence and Inpatient/Outpatient Status

Place of Occurrence × Inpatient/Outpatient Status	Inpatient					Outpatient				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Outpatient examination room	0	2	1	2	5	4	2	6	2	14
Outpatient treatment room	0	0	1	0	1	1	5	0	3	9
Outpatient lobby	0	0	0	0	0	0	2	1	0	3
Emergency room	0	0	0	1	1	2	4	0	0	6
Critical care center	0	0	1	1	2	0	0	1	0	1
Patient room	86	107	89	94	376	0	0	1	0	1
Ward treatment room	5	0	3	4	12	1	0	0	1	2
Operation room	26	47	28	46	147	0	0	0	1	1
ICU	6	9	10	6	31	0	0	0	0	0
CCU	2	1	3	1	7	0	0	0	0	0
NICU	2	0	1	3	6	0	0	0	0	0
Examination room	1	4	4	2	11	0	4	0	0	4
Catheterization laboratory	14	8	7	8	37	1	1	0	0	2
Radiotherapy room	1	0	1	1	3	1	0	0	0	1
Radiography room	3	2	2	5	12	1	0	1	0	2
Radioactive scanning room	0	1	0	1	2	0	0	0	0	0
Dialysis room	2	1	1	0	4	0	0	0	0	0
Delivery room	1	0	0	2	3	0	0	0	0	0
Rehabilitation room	1	0	2	2	5	0	0	0	0	0
Restroom	9	4	3	7	23	0	0	0	0	0
Hallway	6	10	8	6	30	0	0	0	0	0
Bathroom	3	5	1	5	14	0	0	0	0	0
Stairway	0	1	0	1	2	0	0	0	0	0
Unknown	1	4	1	1	7	0	0	0	0	0
Others	17	24	20	23	84	2	15	5	3	25
No choice(Note)	0	2	1	0	3	2	0	0	0	2
Total	186	232	188	222	828	15	33	15	10	73

(Note) "No choice" means no "place of occurrence" or "inpatient/outpatient status" was selected.

No choice(Note)					Aggregate total
January to March	April to June	July to September	October to December	Total	
1	0	0	2	3	22
0	0	0	1	1	11
0	0	0	0	0	3
1	0	1	0	2	9
0	0	1	2	3	6
32	21	31	16	100	477
0	0	0	0	0	14
4	4	10	4	22	170
1	3	0	0	4	35
0	0	1	0	1	8
0	1	2	1	4	10
1	0	0	3	4	19
0	3	3	2	8	47
0	0	0	1	1	5
3	1	1	2	7	21
0	0	0	1	1	3
1	0	0	0	1	5
0	0	0	0	0	3
0	0	1	0	1	6
3	0	6	0	9	32
2	1	3	1	7	37
1	1	1	1	4	18
0	0	1	0	1	3
1	1	0	0	2	9
5	6	7	6	24	133
1	1	1	0	3	8
57	43	70	43	213	1,114

Fig. II-1-25 Summary of Event and Severity of Event

Summary of Event × Severity of Event	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Ordering	0	0	0	0	0	0	1	0	0	1
Drug	1	1	3	0	5	1	2	2	0	5
Blood transfusion	0	0	0	0	0	0	0	1	0	1
Treatment/procedure	12	11	15	10	48	9	14	15	14	52
Medical equipment, etc.	4	3	1	3	11	5	4	3	7	19
Medical device	2	3	1	1	7	2	1	2	4	9
Drainage tube or other tube	2	0	0	2	4	3	3	1	3	10
Dental equipment	0	0	0	0	0	0	0	0	0	0
Examination/test	2	1	4	1	8	2	4	0	2	8
Nursing care	2	2	7	7	18	8	12	15	4	39
Others	18	13	11	8	50	7	8	5	8	28
No choice(Note)	2	1	0	0	3	4	2	0	0	6
Total	41	32	41	29	143	36	47	41	35	159

(Note) "No choice" means no "summary of event" or "severity of event" was selected.

Residual disability (unlikely)					Unknown					No choice[Note]					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
0	0	4	1	5	0	0	0	0	0	0	0	0	0	0	6
8	6	6	15	35	5	4	2	0	11	0	0	1	0	1	57
1	1	0	0	2	0	2	0	1	3	0	0	0	0	0	6
41	53	34	55	183	14	11	11	13	49	1	2	0	1	4	336
16	18	15	24	73	5	10	12	10	37	1	1	0	0	2	142
1	5	1	4	11	4	4	5	2	15	0	0	0	0	0	42
15	13	14	19	61	1	6	7	7	21	1	1	0	0	2	98
0	0	0	1	1	0	0	0	1	1	0	0	0	0	0	2
5	10	4	5	24	3	4	4	2	13	0	2	0	0	2	55
35	44	51	26	156	11	7	6	13	37	1	3	2	0	6	256
16	27	23	25	91	6	15	3	9	33	3	1	0	2	6	208
5	4	11	5	25	3	4	1	4	12	1	0	1	0	2	48
127	163	148	156	594	47	57	39	52	195	7	9	4	3	23	1,114

Fig. II-1-26 Situation and Severity of Event

	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Related to drug										
Drug preparation	0	0	0	0	0	0	0	0	0	0
Subcutaneous/intramuscular injection	0	0	0	0	0	0	0	0	0	0
Intravenous injection	0	0	1	0	1	0	0	0	0	0
Arterial injection	0	0	0	0	0	0	0	0	0	0
Peripheral intravenous drop	0	0	0	0	0	0	2	1	0	3
Central venous injection	0	1	1	0	2	0	0	0	0	0
Oral administration	0	0	0	0	0	0	1	0	0	1
Nose drop/eye drop/ear drop	0	0	0	0	0	0	0	0	0	0
Other drug prescription/administration	0	0	0	0	0	0	0	1	0	1
Oral drug dispensing/management	0	0	0	0	0	0	0	0	0	0
Injection dispensing/management	0	0	0	0	0	0	0	0	0	0
Dispensing/management, others	1	0	1	0	2	0	0	0	0	0
Related to blood transfusion										
Pre-transfusion testing	0	0	0	0	0	0	0	1	0	1
Blood transfusion	0	0	0	0	0	0	0	0	0	0
Blood transfusion, others	0	0	0	0	0	0	0	0	0	0
Related to treatment/procedure										
Craniotomy	1	0	0	0	1	0	0	0	0	0
Thoracotomy	0	0	2	0	2	1	0	0	0	1
Cardiotomy	0	1	0	1	2	0	0	0	0	0
Laparotomy	0	2	3	3	8	0	2	1	1	4
Extremities	0	1	0	0	1	0	1	0	0	1
Endoscopic surgery	0	0	0	0	0	1	1	3	0	5
Surgery, others	0	0	0	1	1	2	2	1	0	5
Preparation for surgery	0	0	0	0	0	0	0	0	0	0
Preoperative procedure	0	1	0	0	1	0	0	0	0	0
Postoperative procedure	1	0	0	1	2	1	0	1	1	3
Surgery, others	0	1	2	1	4	1	2	0	1	4
General anesthesia (inhalation anesthesia and intravenous anesthesia)	0	0	0	0	0	0	1	0	3	4
Local anesthesia	0	0	0	0	0	0	0	0	0	0
Inhalation anesthesia	0	0	0	0	0	0	0	0	0	0
Intravenous anesthesia	0	0	0	0	0	0	0	0	0	0
Vertebral/epidural anesthesia	0	0	0	0	0	0	0	0	0	0
Anesthesia, others	0	0	0	0	0	1	1	0	0	2
Caesarean section	0	0	0	0	0	0	0	0	0	0
Delivery and artificial abortion, others	1	0	0	0	1	0	0	0	0	0
Blood purification (including hemodialysis)	0	1	0	0	1	0	0	0	0	0
IVR (ex. angiocatheter)	2	1	1	2	6	1	1	3	2	7
Radiotherapy	0	1	0	0	1	0	0	0	0	0
Rehabilitation	0	0	0	0	0	0	0	0	0	0
Invasive dental treatment	0	0	0	0	0	0	0	0	0	0

Residual disability (unlikely)					Unknown					No choice (Note)					
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	Aggregate total
															62
1	0	1	1	3	1	0	0	0	1	0	0	0	0	0	4
1	1	1	0	3	0	0	0	0	0	0	0	0	0	0	3
3	2	0	5	10	0	0	1	0	1	0	0	0	0	0	12
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1
2	0	1	5	8	3	1	0	0	4	0	0	0	0	0	15
0	1	0	1	2	0	2	0	0	2	0	0	0	0	0	6
1	4	3	2	10	0	0	1	0	1	0	0	0	0	0	12
0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	1
0	0	0	1	1	0	0	0	1	1	0	0	0	0	0	3
0	0	1	0	1	0	0	1	0	1	0	0	0	0	0	2
0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
															5
1	1	0	0	2	0	0	0	0	0	0	0	0	0	0	3
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	1
															321
0	1	0	1	2	1	0	0	0	1	0	0	0	0	0	4
1	3	0	2	6	1	0	0	0	1	0	0	0	0	0	10
0	0	0	1	1	1	1	0	0	2	0	0	0	0	0	5
2	5	3	5	15	2	0	0	1	3	0	0	0	1	1	31
1	4	0	0	5	0	0	0	1	1	0	1	0	0	1	9
0	2	4	1	7	0	0	0	2	2	0	0	0	0	0	14
2	4	5	4	15	0	0	1	2	3	0	0	0	0	0	24
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1
0	2	0	0	2	0	0	0	0	0	0	0	0	0	0	3
0	0	2	2	4	0	1	0	0	1	0	0	0	0	0	10
2	5	2	7	16	1	1	1	0	3	0	0	0	0	0	27
1	3	3	1	8	0	1	0	0	1	0	0	0	0	0	13
0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	1
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1
1	1	0	0	2	0	0	0	0	0	0	0	0	0	0	2
1	1	0	1	3	0	0	0	0	0	0	0	0	0	0	3
0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	3
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	1	0	1	2	0	0	0	0	0	3
2	1	0	0	3	0	0	1	0	1	0	0	0	0	0	5
8	1	5	6	20	0	0	2	0	2	0	0	0	0	0	35
1	0	0	0	1	0	0	0	1	1	0	0	0	0	0	3
0	1	4	2	7	1	0	0	1	2	0	0	0	0	0	9
0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	2

	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Endoscopic treatment	0	0	0	1	1	0	1	0	1	2
Treatment, others	0	0	0	0	0	2	1	1	2	6
Central venous line	0	0	0	0	0	0	0	0	0	0
Peripheral venous line	1	0	0	0	1	0	0	0	0	0
Catheter for blood purification	0	0	0	0	0	0	0	0	0	0
Feeding tube (NG, ED)	0	0	1	0	1	0	0	0	0	0
Urethral catheter	0	1	0	0	1	0	0	0	0	0
Drainage procedure	1	0	0	0	1	0	1	0	0	1
Wound care	0	0	0	0	0	0	0	0	0	0
Tube placement, others	2	0	0	0	2	0	0	0	0	0
Tracheal intubation	0	0	1	0	1	0	0	1	0	1
Tracheotomy	0	0	0	0	0	0	0	1	0	1
Cardiac compression	0	0	0	0	0	0	0	0	1	1
Oxygen therapy	0	0	0	0	0	0	0	0	0	0
Emergency procedure, others	1	3	0	1	5	0	0	0	0	0
Related to use/management of medical equipment (device)										
Mechanical ventilator	1	0	1	0	2	0	0	1	1	2
Oxygen therapy equipment	0	1	0	0	1	0	0	0	0	0
Oxygenator	0	1	1	0	2	0	0	0	1	1
Defibrillator	0	0	0	0	0	0	0	0	0	0
Pace maker	0	0	0	0	0	0	0	0	0	0
Infusion/transfusion pump	0	0	0	0	0	0	0	0	0	0
Blood purification device	0	0	0	0	0	0	0	0	0	0
ECG, blood pressure monitor	0	1	0	1	2	0	0	0	0	0
Pulse oxymeter	0	0	0	0	0	0	0	0	1	1
Use/management of medical equipment (device), others	0	0	0	0	0	0	0	1	1	2
Related to use/management of drainage tube or other tube										
Central venous line	0	0	0	1	1	0	0	0	0	0
Peripheral venous line	0	0	0	0	0	0	0	0	1	1
Tracheal tube	0	0	0	0	0	0	0	0	0	0
Tracheal cannula	0	0	0	1	1	0	1	0	0	1
Feeding tube (NG, ED)	0	0	0	0	0	0	0	0	0	0
Urethral catheter	0	0	0	0	0	0	0	0	0	0
Chest drainage tube	0	0	0	0	0	0	1	0	0	1
Abdominal drainage tube	0	0	0	0	0	0	0	0	1	1
Ventricular/cisternal drainage tube	0	0	0	0	0	0	0	0	0	0
Subcutaneous continuous suction drainage tube	0	0	0	0	0	0	0	0	0	0
Epidural catheter	0	0	0	0	0	1	0	0	0	1
Catheter/line for blood purification	1	0	0	0	1	0	0	0	0	0
Use/management of drainage tube or other tube, others	0	1	0	0	1	1	0	1	0	2

Residual disability (unlikely)					Unknown					No choice[Note]					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
0	4	1	1	6	0	1	3	0	4	1	0	0	0	1	14
2	5	6	6	19	1	1	1	2	5	0	0	0	0	0	30
5	3	0	2	10	0	0	0	1	1	0	0	0	0	0	11
0	1	1	0	2	0	1	0	0	1	0	0	0	0	0	4
1	1	0	0	2	0	1	0	0	1	0	0	0	0	0	3
0	1	0	0	1	0	0	1	0	1	0	0	0	0	0	3
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
2	0	0	0	2	1	0	1	0	2	0	0	0	0	0	6
0	0	0	0	0	1	2	0	0	3	0	0	0	0	0	3
2	1	0	2	5	1	3	0	0	4	0	0	0	0	0	11
0	1	0	0	1	0	0	0	1	1	0	0	0	0	0	4
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1
1	1	0	0	2	1	0	0	0	1	0	0	0	0	0	8
															43
2	1	0	1	4	0	0	2	0	2	0	0	1	0	1	11
0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	2
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	4
0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1
0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1
0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	2
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	2
1	4	0	1	6	3	4	0	2	9	0	0	0	0	0	17
															82
2	2	2	0	6	0	1	0	1	2	0	0	0	0	0	9
1	0	0	1	2	0	0	0	0	0	0	0	0	0	0	3
3	3	2	2	10	0	0	0	0	0	0	0	0	0	0	10
0	0	0	2	2	0	0	1	1	2	0	0	0	0	0	6
1	2	2	2	7	0	0	0	0	0	0	0	0	0	0	7
0	0	0	1	1	0	0	0	2	2	0	0	0	0	0	3
0	0	0	4	4	0	0	0	0	0	0	0	0	0	0	5
1	3	3	0	7	0	1	0	1	2	1	0	0	0	1	11
2	0	0	0	2	1	0	0	0	1	0	0	0	0	0	3
1	0	0	0	1	0	0	1	0	1	0	0	0	0	0	2
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
1	0	0	0	1	0	1	0	0	1	0	0	0	0	0	3
3	3	2	3	11	0	1	3	1	5	0	0	0	0	0	19

	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Related to examination										
Blood drawing	0	0	1	0	1	0	1	0	0	1
Sample collection, others	2	0	0	0	2	0	1	0	0	1
General imaging	0	0	0	0	0	0	0	0	0	0
MRI	0	0	0	0	0	0	0	0	0	0
Angiocatheter-aided imaging	0	0	1	0	1	1	2	0	0	3
Lower gastrointestinal imaging	0	0	0	0	0	0	1	0	0	1
Imaging, others	1	0	0	0	1	0	0	0	0	0
Upper gastrointestinal	0	0	2	0	2	0	0	0	0	0
Lower gastrointestinal	0	0	0	0	0	0	0	0	0	0
Bronchoscopy	0	0	0	0	0	0	0	1	0	1
Endoscopic examination, others	0	0	0	0	0	0	0	0	0	0
Pathological examination	0	0	0	0	0	0	0	0	2	2
Examination, others	0	0	0	0	0	0	0	0	0	0
Related to nursing care										
Endotracheal/oral suctioning	0	0	0	0	0	1	0	0	0	1
Changing position	0	0	0	0	0	0	1	1	0	2
Bed bath	0	0	0	0	0	1	0	0	0	1
Help with changing clothes	0	0	0	0	0	0	0	0	0	0
Help with eating	0	0	1	0	1	0	0	1	0	1
Help with bathing	0	0	0	1	1	0	0	0	0	0
Help with elimination	0	0	0	0	0	0	0	1	0	1
Help with moving	0	0	0	0	0	1	1	1	0	3
Transportation	0	0	0	0	0	0	0	0	0	0
Tending patient's belongings	0	0	0	0	0	0	0	1	0	1
Meal serving	0	0	0	0	0	0	0	0	0	0
Patient observation	2	2	0	0	4	0	0	0	4	4
Nursing care, others	0	0	0	1	1	0	2	0	0	2
Oral intake	1	0	0	1	2	1	1	0	0	2
While taking a walk	0	0	0	0	0	0	0	0	0	0
While moving from one place to another	0	0	2	1	3	3	4	2	0	9
While going out/sleeping out	0	0	0	0	0	0	0	0	0	0
While eating	0	0	1	0	1	0	1	2	0	3
While bathing	1	1	1	1	4	1	0	0	1	2
While excreting	1	0	1	0	2	3	1	1	1	6
While sleeping	0	0	0	0	0	1	0	0	0	1
Recuperation, others	3	1	3	0	7	1	1	1	0	3
Others	8	7	7	3	25	2	3	1	3	9
No choice(Note)	9	3	6	7	25	8	8	10	6	32
Total	41	32	41	29	143	36	47	41	35	159

(Note) "No choice" means no "situation" or "severity of event" was selected.

Residual disability (unlikely)					Unknown					No choice(Note)					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
															59
1	3	1	0	5	0	1	0	0	1	0	0	0	0	0	8
2	2	1	1	6	0	0	0	1	1	0	0	0	0	0	10
0	1	0	0	1	0	0	0	1	1	0	0	0	0	0	2
0	0	0	1	1	0	0	1	0	1	0	1	0	0	1	3
0	0	2	2	4	0	0	1	0	1	0	0	0	0	0	9
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	2
0	1	0	1	2	0	0	0	0	0	0	0	0	0	0	4
0	1	1	0	2	0	1	0	2	3	0	1	0	0	1	6
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	2
0	0	1	0	1	0	1	0	0	1	0	0	0	0	0	2
0	0	0	1	1	2	0	1	0	3	0	0	0	0	0	6
0	2	0	0	2	0	0	1	0	1	0	0	0	0	0	3
															267
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	1	1	3	5	0	0	0	0	0	0	0	0	0	0	7
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
2	0	0	0	2	0	0	0	0	0	0	0	0	0	0	2
0	1	0	0	1	0	0	0	1	1	0	0	0	0	0	4
0	1	0	1	2	0	0	0	0	0	0	0	0	0	0	3
4	1	1	0	6	1	0	0	0	1	0	0	0	0	0	8
1	0	2	2	5	2	0	0	0	2	0	1	0	0	1	11
0	1	0	1	2	0	0	0	0	0	0	0	0	0	0	2
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	2
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1
2	2	0	0	4	0	1	0	1	2	0	1	0	0	1	15
5	8	3	4	20	2	2	1	3	8	0	0	0	0	0	31
0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	5
1	0	2	0	3	2	0	0	0	2	0	0	0	0	0	5
10	15	14	9	48	3	0	3	5	11	0	1	0	0	1	72
0	1	0	1	2	0	0	0	0	0	0	0	0	0	0	2
1	0	1	0	2	0	0	0	0	0	0	0	0	0	0	6
1	2	0	0	3	0	0	0	1	1	0	0	0	0	0	10
6	2	9	0	17	1	1	0	0	2	0	0	1	0	1	28
2	3	4	4	13	0	1	1	0	2	0	0	0	0	0	16
4	6	7	3	20	3	0	1	0	4	1	0	0	0	1	35
4	8	3	6	21	4	13	2	3	22	1	1	0	2	4	81
16	17	38	32	103	7	9	3	10	29	2	2	1	0	5	194
127	163	148	156	594	47	57	39	52	195	7	9	4	3	23	1,114

Fig. II-1-27 Details of Event and Severity of Event

	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Related to drug										
Dose error	0	1	0	0	1	0	0	1	0	1
Overdose	0	0	1	0	1	0	0	0	0	0
Dosing speed too fast	0	0	1	0	1	0	0	0	0	0
Patient misidentification	0	0	0	0	0	0	0	0	0	0
Drug mix-up	0	0	0	0	0	0	0	0	0	0
Wrong dosing method	0	0	0	0	0	0	0	1	0	1
Drug prescription/administration, others	0	0	0	0	0	0	3	0	0	3
Dispensing error (wrong dose/number)	0	0	0	0	0	0	0	0	0	0
Dispensing/drug management, others	1	0	0	0	1	0	0	0	0	0
Drug/blood product management, others	0	0	1	0	1	0	0	0	0	0
Related to blood transfusion										
Cross-match error	0	0	0	0	0	0	0	1	0	1
Error in documentation/recording of results	0	0	0	0	0	0	0	0	0	0
Transfusion testing, others	0	0	0	0	0	0	0	0	0	0
Irradiation of blood products, blood transfusion, others	0	0	0	0	0	0	0	0	0	0
Related to treatment/procedure										
Patient misidentification	0	0	0	0	0	0	0	0	0	0
Wrong site treatment/procedure	0	0	0	0	0	0	0	1	0	1
Wrong examination/treatment/procedure, others	0	0	0	0	0	1	0	0	1	2
Wrong method (technique)	2	3	3	0	8	1	1	3	2	7
Neglected/forgotten treatment/procedure	0	0	0	0	0	0	0	0	0	0
Unnecessary treatment/procedure	0	0	0	0	0	0	0	1	0	1
Wrong patient position	0	0	0	0	0	0	1	0	0	1
Wrong examination/treatment, others	0	0	0	2	2	1	0	0	1	2
Aspiration	0	1	0	0	1	0	0	0	0	0
Retained foreign object	0	0	0	0	0	0	0	0	0	0
Treatment/procedure, others	8	9	6	8	31	7	12	6	8	33
Use/management of medical equipment (device)										
Assembly	0	0	1	0	1	0	0	0	0	0
Forgot to set up/turn on power	0	0	0	0	0	0	0	0	0	0
Malfunction	0	0	0	0	0	0	0	0	0	0
Lack of knowledge	0	0	0	0	0	0	0	0	1	1
Forgot to set alarm	0	0	0	0	0	0	0	0	0	0
Range of alarm setup	0	0	0	1	1	0	0	0	0	0
Neglect in inspection/management before or during device operation	0	1	0	0	1	0	0	0	0	0
Error in sterilization/cleaning technique	0	0	0	0	0	0	0	0	1	1
Breakage	0	0	0	0	0	0	0	0	0	0
Use/management of medical equipment (device), others	1	2	1	0	4	0	0	2	2	4

Residual disability (unlikely)					Unknown					No choice(Note)					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
															63
0	2	2	2	6	0	0	0	0	0	0	0	0	0	0	8
2	1	3	4	10	1	2	1	1	5	0	0	0	0	0	16
0	0	0	1	1	1	1	0	0	2	0	0	0	0	0	4
0	0	1	3	4	0	0	1	0	1	0	0	0	0	0	5
1	1	0	1	3	1	0	1	0	2	0	0	0	0	0	5
3	1	1	0	5	1	0	0	0	1	0	0	0	0	0	7
2	3	0	5	10	0	0	0	0	0	0	0	1	0	1	14
0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2
															5
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1
0	1	0	0	1	0	1	0	0	1	0	0	0	0	0	2
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1
															313
0	1	1	0	2	0	0	0	0	0	0	0	0	0	0	2
1	3	3	3	10	1	0	0	0	1	0	0	0	0	0	12
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	3
5	9	4	5	23	1	5	5	1	12	0	0	0	1	1	51
0	1	0	0	1	1	0	0	0	1	0	1	0	0	1	3
1	0	3	1	5	0	0	0	0	0	0	0	0	0	0	6
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
3	1	2	4	10	0	0	2	5	7	0	0	0	0	0	21
1	1	1	0	3	0	0	0	0	0	0	0	0	0	0	4
4	4	5	7	20	2	0	1	2	5	0	0	0	0	0	25
17	35	18	27	97	7	8	3	5	23	1	0	0	0	1	185
															43
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
1	1	0	0	2	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	1	0	1	0	0	1	0	1	2
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	1
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	2	0	2	0	0	0	0	0	3
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	1	0	0	1	2	1	0	1	4	0	0	0	0	0	5
3	4	0	3	10	1	3	2	1	7	0	0	0	0	0	25

	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Related to use/management of drainage tube or other tube										
Infusion leakage	0	0	0	0	0	0	0	0	1	1
Self-removal	1	0	0	0	1	0	0	0	0	0
Spontaneous dislodgment	0	0	0	1	1	0	0	0	0	0
Disconnection	0	0	0	0	0	0	0	0	0	0
Blockage	0	0	0	0	0	0	1	0	0	1
Breakage/severance	0	0	0	0	0	0	0	0	1	1
Wrong connection	0	0	0	0	0	0	0	0	0	0
Air bubble in tube	0	0	0	0	0	0	0	0	0	0
Use/management of drainage tube or other tube, others	0	1	0	1	2	2	1	1	0	4
Related to examination										
Patient misidentification	0	0	0	0	0	0	1	0	0	1
Wrong examination/evaluation technique	0	0	1	0	1	0	0	0	0	0
Error in sample collection	1	0	0	0	1	0	1	0	0	1
Sample misidentification	0	0	0	0	0	0	0	0	1	1
Lost sample	0	0	0	0	0	0	0	0	0	0
Sample contamination	0	0	0	0	0	0	0	0	0	0
Management of analytical device/ equipment	0	0	0	0	0	0	0	0	0	0
Preparation of examination device/ equipment	0	0	0	0	0	0	0	0	0	0
Result reporting	0	0	0	0	0	0	0	0	0	0
Examination, others	2	0	3	0	5	1	3	1	1	6
Related to nursing care										
Fall	0	1	3	1	5	7	6	3	1	17
Fall from bed	0	0	0	0	0	1	1	2	1	5
Collision	0	0	0	0	0	0	0	0	1	1
Restraint	0	0	0	0	0	0	0	0	0	0
Severe decubitus (involving muscle layer, Stage III/IV)	0	0	0	0	0	1	1	1	3	6
Aspiration	0	1	2	1	4	1	2	1	0	4
Accidental ingestion	1	0	0	0	1	0	0	0	0	0
Nursing care/recuperation, others	4	1	1	1	7	3	2	3	0	8
Transportation, others	0	0	0	0	0	0	0	0	0	0
Going out/staying out without notice	0	0	0	0	0	0	0	0	0	0
Self medication, others	2	1	2	1	6	0	1	0	0	1
Meal/nutrition, others	0	0	1	1	2	0	0	1	0	1
Others	8	7	7	3	25	2	3	1	3	9
No choice(Note)	10	3	7	8	28	8	7	11	6	32
Total	41	32	41	29	143	36	47	41	35	159

(Note) "No choice" means no "details of event" or "severity of event" was selected.

Residual disability (unlikely)					Unknown					No choice(Note)					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
															82
1	0	0	1	2	0	0	1	0	1	0	0	0	0	0	4
2	5	2	0	9	0	0	0	2	2	0	0	0	0	0	12
2	2	1	2	7	0	0	1	0	1	0	0	0	0	0	9
3	0	1	3	7	0	0	0	0	0	0	0	0	0	0	7
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	2
1	1	1	1	4	0	1	1	1	3	0	0	0	0	0	8
0	1	0	1	2	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1
6	4	6	6	22	1	3	1	3	8	1	0	0	0	1	37
															59
0	1	1	0	2	0	0	0	0	0	0	0	0	0	0	3
1	0	2	2	5	0	0	0	1	1	0	0	0	0	0	7
1	1	0	0	2	0	0	0	0	0	0	0	0	0	0	4
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1
0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	1
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	1	0	1	1	3	0	0	0	0	0	3
2	6	3	5	16	0	4	3	2	9	0	1	0	0	1	37
															277
25	24	30	19	98	11	1	3	6	21	0	1	1	0	2	143
2	7	4	2	15	1	0	1	1	3	0	0	0	0	0	23
2	0	0	0	2	0	0	0	0	0	0	0	0	0	0	3
0	0	1	0	1	0	1	0	0	1	0	0	0	0	0	2
1	3	7	7	18	0	2	0	0	2	0	0	0	0	0	26
0	1	2	1	4	0	0	0	1	1	0	0	0	0	0	13
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
5	6	2	4	17	0	0	0	2	2	0	1	0	0	1	35
2	3	1	0	6	2	0	0	0	2	0	1	0	0	1	9
1	0	0	0	1	0	0	0	0	0	1	0	0	0	1	2
1	1	1	0	3	1	1	1	1	4	0	0	0	0	0	14
1	0	1	0	2	0	0	1	0	1	0	0	0	0	0	6
4	8	3	6	21	4	13	2	3	22	1	1	0	2	4	81
17	16	34	28	95	6	10	3	12	31	2	2	1	0	5	191
127	163	148	156	594	47	57	39	52	195	7	9	4	3	23	1,114

Fig. II-1-28 Place of Occurrence and Summary of Event

Place of occurrence x summary of event	Ordering					Drug					Blood transfusion					Treatment /procedure					Medical equipment, etc.				
																					Medical device				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Outpatient examination room	0	0	1	0	1	1	1	3	0	5	0	0	0	0	0	2	2	3	1	8	0	0	0	0	0
Outpatient treatment room	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	3	1	3	7	0	0	0	0	0
Outpatient lobby	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0
Emergency room	0	0	0	0	0	1	1	0	0	2	0	0	0	0	0	0	1	1	0	2	0	0	0	0	0
Critical care center	0	0	0	1	1	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0
Patient room	0	0	2	0	2	8	8	7	12	35	0	1	0	0	1	22	22	13	13	70	4	4	4	5	17
Ward treatment room	0	0	0	0	0	1	0	0	1	2	0	0	0	0	0	5	0	3	3	11	0	0	0	0	0
Operation room	0	1	0	0	1	1	0	0	0	1	1	2	0	1	4	20	37	26	40	123	4	5	3	4	16
ICU	0	0	0	0	0	1	1	1	0	3	0	0	0	0	0	4	2	4	4	14	0	1	0	0	1
CCU	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1	1	0	0	2	0	0	0	1	1
NICU	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	2	0	3	0	0	0	0	0
Examination room	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	1	2	6	0	0	0	0	0
Catheterization laboratory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9	6	4	5	24	1	2	1	0	4
Radiotherapy room	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	1	1	4	0	0	0	0	0
Radiography room	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	1	1	2	4	8	0	0	0	0	0
Radioactive scanning room	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0
Dialysis room	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1	1	0	4	0	0	0	0	0
Delivery room	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1	0	0	1	2	0	0	0	0	0
Rehabilitation room	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	2	5	0	0	0	0	0
Restroom	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0
Hallway	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	2	0	0	0	0	0
Bathroom	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Stairway	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	2	0	0	0	1	1
Others	0	0	0	0	0	0	2	2	0	4	0	0	0	0	0	7	7	9	12	35	0	1	1	0	2
No choice(Note)	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0
Total	0	1	4	1	6	15	13	14	15	57	1	3	1	1	6	77	91	75	93	336	9	13	9	11	42

(Note) "No choice" means no "place of occurrence" or "summary of event" was selected.

Medical equipment, etc.										Examination					Nursing care					Others					No choice (Note 2)					Aggregate total
Drainage tube or other tube					Dental equipment																									
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1	0	0	0	1	1	1	0	3	5	0	0	0	1	1	22
0	0	0	1	1	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	11
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	2	0	0	0	0	0	0	0	0	0	0	3
0	1	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1	0	0	3	0	0	0	0	0	9
0	0	0	1	1	0	0	0	0	0	0	0	1	0	1	0	0	0	1	1	0	0	0	0	0	0	0	1	0	1	6
16	13	9	15	53	0	0	0	1	1	2	3	2	0	7	33	46	50	33	162	24	26	26	28	104	9	5	8	3	25	477
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	14
0	1	3	1	5	0	0	0	0	0	0	1	0	2	3	0	0	0	0	0	3	3	3	2	11	1	1	3	1	6	170
2	3	3	2	10	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	3	1	0	4	0	2	0	0	2	35
0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	1	0	0	0	1	0	0	0	0	0	8
1	0	1	1	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	2	2	10
0	0	0	0	0	0	0	0	0	0	2	4	3	1	10	0	0	0	0	0	0	1	0	1	2	0	0	0	1	1	19
0	1	1	1	3	0	0	0	0	0	3	2	3	3	11	0	0	0	0	0	1	1	0	1	3	1	0	1	0	2	47
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	5
2	0	1	1	4	0	0	0	0	0	3	2	1	1	7	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	21
0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	3
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	5
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	6
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	8	0	8	7	23	2	2	1	0	5	2	0	0	0	2	32
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7	8	10	3	28	1	2	1	3	7	0	0	0	0	0	37
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	2	5	0	4	11	2	1	2	1	6	0	0	0	0	0	18
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	3	0	0	0	0	0	0	0	0	0	0	3
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	1	1	0	0	2	0	1	0	0	1	9
1	1	3	5	10	0	0	0	0	0	1	7	2	3	13	4	5	8	1	18	11	20	7	11	49	0	2	0	0	2	133
0	1	0	0	1	0	0	0	0	0	1	0	0	0	1	0	1	0	0	1	0	1	1	0	2	1	0	0	0	1	8
22	23	22	31	98	0	0	0	2	2	12	21	12	10	55	57	68	81	50	256	50	64	42	52	208	15	11	13	9	48	1,114

[4] Details of Reports from Medical Institutions Subject to Reporting Requirement (by Month of Occurrence)

The quarterly tabulation of reports on medical adverse events **occurred in 2005** made by medical institutions subject to reporting requirement between January 1 2005 and March 31, 2006 is shown **by month of occurrence** below.

Fig. II-1-29 Month of Occurrence

Month of occurrence		Number of events
2005	January	103
	February	78
	March	92
	April	102
	May	73
	June	85
	July	101
	August	99
	September	85
	October	99
	November	92
	December	94
	No choice(Note)	0
Total		1,103

(Note) "No choice" means no "month of occurrence" was selected.

Fig. II-1-30 Day of Occurrence and Weekday/Holiday Category

Day of occurrence	Weekday					Holiday					No choice(Note)					Aggregate total
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
Mon.	30	52	31	34	147	6	0	2	1	9	0	0	0	0	0	156
Tue.	50	40	53	46	189	0	0	0	0	0	1	0	1	2	4	193
Wed.	49	40	42	41	172	0	0	0	0	0	1	0	2	0	3	175
Thu.	44	46	59	58	207	0	1	0	1	2	1	1	2	0	4	213
Fri.	38	37	42	58	175	1	1	1	1	4	0	2	0	1	3	182
Sat.	12	7	6	5	30	15	20	22	17	74	1	0	1	2	4	108
Sun.	0	0	0	0	0	20	13	20	16	69	1	0	0	0	1	70
No choice(Note)	1	0	0	0	1	0	0	0	0	0	2	0	1	2	5	6
Total	224	222	233	242	921	42	35	45	36	158	7	3	7	7	24	1,103

(Note) "No choice" means no "day of occurrence" or "weekday/holiday category" was selected.

Fig. II-1-31 Time of Occurrence

Time of occurrence	Number of events				
	January to March	April to June	July to September	October to December	Aggregate total
0:00 – before 2:00	11	12	9	15	47
2:00 – before 4:00	12	7	14	9	42
4:00 – before 6:00	10	11	6	10	37
6:00 – before 8:00	14	10	21	11	56
8:00 – before 10:00	27	26	20	19	92
10:00 – before 12:00	36	35	41	41	153
12:00 – before 14:00	24	20	27	34	105
14:00 – before 16:00	41	44	37	49	171
16:00 – before 18:00	26	32	42	31	131
18:00 – before 20:00	12	15	20	22	69
20:00 – before 22:00	11	16	10	14	51
22:00 – before 24:00	17	13	12	14	56
Time unknown	26	13	18	11	68
No choice(Note)	6	6	8	5	25
Total	273	260	285	285	1,103

(Note) “No choice” means no “time of occurrence” was selected.

Fig. II-1-32 Patient Age

Patient age	Number of events					Inpatient				
	January to March	April to June	July to September	October to December	Aggregate total	January to March	April to June	July to September	October to December	Total
0 to 9	11	9	12	11	43	10	7	6	10	33
10s	4	5	2	6	17	4	4	2	5	15
20s	12	10	6	8	36	12	8	6	7	33
30s	8	16	11	7	42	7	10	9	6	32
40s	18	10	14	14	56	13	7	12	14	46
50s	24	25	23	27	99	21	22	19	25	87
60s	38	31	40	46	155	31	28	34	41	134
70s	56	55	69	71	251	51	47	63	63	224
80s	27	29	25	22	103	25	26	19	20	90
90 or above	4	9	6	7	26	3	6	6	7	22
No choice(Note)	71	61	77	66	275	23	25	26	33	107
Total	273	260	285	285	1,103	200	190	202	231	823

(Note) “No choice” means no “patient age” was selected.

Fig. II-1-33 Sex of Patients

Sex	Number of events				
	January to March	April to June	July to September	October to December	Total
Male	112	97	98	118	425
Female	85	93	104	88	370
No choice(Note)	76	70	83	79	308
Total	273	260	285	285	1,103

(Note) “No choice” means no “sex of patient” was selected.

Fig. II-1-34 Inpatient/Outpatient Status and Duration of Hospital Stay

Inpatient/outpatient status		Number of events				
		January to March	April to June	July to September	October to December	Total
Inpatient	Duration: 0 to 31 days	132	134	140	152	558
	Duration: 32 days or longer	63	50	58	73	244
	No choice(Note)	5	6	4	6	21
	Total	200	190	202	231	823
Outpatient	Initial visit	0	2	1	2	5
	Follow-up visit	17	22	15	11	65
	Total	17	24	16	13	70
No choice(Note)		56	46	67	41	210
Aggregate total		273	260	285	285	1,103

(Note) "No choice" means no "inpatient/outpatient status" or "duration of hospitalization" was selected.

Fig. II-1-35 Person Who Identified Event

Person who identified event	Number of events				
	January to March	April to June	July to September	October to December	Total
Medical staff	194	201	212	233	840
Patient himself/herself	13	7	12	6	38
Patient's family/caregiver	10	9	11	6	36
Other patient	10	14	11	6	41
Others	40	21	31	21	113
No choice(Note)	6	8	8	13	35
Total	273	260	285	285	1,103

(Note) "No choice" means no "person who identified event" was selected.

Fig. II-1-36 Job Title of Person Involved

Job title of person involved (Note 1)	Number of events				
	January to March	April to June	July to September	October to December	Total
Doctor	197	189	180	209	775
Dentist	6	4	6	6	22
Nurse	128	135	158	161	582
Assistant nurse	5	4	1	2	12
Pharmacist	0	1	5	4	10
Clinical engineer	2	1	1	0	4
Midwife	0	1	3	3	7
Nursing assistant	2	2	2	2	8
Radiological technologist	4	2	2	1	9
Clinical technologist	5	1	1	0	7
Physical therapist (PT)	1	1	4	2	8
Occupational therapist (OT)	1	0	0	0	1
Medical technologist	0	0	0	0	0
Dental hygienist	0	0	0	0	0
Others	14	11	18	12	55
No choice(Note 2)	33	26	27	27	113
Total	398	378	408	429	1,613

(Note 1) Person involved is a person determined by the medical institution to have been involved in the event occurred; more than 1 person may have been involved.

(Note 2) "No choice" means no "job title of person involved" was selected.

Fig. II-1-37 Summary of Event

Summary of event	January to March		April to June		July to September		October to December		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Ordering	1	0.4	0	0.0	5	1.8	2	0.7	8	0.7
Drug	9	3.3	15	5.8	11	3.9	15	5.3	50	4.5
Blood transfusion	0	0.0	3	1.2	0	0.0	1	0.4	4	0.4
Treatment/procedure	88	32.2	79	30.4	77	27.0	107	37.5	351	31.8
Medical equipment, etc.	27	9.9	32	12.3	34	11.9	41	14.4	134	12.1
Medical device	8	2.9	13	5.0	10	3.5	7	2.5	38	3.4
Drainage tube or other tube	19	7.0	19	7.3	23	8.1	32	11.2	93	8.4
Dental equipment	0	0.0	0	0.0	1	0.4	2	0.7	3	0.3
Examination/test	17	6.2	12	4.6	16	5.6	6	2.1	51	4.6
Nursing care	60	22.0	70	26.9	69	24.2	61	21.4	260	23.6
Others	53	19.4	42	16.2	59	20.7	46	16.1	200	18.1
No choice(Note)	18	6.6	7	2.7	14	4.9	6	2.1	45	4.1
Total	273	100	260	100	285	100	285	100	1,103	100

(Note) "No choice" means no "summary of event" was selected.

Fig. II-1-38 Severity of Event

Severity of event(Note 1)	January to March		April to June		July to September		October to December		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Death	40	14.7	39	15.0	33	11.6	37	13.0	149	13.5
Potential residual disability (likely)	43	15.8	36	13.8	44	15.4	32	11.2	155	14.1
Potential residual disability (unlikely)	125	45.8	137	52.7	155	54.4	168	58.9	585	53.0
Unknown(Note 2)	58	21.2	41	15.8	49	17.2	44	15.4	192	17.4
No choice(Note 3)	7	2.6	7	2.7	4	1.4	4	1.4	22	2.0
Total	273	100	260	100	285	100	285	100	1,103	100

(Note 1) "Severity of event" is not necessarily associated with occurrence of event or negligence.

(Note 2) "Unknown" includes indefinite outcome at the time of reporting (within 2 weeks) and events of warning that did not affect patients' conditions in any way.

(Note 3) "No choice" means no "severity of event" was selected.

Fig. II-1-39 Place of Occurrence

Place of Occurrence	January to March		April to June		July to September		October to December		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Outpatient examination room	4	1.5	2	0.8	10	3.51	3	1.1	19	1.7
Outpatient treatment room	1	0.4	3	1.2	1	0.35	5	1.8	10	0.9
Outpatient lobby	0	0.0	3	1.2	0	0.0	0	0.0	3	0.3
Emergency room	3	1.1	3	1.2	2	0.7	2	0.7	10	0.9
Critical care center	0	0.0	1	0.4	4	1.4	3	1.1	8	0.7
Patient room	118	43.2	108	41.5	118	41.4	127	44.6	471	42.7
Ward treatment room	1	0.4	1	0.4	4	1.4	5	1.8	11	1.0
Operation room	39	14.3	42	16.2	43	15.1	48	16.8	172	15.6
ICU	8	2.9	12	4.6	8	2.8	4	1.4	32	2.9
CCU	3	1.1	0	0.0	5	1.8	1	0.4	9	0.8
NICU	1	0.4	1	0.4	3	1.1	4	1.4	9	0.8
Examination room	3	1.1	6	2.3	6	2.1	5	1.8	20	1.8
Catheterization laboratory	14	5.1	10	3.8	14	4.9	7	2.5	45	4.1
Radiotherapy room	2	0.7	0	0.0	1	0.4	4	1.4	7	0.6
Radiography room	6	2.2	4	1.5	3	1.1	9	3.2	22	2.0
Radioactive scanning room	1	0.4	0	0.0	2	0.7	0	0.0	3	0.3
Dialysis room	2	0.7	1	0.4	1	0.4	1	0.4	5	0.5
Delivery room	0	0.0	0	0.0	0	0.0	2	0.7	2	0.2
Rehabilitation room	0	0.0	0	0.0	3	1.1	2	0.7	5	0.5
Restroom	11	4.0	5	1.9	7	2.5	10	3.5	33	3.0
Hallway	10	3.7	10	3.8	11	3.9	6	2.1	37	3.4
Bathroom	5	1.8	5	1.9	2	0.7	6	2.1	18	1.6
Stairway	0	0.0	1	0.4	1	0.4	1	0.4	3	0.3
Unknown	4	1.5	1	0.4	2	0.7	0	0.0	7	0.6
Others	35	12.8	38	14.6	32	11.2	30	10.5	135	12.2
No choice(Note)	2	0.7	3	1.2	2	0.7	0	0.0	7	0.6
Total	273	100	260	100	285	100	285	100	1,103	100

(Note) "No choice" means no "place of occurrence" was selected.

Fig. II-1-40 Cause of Event

Cause of Event (Note 1)	January to March		April to June		July to September		October to December		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Neglect to check	55	12.3	72	14.2	85	16.2	70	13.8	282	14.2
Neglect to observe	58	13.0	59	11.6	68	12.9	58	11.4	243	12.2
Misjudgment	50	11.2	66	13.0	56	10.6	69	13.6	241	12.1
Lack of knowledge	15	3.4	30	5.9	27	5.1	21	4.1	93	4.7
Deficiency of technique/skill	26	5.8	30	5.9	19	3.6	21	4.1	96	4.8
Delayed reporting	3	0.7	11	2.2	10	1.9	11	2.2	35	1.8
Under unusual physical condition	16	3.6	16	3.2	17	3.2	11	2.2	60	3.0
Under unusual psychological condition	13	2.9	5	1.0	8	1.5	6	1.2	32	1.6
System failure	10	2.2	10	2.0	7	1.3	16	3.2	43	2.2
Inadequate coordination	22	4.9	30	5.9	28	5.3	30	5.9	110	5.5
Inadequate documentation	3	0.7	4	0.8	6	1.1	1	0.2	14	0.7
Similarity in patient's appearance or name	0	0.0	0	0.0	1	0.2	1	0.2	2	0.1
Busy working condition	13	2.9	13	2.6	10	1.9	14	2.8	50	2.5
Problem in environment	11	2.5	13	2.6	8	1.5	16	3.2	48	2.4
Problem in the drug	2	0.4	7	1.4	3	0.6	5	1.0	17	0.9
Problem in medical device	3	0.7	13	2.6	13	2.5	9	1.8	38	1.9
Problem in other items	9	2.0	6	1.2	6	1.1	4	0.8	25	1.3
Problem in facility	12	2.7	14	2.8	8	1.5	9	1.8	43	2.2
Problem in education/training	4	0.9	10	2.0	22	4.2	20	3.9	56	2.8
Lack of explanation	19	4.3	15	3.0	24	4.6	21	4.1	79	4.0
Others	73	16.3	72	14.2	81	15.4	78	15.4	304	15.3
No choice (Note 2)	30	6.7	11	2.2	19	3.6	16	3.2	76	3.8
Total	447	100	507	100	526	100	507	100	1,987	100

(Note 1) "Cause of event" may be more than one.

(Note 2) "No choice" means no "cause of event" was selected.

Fig. II-1-41 Clinical Department

Clinical Department (Note 1)	January to March		April to June		July to September		October to December		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Internal medicine	23	6.6	36	10.3	33	9.6	27	8.2	119	8.7
Anesthesiology	14	4.0	16	4.6	9	2.6	8	2.4	47	3.4
Cardiovascular medicine	20	5.8	19	5.4	26	7.5	15	4.5	80	5.8
Neurology	14	4.0	10	2.9	4	1.2	10	3.0	38	2.8
Respiratory tract medicine	14	4.0	10	2.9	14	4.1	14	4.2	52	3.8
Gastrointestinal medicine	18	5.2	17	4.9	25	7.2	29	8.8	89	6.5
Hematology	2	0.6	6	1.7	3	0.9	8	2.4	19	1.4
Circulatory surgery	7	2.0	10	2.9	2	0.6	2	0.6	21	1.5
Allergy	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Rheumatism	1	0.3	0	0.0	0	0.0	1	0.3	2	0.1
Pediatrics	12	3.5	13	3.7	10	2.9	12	3.6	47	3.4
General surgery	28	8.1	35	10.0	26	7.5	34	10.3	123	9.0
Orthopedics	24	6.9	37	10.6	32	9.3	28	8.5	121	8.8
Plastic surgery	4	1.2	4	1.1	4	1.2	2	0.6	14	1.0
Cosmetic surgery	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Neurosurgery	23	6.6	19	5.4	14	4.1	16	4.8	72	5.3
Respiratory surgery	8	2.3	3	0.9	12	3.5	7	2.1	30	2.2
Cardiovascular surgery	17	4.9	10	2.9	25	7.2	16	4.8	68	5.0
Pediatric surgery	2	0.6	3	0.9	0	0.0	4	1.2	9	0.7
Pain clinic	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Dermatology	8	2.3	4	1.1	6	1.7	2	0.6	20	1.5
Urology	14	4.0	8	2.3	9	2.6	8	2.4	39	2.8
Venereology	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Proctology	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Gynecology/Obstetrics	3	0.9	7	2.0	4	1.2	0	0.0	14	1.0
Obstetrics	0	0.0	0	0.0	2	0.6	5	1.5	7	0.5
Gynecology	3	0.9	4	1.1	6	1.7	3	0.9	16	1.2
Ophthalmology	2	0.6	6	1.7	7	2.0	8	2.4	23	1.7
Otolaryngology	4	1.2	4	1.1	8	2.3	8	2.4	24	1.8
Psychosomatic medicine	2	0.6	0	0.0	1	0.3	0	0.0	3	0.2
Psychiatry	20	5.8	20	5.7	19	5.5	10	3.0	69	5.0
Rehabilitation	3	0.9	6	1.7	3	0.9	2	0.6	14	1.0
Radiology	10	2.9	6	1.7	6	1.7	10	3.0	32	2.3
Dentistry	0	0.0	3	0.9	2	0.6	0	0.0	5	0.4
Orthodontics	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pediatric dentistry	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Dental/oral surgery	3	0.9	3	0.9	5	1.4	8	2.4	19	1.4
Others	33	9.5	25	7.1	20	5.8	24	7.3	102	7.4
No choice (Note 2)	10	2.9	6	1.7	8	2.3	9	2.7	33	2.4
Total	346	100	350	100	345	100	330	100	1,371	100

(Note 1) More than one “clinical department” may have been involved in one event.

(Note 2) “No choice” means no “clinical department” was selected.

Fig. II-1-42 Years of Experience of Person Involved by Job Title (Doctor, Dentist, Nurse, Pharmacist)

Years of experience × Job title of person involved (Note 1)	Doctor					Dentist				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
0 year	5	5	3	7	20	0	0	0	1	1
1 year	10	3	5	4	22	1	0	2	0	3
2 years	11	7	9	12	39	0	0	0	1	1
3 years	12	9	7	13	41	0	0	0	0	0
4 years	10	9	10	11	40	0	0	0	2	2
5 years	8	11	10	4	33	1	1	0	0	2
6 years	4	9	9	7	29	0	2	0	0	2
7 years	4	8	11	7	30	2	0	1	0	3
8 years	4	9	2	7	22	0	0	0	0	0
9 years	8	12	6	11	37	0	0	0	0	0
10 years	10	5	9	9	33	0	0	1	0	1
11 to 20 years	60	62	51	73	246	2	0	1	1	4
21 to 30 years	18	20	18	21	77	0	0	1	1	2
30 years or longer	7	3	2	3	15	0	0	0	0	0
No choice (Note 2)	26	17	28	20	91	0	1	0	0	1
Total	197	189	180	209	775	6	4	6	6	22

(Note 1) Person involved is a person determined by the medical institution to have been involved in the event occurred; more than 1 person may have been involved.

(Note 2) "No choice" means no "years of experience" was selected.

Nurse					Pharmacist				
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
11	4	23	15	53	0	0	1	2	3
10	10	8	20	48	0	0	0	0	0
14	15	12	15	56	0	0	0	0	0
10	17	12	13	52	0	0	0	0	0
8	3	15	7	33	0	0	1	0	1
10	9	6	9	34	0	0	0	0	0
3	2	6	3	14	0	0	0	0	0
5	7	8	3	23	0	0	0	0	0
7	6	2	4	19	0	0	0	1	1
5	1	1	4	11	0	0	0	0	0
4	4	1	4	13	0	0	0	0	0
10	25	27	24	86	0	1	1	0	2
14	14	11	22	61	0	0	1	0	1
3	5	4	4	16	0	0	0	1	1
14	13	22	14	63	0	0	1	0	1
128	135	158	161	582	0	1	5	4	10

Fig. II-1-43 Number of Years Person Involved (Doctor, Dentist, Nurse, Pharmacist) Has Been Working at Current Department

Number of years at current department × Job title of person involved(Note 1)	Doctor					Dentist				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
0 year	34	34	27	30	125	0	1	1	1	3
1 year	27	22	21	30	100	0	1	1	1	3
2 years	11	20	22	16	69	0	0	1	2	3
3 years	19	16	11	24	70	1	0	0	0	1
4 years	7	9	10	11	37	0	0	1	1	2
5 years	6	7	17	7	37	0	1	0	0	1
6 years	2	11	5	10	28	0	0	0	0	0
7 years	5	2	5	3	15	0	0	0	0	0
8 years	3	5	4	7	19	0	0	0	0	0
9 years	6	2	3	5	16	0	0	0	0	0
10 years	2	1	1	3	7	0	0	0	0	0
11 to 20 years	29	27	14	25	95	0	0	1	0	1
21 to 30 years	3	4	5	3	15	0	0	1	0	1
30 years or longer	1	0	0	0	1	0	0	0	0	0
No choice(Note 2)	42	29	35	35	141	5	1	0	1	7
Total	197	189	180	209	775	6	4	6	6	22

(Note 1) Person involved is a person determined by the medical institution to have been involved in the event occurred; more than 1 person may have been involved.

(Note 2) “No choice” means no “number of years at current department” was selected.

Nurse					Pharmacist				
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
26	17	41	38	122	0	0	1	3	4
24	26	21	36	107	0	1	0	0	1
19	28	19	24	90	0	0	0	1	1
18	17	15	15	65	0	0	0	0	0
8	5	13	9	35	0	0	1	0	1
8	10	7	9	34	0	0	1	0	1
0	1	6	0	7	0	0	0	0	0
2	6	1	3	12	0	0	0	0	0
2	2	2	3	9	0	0	0	0	0
1	0	1	3	5	0	0	0	0	0
0	0	2	1	3	0	0	0	0	0
2	3	2	1	8	0	0	0	0	0
1	0	1	0	2	0	0	1	0	1
1	0	0	0	1	0	0	0	0	0
16	20	27	19	82	0	0	1	0	1
128	135	158	161	582	0	1	5	4	10

Fig. II-1-44 Cause of Event and Summary of Event

Cause of event (Note 1) × summary of event	Ordering					Drug					Blood transfusion					Treatment /procedure					Medical equipment, etc. / Medical device				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Neglect to check	1	0	3	2	6	7	14	9	10	40	0	1	0	1	2	23	20	24	32	99	2	8	6	1	17
Neglect to observe	0	0	0	0	0	1	1	3	2	7	0	0	0	0	0	15	6	17	16	54	4	5	3	1	13
Misjudgment	0	0	2	0	2	3	6	0	3	12	0	2	0	0	2	20	20	13	28	81	0	2	1	1	4
Lack of knowledge	0	0	1	0	1	3	7	1	7	18	0	1	0	0	1	3	7	6	3	19	0	4	2	0	6
Deficiency of technique/skill	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	15	16	10	14	55	1	1	1	0	3
Delayed reporting	0	0	1	0	1	0	2	1	0	3	0	1	0	0	1	0	4	2	4	10	0	1	0	0	1
Under unusual physical condition	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8	5	5	3	21	0	1	0	0	1
Under unusual psychological condition	0	0	0	0	0	1	0	1	0	2	0	1	0	0	1	5	2	3	4	14	0	1	0	0	1
System failure	0	0	1	0	1	2	2	1	4	9	0	0	0	1	1	1	3	1	4	9	1	1	2	1	5
Inadequate coordination	1	0	2	1	4	5	2	2	4	13	0	0	0	1	1	1	12	10	9	32	0	3	1	1	5
Inadequate documentation	0	0	0	0	0	2	1	2	0	5	0	0	0	1	1	0	1	1	0	2	0	0	0	0	0
Similarity in patient's appearance or name	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0
Busy working condition	0	0	1	0	1	3	1	1	2	7	0	0	0	0	0	2	2	1	5	10	1	1	2	1	5
Problem in environment	0	0	0	0	0	2	0	0	0	2	0	0	0	0	0	2	0	1	3	6	0	1	0	0	1
Problem in drug	0	0	0	0	0	1	4	2	2	9	0	0	0	0	0	1	1	0	0	2	0	0	1	0	1
Problem in medical device	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	2	4	1	8	1	5	5	4	15
Problem in other items	0	0	0	0	0	0	0	1	0	1	0	1	0	0	1	1	1	0	3	5	3	0	1	0	4
Problem in facility	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1	0	4	1	6	0	0	0	1	1
Problem in education/training	0	0	1	0	1	0	0	2	2	4	0	0	0	0	0	0	3	4	8	15	0	2	3	0	5
Lack of explanation	0	0	0	0	0	2	0	0	3	5	0	0	0	0	0	0	6	9	1	16	1	1	0	1	3
Others	0	0	1	0	1	2	0	1	0	3	0	0	0	0	0	27	27	22	36	112	0	3	1	2	6
No choice (Note 2)	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	9	3	3	4	19	0	0	0	0	0
Total	2	0	14	4	20	34	40	27	40	141	0	8	0	4	12	135	141	141	179	596	14	40	29	14	97

(Note 1) "Cause of event" may have been more than one.

(Note 2) "No choice" means no "cause of event" or "summary of event" was selected.

Medical equipment, etc.										Examination					Nursing care					Others					No choice(Note 2)					Aggregate total
Drainage tube or other tube					Dental equipment																									
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
6	6	10	8	30	0	0	1	0	1	4	1	4	1	10	3	10	16	7	36	7	7	7	5	26	2	5	5	3	15	282
4	5	5	13	27	0	0	0	0	0	0	1	1	0	2	23	30	28	18	99	9	9	7	6	31	2	2	4	2	10	243
4	6	11	9	30	0	0	0	0	0	1	1	1	2	5	14	21	17	18	70	3	6	8	7	24	5	2	3	1	11	241
2	3	5	4	14	0	0	0	1	1	0	0	2	1	3	4	3	5	3	15	2	4	3	2	11	1	1	2	0	4	93
1	6	3	4	14	0	0	0	0	0	3	2	1	1	7	4	1	3	1	9	0	1	1	0	2	2	3	0	0	5	96
0	0	1	2	3	0	0	0	0	0	0	0	1	0	1	1	2	1	2	6	1	1	3	2	7	1	0	0	1	2	35
1	3	0	1	5	0	0	0	0	0	1	0	2	1	4	0	3	2	4	9	4	4	7	2	17	2	0	1	0	3	60
2	1	1	0	4	0	0	0	0	0	0	0	0	0	0	2	0	2	2	6	2	0	0	0	2	1	0	1	0	2	32
0	2	1	0	3	0	0	0	0	0	1	1	0	0	2	1	0	0	2	3	4	1	0	3	8	0	0	1	1	2	43
0	3	1	4	8	0	0	0	0	0	2	1	2	0	5	10	6	6	7	29	2	3	2	2	9	1	0	2	1	4	110
1	1	1	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	2	0	0	1	0	1	14
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2
1	2	1	2	6	0	0	0	0	0	0	0	0	0	0	4	7	3	3	17	1	0	1	1	3	1	0	0	0	1	50
1	0	1	0	2	0	0	0	0	0	0	1	0	0	1	3	8	4	8	23	3	2	1	4	10	0	1	1	1	3	48
0	1	0	0	1	0	0	0	0	0	0	0	0	1	1	0	0	0	2	2	0	0	0	0	0	0	1	0	0	1	17
1	2	1	2	6	0	0	1	1	2	0	2	0	0	2	0	0	0	0	0	0	1	0	1	2	0	0	2	0	2	38
0	2	1	0	3	0	0	0	0	0	1	0	1	0	2	2	2	1	1	6	1	0	1	0	2	1	0	0	0	1	25
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	8	2	1	15	6	5	2	5	18	1	1	0	0	2	43
1	2	1	1	5	0	0	0	0	0	0	0	3	1	4	0	2	2	6	10	2	1	5	1	9	1	0	1	1	3	56
2	0	0	0	2	0	0	0	0	0	1	3	0	2	6	7	3	11	11	32	6	2	4	3	15	0	0	0	0	0	79
5	4	5	6	20	0	0	0	0	0	7	4	6	0	17	9	17	19	14	59	20	17	22	20	79	3	0	4	0	7	304
2	0	0	2	4	0	0	0	0	0	0	0	0	1	1	9	2	5	2	18	6	6	10	6	28	4	0	0	1	5	76
34	49	49	58	190	0	0	2	2	4	21	17	24	11	73	100	125	127	112	464	79	71	85	70	305	28	16	28	13	85	1,987

Fig. II-1-45 Place of Occurrence and Severity of Event

Place of Occurrence × Severity of Event	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Outpatient examination room	0	0	0	0	0	0	0	1	0	1
Outpatient treatment room	0	0	0	0	0	0	0	0	0	0
Outpatient lobby	0	1	0	0	1	0	0	0	0	0
Emergency room	1	0	0	0	1	0	1	0	0	1
Critical care center	0	0	1	1	2	0	1	0	0	1
Patient room	19	14	13	16	62	16	19	20	14	69
Ward treatment room	0	0	0	0	0	0	0	1	1	2
Operation room	2	8	2	3	15	11	5	10	7	33
ICU	5	3	1	1	10	0	0	1	1	2
CCU	0	0	2	0	2	0	0	0	1	1
NICU	1	0	1	0	2	0	0	0	1	1
Examination room	0	0	1	2	3	1	0	1	0	2
Catheterization laboratory	0	3	1	1	5	2	3	4	0	9
Radiotherapy room	0	0	0	1	1	0	0	0	1	1
Radiography room	1	1	0	2	4	1	2	0	1	4
Radioactive scanning room	0	0	0	0	0	0	0	0	0	0
Dialysis room	0	1	0	1	2	0	0	0	0	0
Delivery room	0	0	0	0	0	0	0	0	0	0
Rehabilitation room	0	0	0	0	0	0	0	0	0	0
Restroom	0	0	1	1	2	3	1	0	0	4
Hallway	0	0	2	0	2	2	2	2	0	6
Bathroom	2	1	1	2	6	1	0	0	1	2
Stairway	0	0	0	1	1	0	0	0	0	0
Unknown	0	0	0	0	0	2	0	0	0	2
Others	9	6	7	5	27	4	2	4	4	14
No choice(Note)	0	1	0	0	1	0	0	0	0	0
Total	40	39	33	37	149	43	36	44	32	155

(Note) "No choice" means no "place of occurrence" or "severity of event" was selected.

Residual disability (unlikely)					Unknown					No choice(Note)					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
3	2	4	2	11	1	0	5	1	7	0	0	0	0	0	19
0	2	1	4	7	1	0	0	1	2	0	1	0	0	1	10
0	2	0	0	2	0	0	0	0	0	0	0	0	0	0	3
2	1	1	2	6	0	1	1	0	2	0	0	0	0	0	10
0	0	2	2	4	0	0	1	0	1	0	0	0	0	0	8
55	56	71	82	264	26	17	11	15	69	2	2	3	0	7	471
1	0	2	4	7	0	1	1	0	2	0	0	0	0	0	11
18	23	25	27	93	8	5	6	9	28	0	1	0	2	3	172
2	5	4	1	12	1	4	2	1	8	0	0	0	0	0	32
2	0	3	0	5	0	0	0	0	0	1	0	0	0	1	9
0	0	0	2	2	0	1	2	1	4	0	0	0	0	0	9
0	5	2	2	9	2	1	2	1	6	0	0	0	0	0	20
8	4	7	6	25	4	0	2	0	6	0	0	0	0	0	45
2	0	1	1	4	0	0	0	1	1	0	0	0	0	0	7
4	1	2	6	13	0	0	1	0	1	0	0	0	0	0	22
0	0	0	0	0	0	0	2	0	2	1	0	0	0	1	3
2	0	0	0	2	0	0	1	0	1	0	0	0	0	0	5
0	0	0	1	1	0	0	0	1	1	0	0	0	0	0	2
0	0	3	1	4	0	0	0	1	1	0	0	0	0	0	5
7	4	5	7	23	1	0	1	2	4	0	0	0	0	0	33
6	7	4	4	21	2	1	2	2	7	0	0	1	0	1	37
1	4	1	2	8	1	0	0	1	2	0	0	0	0	0	18
0	1	1	0	2	0	0	0	0	0	0	0	0	0	0	3
1	0	1	0	2	1	1	1	0	3	0	0	0	0	0	7
10	20	13	12	55	9	8	8	7	32	3	2	0	2	7	135
1	0	2	0	3	1	1	0	0	2	0	1	0	0	1	7
125	137	155	168	585	58	41	49	44	192	7	7	4	4	22	1,103

Fig. II-1-46 Place of Occurrence and Inpatient/Outpatient Status

Place of Occurrence × Inpatient/Outpatient Status	Inpatient					Outpatient				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Outpatient examination room	1	1	1	2	5	2	1	8	0	11
Outpatient treatment room	0	0	1	0	1	1	3	0	4	8
Outpatient lobby	0	0	0	0	0	0	3	0	0	3
Emergency room	0	0	1	1	2	2	3	0	1	6
Critical care center	0	1	1	2	4	0	0	1	0	1
Patient room	84	90	90	107	371	0	1	0	0	1
Ward treatment room	1	1	4	4	10	0	0	0	1	1
Operation room	36	37	33	44	150	0	0	0	1	1
ICU	6	10	8	4	28	0	0	0	0	0
CCU	3	0	4	1	8	0	0	0	0	0
NICU	1	0	1	3	5	0	0	0	0	0
Examination room	1	3	5	3	12	1	3	0	0	4
Catheterization laboratory	11	6	11	6	34	2	0	0	0	2
Radiotherapy room	1	0	1	2	4	1	0	0	1	2
Radiography room	4	3	1	5	13	1	0	1	1	3
Radioactive scanning room	1	0	1	0	2	0	0	0	0	0
Dialysis room	1	1	1	1	4	0	0	0	0	0
Delivery room	0	0	0	2	2	0	0	0	0	0
Rehabilitation room	0	0	2	2	4	0	0	0	0	0
Restroom	9	3	3	9	24	0	0	0	0	0
Hallway	8	9	7	6	30	0	0	0	0	0
Bathroom	4	4	1	5	14	0	0	0	0	0
Stairway	0	1	0	1	2	0	0	0	0	0
Unknown	4	0	2	0	6	0	0	0	0	0
Others	24	18	22	21	85	5	10	6	4	25
No choice(Note)	0	2	1	0	3	2	0	0	0	2
Total	200	190	202	231	823	17	24	16	13	70

(Note) “No choice” means no “place of occurrence” or “inpatient/outpatient status” was selected.

No choice(Note)					Aggregate total
January to March	April to June	July to September	October to December	Total	
1	0	1	1	3	19
0	0	0	1	1	10
0	0	0	0	0	3
1	0	1	0	2	10
0	0	2	1	3	8
34	17	28	20	99	471
0	0	0	0	0	11
3	5	10	3	21	172
2	2	0	0	4	32
0	0	1	0	1	9
0	1	2	1	4	9
1	0	1	2	4	20
1	4	3	1	9	45
0	0	0	1	1	7
1	1	1	3	6	22
0	0	1	0	1	3
1	0	0	0	1	5
0	0	0	0	0	2
0	0	1	0	1	5
2	2	4	1	9	33
2	1	4	0	7	37
1	1	1	1	4	18
0	0	1	0	1	3
0	1	0	0	1	7
6	10	4	5	25	135
0	1	1	0	2	7
56	46	67	41	210	1,103

Fig. II-1-47 Summary of Event and Severity of Event

Summary of Event × Severity of Event	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Ordering	0	0	0	0	0	1	0	0	0	1
Drug	1	2	1	0	4	0	3	0	0	3
Blood transfusion	0	0	0	0	0	0	1	0	0	1
Treatment/procedure	11	19	7	19	56	15	9	19	15	58
Medical equipment, etc.	4	3	2	2	11	5	3	2	7	17
Medical device	2	3	2	0	7	2	2	1	3	8
Drainage tube or other tube	2	0	0	2	4	3	1	1	4	9
Dental equipment	0	0	0	0	0	0	0	0	0	0
Examination/test	1	2	4	1	8	4	2	2	0	8
Nursing care	3	2	6	9	20	8	12	12	5	37
Others	18	11	13	6	48	8	4	9	4	25
No choice(Note)	2	0	0	0	2	2	2	0	1	5
Total	40	39	33	37	149	43	36	44	32	155

(Note) “No choice” means no “summary of event” or “severity of event” was selected.

Residual disability (unlikely)					Unknown					No choice(Note)					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
0	0	5	2	7	0	0	0	0	0	0	0	0	0	0	8
5	5	8	15	33	3	4	2	0	9	0	1	0	0	1	50
0	1	0	0	1	0	1	0	1	2	0	0	0	0	0	4
45	37	41	56	179	16	12	10	14	52	1	2	0	3	6	351
13	14	16	25	68	4	12	14	7	37	1	0	0	0	1	134
1	3	3	4	11	3	5	4	0	12	0	0	0	0	0	38
12	11	13	20	56	1	7	9	6	23	1	0	0	0	1	93
0	0	0	1	1	0	0	1	1	2	0	0	0	0	0	3
6	6	5	4	21	5	1	5	1	12	1	1	0	0	2	51
36	48	42	34	160	12	5	7	13	37	1	3	2	0	6	260
12	22	29	28	91	12	5	7	7	31	3	0	1	1	5	200
8	4	9	4	25	6	1	4	1	12	0	0	1	0	1	45
125	137	155	168	585	58	41	49	44	192	7	7	4	4	22	1,103

Fig. II-1-48 Situation and Severity of Event

Situation × Severity of Event	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Related to drug										
Drug preparation	0	0	0	0	0	0	0	0	0	0
Subcutaneous/intramuscular injection	0	0	0	0	0	0	0	0	0	0
Intravenous injection	1	0	0	0	1	0	0	0	1	1
Arterial injection	0	0	0	0	0	0	0	0	0	0
Peripheral intravenous drop	0	0	0	0	0	0	2	0	0	2
Central venous injection	0	2	0	0	2	0	0	0	0	0
Oral administration	0	0	0	0	0	0	1	0	0	1
Nose drop/eye drop/ear drop	0	0	0	0	0	0	0	0	0	0
Other drug prescription/administration	0	0	0	0	0	0	1	0	0	1
Oral drug dispensing/management	0	0	0	0	0	0	0	0	0	0
Injection dispensing/management	0	0	0	0	0	0	0	0	0	0
Dispensing/management, others	0	0	1	0	1	0	0	0	0	0
Related to blood transfusion										
Pre-transfusion testing	0	0	0	0	0	0	1	0	0	1
Blood transfusion	0	0	0	0	0	0	0	0	0	0
Blood transfusion, others	0	0	0	0	0	0	0	0	0	0
Related to treatment/procedure										
Craniotomy	1	0	0	0	1	0	0	0	0	0
Thoracotomy	0	2	0	0	2	0	0	0	1	1
Cardiotomy	0	1	1	1	3	0	0	0	0	0
Laparotomy	0	4	1	3	8	1	0	1	1	3
Extremities	0	1	0	0	1	0	1	0	0	1
Endoscopic surgery	0	0	0	0	0	1	0	3	0	4
Surgery, others	0	0	0	2	2	2	3	0	0	5
Preparation for surgery	0	0	0	0	0	0	0	0	0	0
Preoperative procedure	1	0	0	0	1	0	0	0	0	0
Postoperative procedure	0	0	1	0	1	1	0	1	1	3
Surgery, others	1	1	1	1	4	2	0	1	4	7
General anesthesia (inhalation anesthesia and intravenous anesthesia)	0	0	0	0	0	1	0	1	2	4
Local anesthesia	0	0	0	0	0	0	0	0	0	0
Inhalation anesthesia	0	0	0	0	0	0	0	0	0	0
Intravenous anesthesia	0	0	0	0	0	0	0	0	0	0
Vertebral/epidural anesthesia	0	0	0	0	0	0	0	0	0	0
Anesthesia, others	0	0	0	0	0	2	0	0	0	2
Caesarean section	0	0	0	1	1	0	0	0	0	0
Delivery and artificial abortion, others	0	0	0	0	0	0	0	0	0	0
Blood purification (including hemodialysis)	0	1	0	1	2	0	0	0	0	0
IVR (ex. Angiocatheter)	1	2	1	1	5	0	2	4	1	7
Radiotherapy	1	0	0	0	1	0	0	0	0	0
Rehabilitation	0	0	0	0	0	0	0	0	0	0
Invasive dental treatment	0	0	0	0	0	0	0	0	0	0

Residual disability (unlikely)					Unknown					No choice(Note)					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
															60
1	0	1	3	5	1	0	0	0	1	0	0	0	0	0	6
2	0	1	0	3	0	0	0	0	0	0	0	0	0	0	3
2	2	1	5	10	0	0	1	0	1	0	0	0	0	0	13
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1
1	0	1	6	8	1	1	0	0	2	0	0	0	0	0	12
0	1	1	0	2	0	2	0	0	2	0	0	0	0	0	6
1	2	5	1	9	0	0	1	0	1	0	0	0	0	0	11
0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1
0	0	0	1	1	0	0	1	0	1	0	0	0	0	0	3
0	0	1	0	1	0	0	1	0	1	0	0	0	0	0	2
0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
															3
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	2
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
															324
1	0	0	1	2	1	0	0	0	1	0	0	0	0	0	4
2	1	1	2	6	1	0	0	0	1	0	0	0	0	0	10
0	0	1	1	2	2	0	0	0	2	0	0	0	0	0	7
2	3	3	6	14	2	0	1	0	3	0	0	0	1	1	29
3	2	0	0	5	0	0	1	0	1	0	1	0	0	1	9
1	3	2	1	7	0	0	1	1	2	0	0	0	1	1	14
4	4	5	3	16	0	1	1	1	3	0	0	0	0	0	26
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1
0	2	0	1	3	0	0	0	0	0	0	0	0	0	0	4
0	0	2	2	4	0	1	0	1	2	0	0	0	0	0	10
5	3	5	4	17	0	2	0	1	3	0	0	0	0	0	31
1	2	4	1	8	0	1	0	1	2	0	0	0	0	0	14
0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1
0	1	0	1	2	0	0	0	0	0	0	0	0	0	0	2
0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	3
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	1	0	1	2	0	0	0	0	0	2
2	0	1	0	3	0	0	1	0	1	0	0	0	0	0	6
8	1	4	7	20	0	1	1	0	2	0	0	0	0	0	34
1	0	0	0	1	0	0	1	1	2	0	0	0	0	0	4
0	1	5	1	7	1	0	0	1	2	0	0	0	0	0	9
0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	2

Situation × Severity of Event	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Endoscopic treatment	0	0	0	3	3	1	0	0	1	2
Treatment, others	0	0	0	0	0	3	0	2	0	5
Central venous line	0	0	0	0	0	0	0	0	0	0
Peripheral venous line	1	0	0	1	2	0	0	0	0	0
Catheter for blood purification	0	0	0	0	0	0	0	0	0	0
Feeding tube (NG, ED)	0	1	0	0	1	0	0	0	0	0
Urethral catheter	1	0	0	0	1	0	0	0	0	0
Drainage procedure	1	0	0	0	1	0	0	0	1	1
Wound care	0	0	0	0	0	0	0	0	0	0
Tube placement, others	1	0	0	0	1	0	0	0	0	0
Tracheal intubation	0	1	0	0	1	0	1	0	0	1
Tracheotomy	0	0	0	1	1	0	0	1	0	1
Cardiac compression	0	0	0	0	0	0	0	0	1	1
Oxygen therapy	0	0	0	0	0	0	0	0	0	0
Emergency procedure, others	2	2	0	1	5	0	0	0	0	0
Related to use/management of medical equipment (device)										
Mechanical ventilator	1	0	1	0	2	0	1	0	1	2
Oxygen therapy equipment	0	1	0	0	1	0	0	0	0	0
Oxygenator	0	2	0	0	2	0	0	0	1	1
Defibrillator	0	0	0	0	0	0	0	0	0	0
Pace maker	0	0	0	0	0	0	0	0	0	0
Infusion/transfusion pump	0	0	0	0	0	0	0	0	0	0
ECG, blood pressure monitor	0	0	1	0	1	0	0	0	0	0
Pulse oxymeter	0	0	0	0	0	0	0	0	1	1
Use/management of medical equipment (device), others	0	0	0	0	0	0	1	1	0	2
Related to use/management of drainage tube or other tube										
Central venous line	0	0	0	1	1	0	0	0	0	0
Peripheral venous line	0	0	0	0	0	0	0	0	1	1
Tracheal tube	0	0	0	0	0	0	0	0	0	0
Tracheal cannula	0	0	0	1	1	0	1	0	1	2
Feeding tube (NG, ED)	0	0	0	0	0	0	0	0	0	0
Urethral catheter	0	0	0	0	0	0	0	0	0	0
Chest drainage tube	0	0	0	0	0	1	0	0	0	1
Abdominal drainage tube	0	0	0	0	0	0	0	0	1	1
Ventricular/cisternal drainage tube	0	0	0	0	0	0	0	0	0	0
Subcutaneous continuous suction drainage tube	0	0	0	0	0	0	0	0	0	0
Epidural catheter	0	0	0	0	0	0	0	0	0	0
Catheter/line for blood purification	1	0	0	0	1	0	0	0	0	0
Use/management of drainage tube or other tube, others	0	1	0	0	1	1	0	2	0	3

Residual disability (unlikely)					Unknown					No choice(Note)					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
1	3	2	1	7	1	1	2	0	4	1	0	0	0	1	17
1	8	3	5	17	1	1	1	2	5	0	0	0	0	0	27
3	2	1	3	9	0	0	0	1	1	0	0	0	0	0	10
0	1	1	0	2	0	1	0	0	1	0	0	0	0	0	5
1	0	0	0	1	1	0	0	0	1	0	0	0	0	0	2
1	0	0	0	1	0	0	1	0	1	0	0	0	0	0	3
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
1	0	0	0	1	1	0	1	0	2	0	0	0	0	0	5
0	0	0	0	0	2	0	0	0	2	0	0	0	0	0	2
1	0	1	4	6	1	3	0	0	4	0	0	0	0	0	11
0	1	0	0	1	0	0	0	1	1	0	0	0	0	0	4
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	3
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1
0	1	0	0	1	1	0	0	0	1	0	0	0	0	0	7
															35
0	1	0	1	2	0	1	1	0	2	0	0	1	0	1	9
0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	2
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	4
0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1
0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1
0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	2
1	2	2	0	5	3	2	1	0	6	0	0	0	0	0	13
															81
3	2	1	2	8	0	1	1	1	3	0	0	0	0	0	12
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	2
5	0	2	3	10	0	0	0	0	0	0	0	0	0	0	10
0	0	1	2	3	0	0	1	2	3	0	0	0	0	0	9
0	2	3	1	6	0	0	0	0	0	0	0	0	0	0	6
0	0	0	1	1	0	0	0	2	2	0	0	0	0	0	3
0	0	1	3	4	0	0	0	0	0	0	0	0	0	0	5
1	4	1	0	6	0	0	1	0	1	0	0	0	0	0	8
0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	1
1	0	0	0	1	0	0	1	0	1	0	0	0	0	0	2
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1	0	0	0	1	0	1	0	0	1	0	0	0	0	0	3
3	2	2	3	10	0	3	3	0	6	0	0	0	0	0	20

Situation × Severity of Event	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Related to examination										
Blood drawing	0	0	1	0	1	1	0	0	0	1
Sample collection, others	2	0	0	0	2	1	0	0	0	1
General imaging	0	0	0	0	0	0	0	0	0	0
MRI	0	0	0	0	0	0	0	0	0	0
Angiocatheter-aided imaging	0	1	0	0	1	1	2	0	0	3
Lower gastrointestinal imaging	0	0	0	0	0	0	1	0	0	1
Imaging, others	0	0	0	0	0	0	0	0	0	0
Upper gastrointestinal	0	0	2	1	3	0	0	0	0	0
Lower gastrointestinal	0	0	0	0	0	0	0	0	0	0
Bronchoscopy	0	0	0	0	0	0	0	1	0	1
Endoscopic examination, others	0	0	0	0	0	0	0	0	0	0
Pathological examination	0	0	0	0	0	0	0	1	1	2
Examination, others	0	0	0	0	0	0	0	0	0	0
Related to nursing care										
Endotracheal/oral suctioning	0	0	0	0	0	0	0	0	0	0
Changing position	0	0	0	0	0	0	2	0	0	2
Bed bath	0	0	0	0	0	0	0	0	0	0
Help with changing clothes	0	0	0	0	0	0	0	0	0	0
Help with eating	0	0	1	1	2	0	0	1	0	1
Help with bathing	0	0	0	1	1	0	0	0	0	0
Help with elimination	0	0	0	0	0	0	1	0	0	1
Help with moving	0	0	0	0	0	1	0	1	0	2
Transportation	0	0	0	0	0	0	0	0	0	0
Tending patient’s belongings	0	0	0	0	0	0	0	1	1	2
Meal serving	0	0	0	0	0	0	0	0	0	0
Patient observation	3	1	0	0	4	0	0	2	2	4
Nursing care, others	0	0	0	1	1	0	1	0	0	1
Oral intake	1	0	0	1	2	2	0	0	0	2
While taking a walk	0	0	0	0	0	0	0	0	0	0
While moving from one place to another	0	0	2	1	3	2	5	1	2	10
While going out/sleeping out	0	0	0	0	0	0	0	0	0	0
While eating	0	0	1	0	1	0	2	1	0	3
While bathing	1	1	1	1	4	1	0	0	1	2
While excreting	1	1	0	0	2	2	1	1	1	5
While sleeping	0	0	0	0	0	0	0	1	0	1
Recuperation, others	4	0	3	1	8	1	1	1	0	3
Others	6	9	5	2	22	2	1	3	2	8
No choice(Note)	8	4	9	9	30	13	4	12	2	31
Total	40	39	33	37	149	43	36	44	32	155

(Note) “No choice” means no “situation” or “severity of event” was selected.

Residual disability (unlikely)					Unknown					No choice(Note)					
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	Aggregate total
															58
0	3	0	0	3	1	0	0	0	1	0	0	0	0	0	6
3	0	0	1	4	0	0	1	1	2	0	0	0	0	0	9
1	0	0	0	1	0	0	1	0	1	0	0	0	0	0	2
0	0	1	1	2	0	0	1	0	1	1	0	0	0	1	4
0	2	2	0	4	0	0	1	0	1	0	0	0	0	0	9
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	1
0	1	0	1	2	0	0	0	0	0	0	0	0	0	0	5
0	1	1	0	2	1	0	1	1	3	0	1	0	0	1	6
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	2
0	0	1	0	1	0	1	0	0	1	0	0	0	0	0	2
0	0	1	0	1	2	0	1	0	3	0	0	0	0	0	6
0	1	1	1	3	0	0	1	0	1	0	0	0	0	0	4
															270
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1
0	1	2	2	5	0	0	0	0	0	0	0	0	0	0	7
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	2	0	0	0	0	0	0	0	0	0	0	2
1	0	0	0	1	0	0	0	1	1	0	0	0	0	0	5
0	1	0	1	2	0	0	0	0	0	0	0	0	0	0	3
3	0	1	0	4	1	0	0	0	1	0	0	0	0	0	6
0	0	2	2	4	1	0	0	0	1	0	1	0	0	1	8
0	1	1	0	2	0	0	0	0	0	0	0	0	0	0	2
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	3
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1
2	2	0	0	4	0	1	0	2	3	0	1	0	0	1	16
6	5	3	6	20	3	0	1	5	9	0	0	0	0	0	31
0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	5
1	0	2	1	4	1	0	0	0	1	0	0	0	0	0	5
11	17	11	12	51	2	0	4	4	10	0	1	0	0	1	75
0	1	1	0	2	0	0	0	0	0	0	0	0	0	0	2
1	0	1	0	2	0	0	0	0	0	0	0	0	0	0	6
1	2	0	0	3	0	0	0	1	1	0	0	0	0	0	10
6	5	6	3	20	1	1	0	0	2	0	0	1	0	1	30
2	5	3	3	13	0	2	0	0	2	0	0	0	0	0	16
4	5	6	4	19	3	0	2	0	5	1	0	0	0	1	36
4	4	6	9	23	11	6	2	4	23	1	0	1	1	3	79
11	20	35	35	101	9	6	4	7	26	2	1	1	1	5	193
125	137	155	168	585	58	41	49	44	192	7	7	4	4	22	1,103

Fig. II-1-49 Details of Event and Severity of Event

Details of Event x Severity of Event	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Related to drug										
Dose error	0	1	0	0	1	0	1	0	0	1
Overdose	1	0	0	0	1	0	0	0	1	1
Dosing speed too fast	0	1	0	0	1	0	0	0	0	0
Patient misidentification	0	0	0	0	0	0	0	0	0	0
Drug mix-up	0	0	0	0	0	0	0	0	0	0
Wrong dosing method	0	0	0	0	0	0	1	0	0	1
Drug prescription/administration, others	0	0	0	0	0	0	2	0	0	2
Dispensing error (wrong dose/number)	0	0	0	0	0	0	0	0	0	0
Dispensing/drug management, others	0	0	0	0	0	0	0	0	0	0
Drug/blood product management, others	0	0	1	0	1	0	0	0	0	0
Related to blood transfusion										
Cross-match error	0	0	0	0	0	0	1	0	0	1
Error in documentation/recording of results	0	0	0	0	0	0	0	0	0	0
Transfusion testing, others	0	0	0	0	0	0	0	0	0	0
Irradiation of blood products, blood transfusion, others	0	0	0	0	0	0	0	0	0	0
Related to treatment/procedure										
Patient misidentification	0	0	0	0	0	0	0	0	0	0
Wrong site treatment/procedure	0	0	0	1	1	0	0	1	0	1
Wrong examination/treatment/procedure, others	0	0	0	0	0	1	0	0	1	2
Wrong method (technique)	4	3	1	1	9	1	3	1	2	7
Neglected/forgotten treatment/procedure	0	0	0	0	0	0	0	0	0	0
Unnecessary treatment/procedure	0	0	0	0	0	0	0	1	0	1
Wrong patient position	0	0	0	0	0	0	0	0	0	0
Wrong examination/treatment, others	0	0	0	3	3	1	0	0	0	1
Aspiration	0	1	0	0	1	0	0	0	0	0
Retained foreign object	0	0	0	0	0	0	0	0	0	0
Treatment/procedure, others	7	11	4	10	32	11	3	11	10	35
Use/management of medical equipment (device)										
Assembly	0	0	1	0	1	0	0	0	0	0
Forgot to set up/turn on power	0	0	0	0	0	0	0	0	0	0
Malfunction	0	0	0	0	0	0	0	0	0	0
Lack of knowledge	0	0	0	0	0	0	0	0	1	1
Forgot to set up alarm	0	0	0	0	0	0	0	0	0	0
Range of alarm setup	0	0	1	0	1	0	0	0	0	0
Neglect in inspection/management before or during device operation	0	0	0	0	0	0	0	0	0	0
Error in sterilization/clean technique	0	0	0	0	0	0	0	1	0	1
Breakage	0	0	0	0	0	0	0	0	0	0
Use/management of medical equipment (device), others	1	3	0	0	4	0	2	0	2	4

Residual disability (unlikely)					Unknown					No choice(Note)					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
															60
0	2	4	1	7	0	0	0	0	0	0	0	0	0	0	9
1	0	4	4	9	1	2	2	0	5	0	0	0	0	0	16
0	0	1	0	1	0	1	0	0	1	0	0	0	0	0	3
0	0	1	3	4	0	0	1	0	1	0	0	0	0	0	5
1	1	0	3	5	1	0	1	0	2	0	0	0	0	0	7
2	1	1	0	4	0	0	0	0	0	0	0	0	0	0	5
3	1	0	6	10	0	0	0	0	0	0	1	0	0	1	13
0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
															3
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
															318
0	1	1	0	2	0	0	0	0	0	0	0	0	0	0	2
1	4	2	3	10	0	0	0	0	0	0	0	0	0	0	12
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
10	3	4	7	24	2	6	3	1	12	0	0	0	1	1	53
1	0	0	0	1	1	0	0	0	1	0	1	0	0	1	3
1	0	3	2	6	0	0	0	0	0	0	0	0	0	0	7
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1
1	0	2	4	7	0	2	1	4	7	0	0	0	0	0	18
1	0	1	0	2	0	0	0	1	1	0	0	0	0	0	4
4	2	9	5	20	2	0	2	1	5	0	0	0	0	0	25
22	30	20	25	97	10	4	6	5	25	1	0	0	1	2	191
															36
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
1	1	0	0	2	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	1	0	1	0	0	1	0	1	2
0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	1
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	2	0	2	0	0	0	0	0	2
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	1	1	0	0	2	0	0	0	0	0	2
1	2	0	4	7	2	2	2	1	7	0	0	0	0	0	22

Details of Event x Severity of Event	Death					Residual disability (likely)				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Related to use/management of drainage tube or other tube										
Infusion leakage	0	0	0	0	0	0	0	0	1	1
Self-removal	1	0	0	0	1	0	0	0	0	0
Spontaneous dislodgment	0	0	0	1	1	0	0	0	0	0
Disconnection	0	0	0	0	0	0	0	1	0	1
Blockage	0	0	0	0	0	0	1	0	1	2
Breakage/severance	0	0	0	0	0	0	0	0	1	1
Wrong connection	0	0	0	0	0	0	0	0	0	0
Air bubble in tube	0	0	0	0	0	0	0	0	0	0
Use/management of drainage tube or other tube, others	0	1	0	1	2	2	0	1	0	3
Related to examination										
Patient misidentification	0	0	0	0	0	1	0	0	0	1
Wrong examination/evaluation technique	0	0	1	1	2	0	0	0	0	0
Error in sample collection	1	0	0	0	1	1	0	0	0	1
Sample misidentification	0	0	0	0	0	0	0	1	0	1
Lost sample	0	0	0	0	0	0	0	0	0	0
Sample contamination	0	0	0	0	0	0	0	0	0	0
Management of analytical device/equipment	0	0	0	0	0	0	0	0	0	0
Preparation of examination device/equipment	0	0	0	0	0	0	0	0	0	0
Result reporting	0	0	0	0	0	0	0	0	0	0
Examination, others	1	1	2	0	4	1	3	1	1	6
Related to nursing care										
Fall	0	2	2	1	5	4	7	1	3	15
Fall from bed	0	0	0	0	0	0	1	3	1	5
Collision	0	0	0	0	0	0	0	1	0	1
Restraint	0	0	0	0	0	0	0	0	0	0
Severe decubitus (involving muscle layer, Stage III/IV)	0	0	0	0	0	0	2	1	3	6
Aspiration	0	1	2	3	6	1	1	1	0	3
Accidental ingestion	1	0	0	0	1	0	0	0	0	0
Nursing care/recuperation, others	5	0	1	1	7	4	1	3	0	8
Transportation, others	0	0	0	0	0	0	0	0	0	0
Going out/staying out without notice	0	0	0	0	0	0	0	0	0	0
Self medication, others	3	0	2	1	6	0	1	0	0	1
Meal/nutrition, others	0	0	1	1	2	0	1	0	0	1
Others	6	9	5	2	22	2	1	3	2	8
No choice(Note)	9	5	9	10	33	13	4	12	2	31
Total	40	39	33	37	149	43	36	44	32	155

(Note) "No choice" means no "details of event" or "severity of event" was selected.

Residual disability (unlikely)					Unknown					No choice[Note]					Aggregate total
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
															81
1	0	0	1	2	0	1	0	0	1	0	0	0	0	0	4
4	2	2	1	9	0	0	0	2	2	0	0	0	0	0	12
0	2	1	2	5	0	0	1	0	1	0	0	0	0	0	7
2	1	0	5	8	0	0	0	0	0	0	0	0	0	0	9
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	3
1	1	1	1	4	0	2	1	1	4	0	0	0	0	0	9
1	0	0	1	2	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1
5	4	7	4	20	1	2	4	2	9	0	0	0	0	0	34
															58
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	2
0	0	4	1	5	0	0	0	1	1	0	0	0	0	0	8
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	3
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	1	1	0	1	0	0	1	2
0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	1	0	2	0	3	0	0	0	0	0	3
5	5	3	4	17	3	1	5	0	9	1	0	0	0	1	37
															283
25	30	22	28	105	8	2	3	6	19	0	1	1	0	2	146
2	7	5	0	14	1	0	1	2	4	0	0	0	0	0	23
2	0	0	0	2	0	0	0	0	0	0	0	0	0	0	3
0	0	1	0	1	1	0	0	0	1	0	0	0	0	0	2
2	2	8	8	20	1	1	0	0	2	0	0	0	0	0	28
1	0	2	1	4	0	0	1	0	1	0	0	0	0	0	14
0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	2
6	4	3	4	17	0	0	0	2	2	0	1	0	0	1	35
0	3	1	0	4	1	0	0	0	1	0	1	0	0	1	6
1	0	0	0	1	0	0	0	0	0	1	0	0	0	1	2
1	1	1	1	4	1	1	2	1	5	0	0	0	0	0	16
1	0	1	0	2	0	0	1	0	1	0	0	0	0	0	6
4	4	6	8	22	11	6	2	3	22	1	0	1	1	3	77
11	18	32	29	90	8	7	4	9	28	2	1	1	1	5	187
125	137	155	168	585	58	41	49	44	192	7	7	4	4	22	1,103

Fig. II-1-50 Place of Occurrence and Summary of Event

Place of occurrence x summary of event	Ordering					Drug					Blood transfusion					Treatment /procedure					Medical equipment, etc. Medical device				
	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total
Outpatient examination room	0	0	1	0	1	0	1	3	0	4	0	0	0	0	0	3	0	3	1	7	0	0	0	0	0
Outpatient treatment room	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	1	4	8	0	0	0	0	0
Outpatient lobby	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0
Emergency room	0	0	0	0	0	1	1	0	0	2	0	0	0	0	0	0	1	1	2	4	0	0	0	0	0
Critical care center	0	0	1	0	1	0	0	0	0	0	0	1	0	0	1	0	0	0	1	1	0	0	0	0	0
Patient room	0	0	2	2	4	6	9	5	12	32	0	0	0	0	0	25	15	12	18	70	2	6	3	5	16
Ward treatment room	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1	1	4	3	9	0	0	0	0	0
Operation room	1	0	0	0	1	1	0	0	0	1	0	2	0	1	3	29	34	29	41	133	3	4	4	2	13
ICU	0	0	0	0	0	0	1	1	0	2	0	0	0	0	0	3	4	2	3	12	0	1	0	0	1
CCU	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	2	0	0	0	2	0	0	1	0	1
NICU	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	2	0	3	0	0	0	0	0
Examination room	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	1	4	8	0	0	0	0	0
Catheterization laboratory	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	6	5	8	4	23	3	0	1	0	4
Radiotherapy room	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	1	3	6	0	0	0	0	0
Radiography room	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	1	3	0	5	9	0	0	0	0	0
Radioactive scanning room	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0
Dialysis room	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	4	0	0	0	0	0
Delivery room	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0
Rehabilitation room	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	2	5	0	0	0	0	0
Restroom	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	2	3	0	0	0	0	0
Hallway	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	2	0	0	0	0	0
Bathroom	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Stairway	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2	0	0	1	0	1
Others	0	0	0	0	0	0	3	1	0	4	0	0	0	0	0	10	7	7	12	36	0	2	0	0	2
No choice(Note)	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0
Total	1	0	5	2	8	9	15	11	15	50	0	3	0	1	4	88	79	77	107	351	8	13	10	7	38

(Note) "No choice" means no "place of occurrence" or "summary of event" was selected.

Medical equipment, etc.										Examination					Nursing care					Others					No choice (Note 2)					Aggregate total
Drainage tube or other tube					Dental equipment																									
January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	January to March	April to June	July to September	October to December	Total	
0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1	0	0	0	1	0	1	2	1	4	0	0	0	1	1	19
0	0	0	1	1	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	2	0	0	0	0	0	0	0	0	0	0	3
0	1	1	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2	0	0	0	0	0	10
0	0	0	1	1	0	0	0	0	0	0	0	2	0	2	0	0	0	1	1	0	0	0	0	0	0	0	1	0	1	8
13	8	10	16	47	0	0	0	1	1	2	3	1	0	6	37	45	43	41	166	22	19	33	30	104	11	3	9	2	25	471
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11
0	0	3	2	5	0	0	0	0	0	1	0	1	1	3	0	0	0	0	0	3	1	3	1	8	1	1	3	0	5	172
2	4	3	1	10	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	2	1	1	0	4	1	1	0	0	2	32
0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	1	0	0	0	1	0	0	0	0	0	9
0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	2	2	9
0	0	0	0	0	0	0	0	0	0	2	3	4	0	9	0	0	0	0	0	0	1	1	0	2	0	0	0	1	1	20
0	1	1	1	3	0	0	0	0	0	2	3	3	1	9	0	0	0	0	0	2	0	1	1	4	1	1	0	0	2	45
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	7
2	0	1	1	4	0	0	0	0	0	2	1	2	2	7	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	22
0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	3
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	5
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5
1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	7	3	6	8	24	1	2	1	0	4	1	0	0	0	1	33
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	7	8	8	3	26	3	1	2	2	8	0	0	0	0	0	37
0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	3	4	0	4	11	2	1	2	1	6	0	0	0	0	0	18
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	3	0	0	0	0	0	0	0	0	0	0	3
0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	0	0	0	0	0	1	0	0	0	1	7
1	3	2	4	10	0	0	0	1	1	5	2	3	2	12	4	6	7	3	20	14	14	12	8	48	1	1	0	0	2	135
0	1	0	0	1	0	0	0	0	0	1	0	0	0	1	0	1	0	0	1	0	1	1	0	2	0	0	0	0	0	7
19	19	23	32	93	0	0	1	2	3	17	12	16	6	51	60	70	69	61	260	53	42	59	46	200	18	7	14	6	45	1,103

[5] Details of Reports from Participating Medical Institutions (by Month of Report)

The tabulation of reports made by registered medical institutions (medical institutions subject to reporting requirement and registered participating medical institutions) between January 1 and December 31, 2005 is shown below.

Fig. II-1-51 Month of Occurrence

Month of occurrence		Number of events
2005	November and therebefore	37
	December	59
2006	January	117
	February	94
	March	100
	April	123
	May	90
	June	96
	July	103
	August	103
	September	89
	October	100
	November	90
	December	61
	No choice(Note)	3
Total		1,265

(Note) "No choice" means no "month of occurrence" was selected.

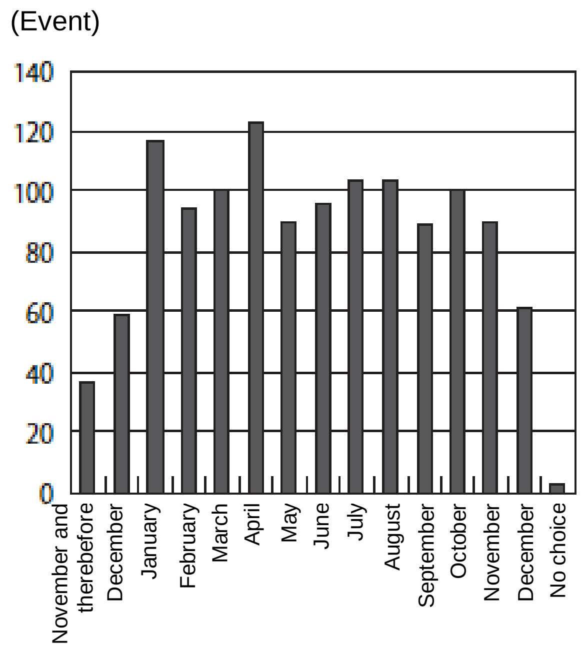


Fig. II-1-52 Day of Occurrence and Weekday/Holiday Category

Day of occurrence	Weekday	Holiday	No choice(Note)	Total
Mon.	174	10	1	185
Tue.	215	3	5	223
Wed.	200	3	4	207
Thu.	229	5	5	239
Fri.	197	8	3	208
Sat.	39	76	4	119
Sun.	0	74	1	75
No choice(Note)	1	0	8	9
Total	1,055	179	30	1,265

(Note) "No choice" means no "day of occurrence" or "weekday/holiday category" was selected.

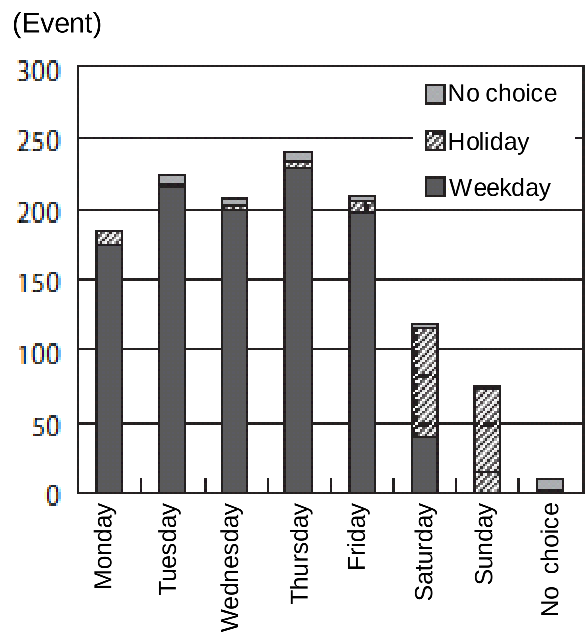


Fig. II-1-53 Time of Occurrence

Time of occurrence	Number of events
0:00 – before 2:00	54
2:00 – before 4:00	49
4:00 – before 6:00	41
6:00 – before 8:00	60
8:00 – before 10:00	116
10:00 – before 12:00	177
12:00 – before 14:00	120
14:00 – before 16:00	196
16:00 – before 18:00	140
18:00 – before 20:00	83
20:00 – before 22:00	55
22:00 – before 24:00	60
Time unknown	82
No choice(Note)	32
Total	1,265

(Note) "No choice" means no "time of occurrence" was selected.

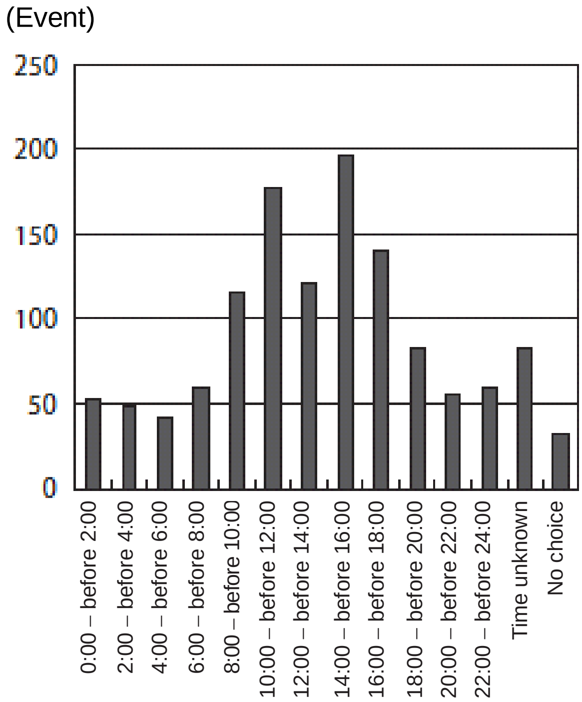


Fig. II-1-54 Patient Age

Patient age	Number of events	Inpatient
0 to 9	50	38
10s	16	14
20s	45	42
30s	49	40
40s	65	53
50s	109	95
60s	186	160
70s	284	255
80s	118	105
90 or above	32	28
No choice(Note)	311	118
Aggregate total	1,265	948

(Note) "No choice" means no "patient age" was selected.

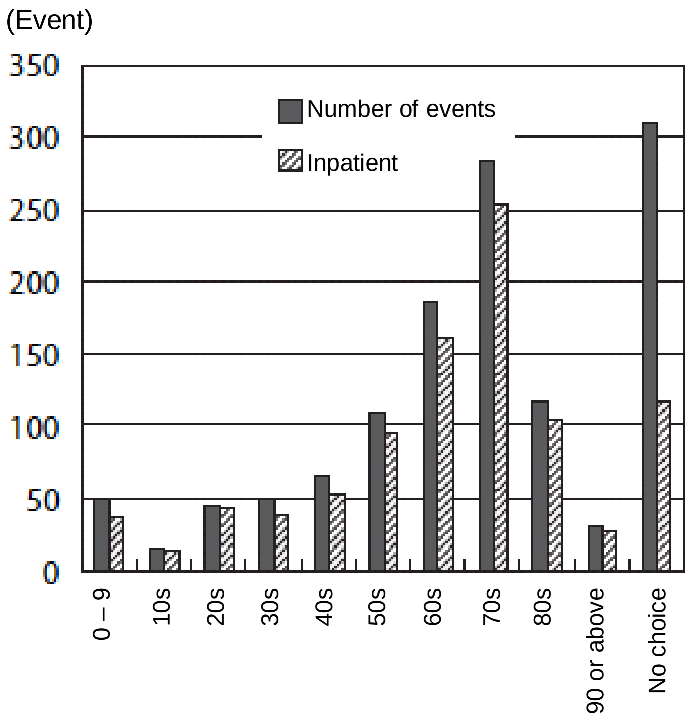


Fig. II-1-55 Sex of Patients

Sex	Number of events
Male	485
Female	432
No choice(Note)	348
Total	1,265

(Note) "No choice" means no "sex of patient" was selected.

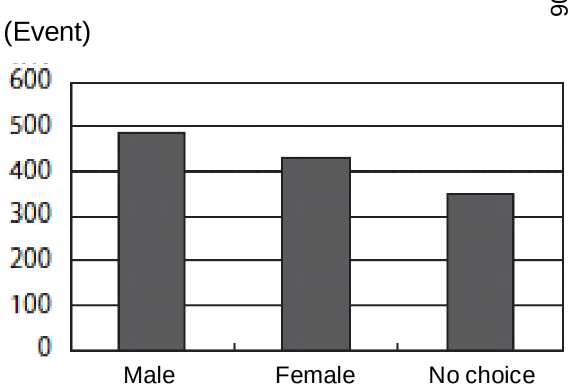


Fig. II-1-56 Inpatient/Outpatient Status and Duration of Hospital Stay

Inpatient/outpatient status		Number of events
Inpatient	Duration: 0 to 31 days	635
	Duration: 32 days or longer	289
	No choice(Note)	24
	Total	948
Outpatient	Initial visit	8
	Follow-up visit	77
	Total	85
No choice(Note)		232
Aggregate total		1,265

(Note) "No choice" means no "inpatient/outpatient status" or "duration of hospitalization" was selected.

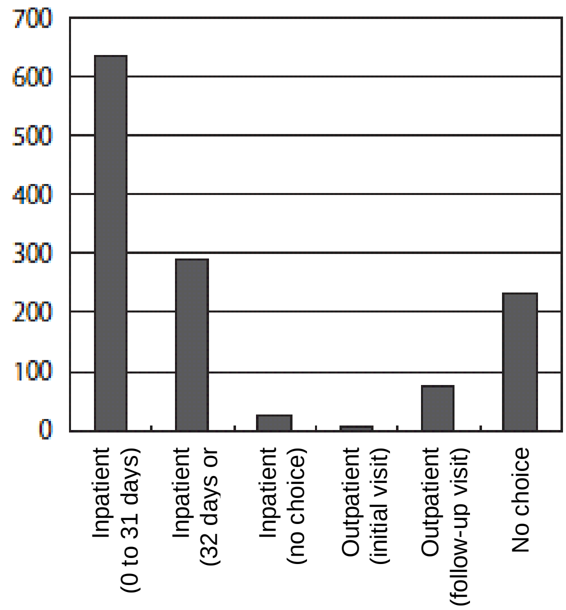


Fig. II-1-57 Person Who Identified Event

Person who identified event	Number of events
Person involved himself/herself	523
Coworker with same job title	194
Coworker with other job title	91
Medical staff	964
Patient himself/herself	42
Patient's family/caregiver	47
Other patient	48
Others	125
No choice(Note)	39
Total	1,265

(Note) "No choice" means no "person who identified event" was selected.

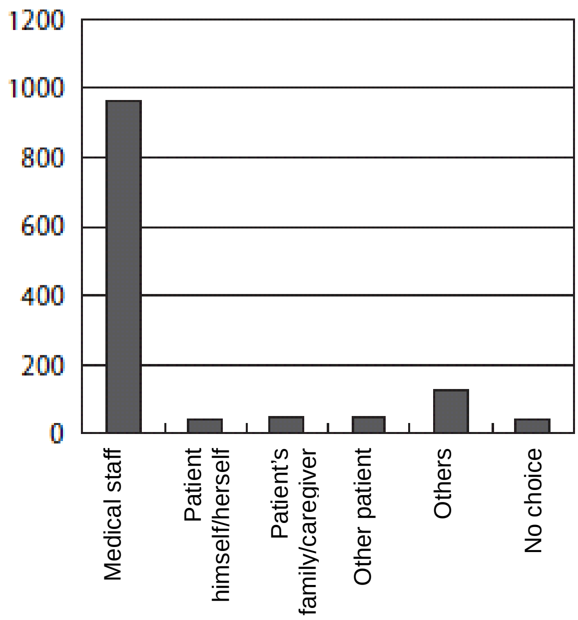
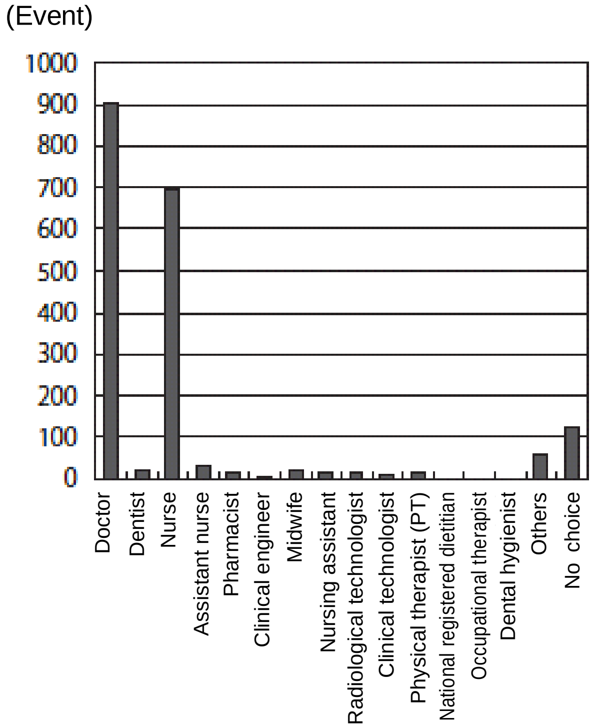


Fig. II-1-58 Job Title of Person Involved

Job title of person involved (Note 1)	Number of events
Doctor	906
Dentist	21
Nurse	697
Assistant nurse	34
Pharmacist	13
Clinical engineer	4
Midwife	20
Nursing assistant	14
Radiological technologist	14
Clinical technologist	8
Physical therapist (PT)	13
National registered dietitian	1
Occupational therapist (OT)	1
Dental hygienist	2
Others	58
No choice (Note 2)	126
Total	1,932



(Note 1) Person involved is a person determined by the medical institution to have been involved in the event occurred; more than 1 person may have been involved.

(Note 2) "No choice" means no "job title of person involved" was selected.

Fig. II-1-59 Years of Experience of Person Involved by Job Title (Doctor, Dentist, Nurse, Pharmacist)

Job title of person involved (Note 1) × Years of experience	0 year	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years	9 years	10 years	11 to 20 years	21 to 30 years	30 years or longer	No choice (Note 2)	Total
Doctor	24	35	39	52	44	39	29	38	38	45	45	274	92	18	94	906
Dentist	1	3	1	0	2	2	2	3	1	0	1	3	1	0	1	21
Nurse	60	57	65	64	39	47	23	32	23	12	18	99	78	15	65	697
Pharmacist	2	0	0	0	1	2	0	0	1	0	0	4	2	0	1	13

(Note 1) Person involved is a person determined by the medical institution to have been involved in the event occurred; more than 1 person may have been involved.

(Note 2) "No choice" means no "years of experience" was selected.

Fig. II-1-60 Number of Years Person Involved (Doctor, Dentist, Nurse, Pharmacist) Has Been Working at Current Department

Job title of person involved (Note 1) × Number of years at current department	0 year	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years	9 years	10 years	11 to 20 years	21 to 30 years	30 years or longer	No choice (Note 2)	Total
Doctor	165	118	85	77	43	42	29	21	17	21	12	103	18	2	153	906
Dentist	3	4	2	1	1	1	0	0	0	0	0	1	1	0	7	21
Nurse	146	131	111	76	41	41	14	14	11	4	4	11	2	1	90	697
Pharmacist	2	4	3	0	1	1	0	0	0	0	0	0	1	0	1	13

(Note 1) Person involved is a person determined by the medical institution to have been involved in the event occurred; more than 1 person may have been involved.

(Note 2) "No choice" means no "Number of years at current department" was selected.

Fig. II-1-61 Summary of Event

Summary of event	January to December 2005	
	Number of events	%
Ordering	6	0.5
Drug	71	5.6
Blood transfusion	8	0.6
Treatment/procedure	378	29.9
Medical equipment, etc.	153	12.1
Medical device	45	3.6
Drainage tube or other tube	104	8.2
Dental equipment	4	0.3
Examination/test	60	4.7
Nursing care	302	23.9
Others	235	18.6
No choice(Note)	52	4.1
Total	1,265	100

(Note) "No choice" means no "summary of event" was selected.

Fig. II-1-62 Severity of Event

Severity of event(Note 1)	January to December 2005	
	Number of events	%
Death	169	13.4
Potential residual disability (likely)	192	15.2
Potential residual disability (unlikely)	664	52.5
Unknown(Note 2)	211	16.7
No choice(Note 3)	29	2.3
Total	1,265	100

(Note 1) "Severity of event" is not necessarily associated with occurrence of event or negligence.

(Note 2) "Unknown" includes indefinite outcome at the time of reporting (within 2 weeks) and events of warning that did not affect patients' conditions in any way.

(Note 3) "No choice" means no "severity of event" was selected.

Fig. II-1-63 Place of Occurrence

Place of Occurrence	January to December 2005	
	Number of events	%
Outpatient examination room	24	1.9
Outpatient treatment room	11	0.9
Outpatient lobby	3	0.2
Emergency room	9	0.7
Critical care center	8	0.6
Patient room	540	42.7
Ward treatment room	15	1.2
Operation room	195	15.4
ICU	38	3.0
CCU	9	0.7
NICU	10	0.8
Examination room	20	1.6
Catheterization laboratory	51	4.0
Radiotherapy room	5	0.4
Radiography room	24	1.9
Radioactive scanning room	4	0.3
Dialysis room	6	0.5
Delivery room	6	0.5
Rehabilitation room	8	0.6
Restroom	34	2.7
Hallway	45	3.6
Bathroom	20	1.6
Stairway	4	0.3
Unknown	9	0.7
Others	158	12.5
No choice(Note)	9	0.7
Total	1,265	100

(Note) "No choice" means no "place of occurrence" was selected.

Fig. II-1-64 Cause of Event

Cause of Event (Note 1)	Number of events	%
Neglect to check	332	14.0
Neglect to observe	294	12.4
Misjudgment	291	12.3
Lack of knowledge	117	4.9
Deficiency of technique/skill	113	4.8
Delayed reporting	41	1.7
Under unusual physical condition	66	2.8
Under unusual psychological condition	39	1.6
System failure	57	2.4
Inadequate coordination	146	6.2
Inadequate documentation	19	0.8
Similarity in patient’s appearance or name	3	0.1
Busy working condition	65	2.7
Problem in environment	57	2.4
Problem in drug	20	0.8
Problem in medical device	41	1.7
Problem in other items	34	1.4
Problem in facility	53	2.2
Problem in education/training	67	2.8
Lack of explanation	88	3.7
Others	344	14.5
No choice(Note 2)	80	3.4
Total	2,367	100

(Note 1) “Cause of event” may be more than one.

(Note 2) “No choice” means no “cause of event” was selected.

Fig. II-1-65 Cause of Event and Summary of Event

Cause of Event(Note 1) × Summary of Event	Ordering	Drug	Blood transfusion	Treatment/ procedure	Medical equipment, etc.			Examination/test	Nursing care	Others	No choice(Note)	Total
					Medical device	Drainage tube or other tube	Dental equipment					
Neglect to check	4	50	4	111	22	34	1	12	43	34	17	332
Neglect to observe	0	10	0	64	14	28	1	4	118	42	13	294
Misjudgment	2	19	3	99	5	29	0	5	84	32	13	291
Lack of knowledge	1	26	1	26	8	15	1	2	22	11	4	117
Deficiency of technique/skill	0	2	0	67	4	14	1	7	11	2	5	113
Delayed reporting	1	4	1	11	2	2	0	1	9	8	2	41
Under unusual physical condition	0	1	0	23	1	5	0	3	9	20	4	66
Under unusual psychological condition	0	2	1	15	1	4	0	0	8	5	3	39
System failure	1	12	1	10	7	3	0	3	6	12	2	57
Inadequate coordination	3	18	1	34	7	13	1	8	36	20	5	146
Inadequate documentation	0	5	1	5	0	4	0	0	1	2	1	19
Similarity in patient's appearance or name	0	1	0	1	0	0	0	0	0	0	1	3
Busy working condition	1	9	1	10	6	7	1	0	22	6	2	65
Problem in environment	0	2	0	7	2	2	0	1	27	13	3	57
Problem in the drug	0	11	0	2	2	1	0	0	2	1	1	20
Problem in medical device	0	0	1	7	15	6	2	3	0	5	2	41
Problem in other items	0	2	1	6	4	6	1	3	7	3	1	34
Problem in facility	0	0	0	6	2	0	0	0	21	22	2	53
Problem in education/training	1	8	0	17	5	6	0	2	13	11	4	67
Lack of explanation	0	8	0	14	3	2	0	5	35	20	1	88
Others	1	10	2	112	9	25	0	23	67	87	8	344
No choice(Note 2)	1	0	1	18	0	4	0	2	19	29	6	80
Total	16	200	19	665	119	210	9	84	560	385	100	2,367

(Note 1) "Cause of event" may be more than one.

(Note 2) "No choice" means no "cause of event" or "summary of event" was selected.

Fig. II-1-66 Place of Occurence and Severity of Event

Place of Occurence X Severity of Event	Death	Residual disability (likely)	Residual disability (unlikely)	Unknown	No choice(Note)	Total
Outpatient examination room	0	2	14	7	1	24
Outpatient treatment room	0	0	7	3	1	11
Outpatient lobby	1	0	2	0	0	3
Emergency room	1	1	5	2	0	9
Critical care center	2	1	4	1	0	8
Patient room	76	81	295	78	10	540
Ward treatment room	0	2	10	3	0	15
Operation room	14	41	105	32	3	195
ICU	12	3	14	9	0	38
CCU	2	1	5	0	1	9
NICU	2	1	3	4	0	10
Examination room	1	2	11	6	0	20
Catheterization laboratory	7	11	27	6	0	51
Radiotherapy room	0	1	4	0	0	5
Radiography room	3	5	14	2	0	24
Radioactive scanning room	0	0	1	2	1	4
Dialysis room	1	0	3	1	1	6
Delivery room	0	2	3	1	0	6
Rehabilitation room	0	1	4	2	1	8
Restroom	2	5	24	3	0	34
Hallway	2	9	26	7	1	45
Bathroom	6	2	8	4	0	20
Stairway	1	1	2	0	0	4
Unknown	0	2	3	4	0	9
Others	35	18	67	31	7	158
No choice(Note)	1	0	3	3	2	9
Total	169	192	664	211	29	1,265

(Note) "No choice" means no "place of occurrence" or "severity of event" was selected.

Fig. II-1-67 Place of Occurrence and Inpatient/Outpatient Status

Place of Occurrence X Inpatient/Outpatient Status	Inpatient	Outpatient	No choice(Note)	Total
Outpatient examination room	5	16	3	24
Outpatient treatment room	1	9	1	11
Outpatient lobby	0	3	0	3
Emergency room	1	6	2	9
Critical care center	2	2	4	8
Patient room	433	1	106	540
Ward treatment room	13	2	0	15
Operation room	168	1	26	195
ICU	33	0	5	38
CCU	8	0	1	9
NICU	6	0	4	10
Examination room	11	5	4	20
Catheterization laboratory	40	2	9	51
Radiotherapy room	3	1	1	5
Radiography room	15	2	7	24
Radioactive scanning room	2	1	1	4
Dialysis room	4	1	1	6
Delivery room	5	0	1	6
Rehabilitation room	6	1	1	8
Restroom	24	1	9	34
Hallway	36	0	9	45
Bathroom	16	0	4	20
Stairway	3	0	1	4
Unknown	7	0	2	9
Others	103	29	26	158
No choice(Note)	3	2	4	9
Total	948	85	232	1,265

(Note) “No choice” means no “place of occurrence” or “inpatient/outpatient status” was selected.

Fig. II-1-68 Situation and Severity of Event

Situation X Severity of Event	Death	Residual disability (likely)	Residual disability (unlikely)	Unknown	No choice(Note)	Total
Related to drug						76
Drug preparation	0	0	3	2	0	5
Subcutaneous/intramuscular injection	0	0	4	0	0	4
Intravenous injection	2	1	12	1	0	16
Arterial injection	0	0	1	0	0	1
Peripheral intravenous drop	0	3	10	4	0	17
Central venous injection	2	0	2	2	0	6
Oral administration	0	2	12	1	0	15
Nose drop/eye drop/ear drop	0	0	0	0	1	1
Other drug prescription/administration	0	1	1	1	0	3
Oral drug dispensing/management	1	0	1	1	0	3
Injection dispensing/management	0	0	1	1	0	2
Dispensing/management, others	2	0	0	1	0	3
Related to blood transfusion						6
Pre-transfusion testing	0	1	2	0	0	3
Blood transfusion	0	1	1	0	0	2
Blood transfusion, others	0	0	0	1	0	1
Related to treatment/procedure						362
Craniotomy	1	0	3	1	0	5
Thoracotomy	3	1	6	1	0	11
Cardiotomy	2	0	1	2	0	5
Laparotomy	8	4	18	4	1	35
Extremities	1	2	6	1	1	11
Endoscopic surgery	0	5	10	3	1	19
Surgery, others	1	7	18	3	0	29
Preparation for surgery	0	0	1	0	0	1
Preoperative procedure	1	0	3	0	0	4
Postoperative procedure	2	4	4	1	0	11
Surgery, others	5	4	17	3	0	29
General anesthesia (inhalation anesthesia and intravenous anesthesia)	0	5	8	1	0	14
Local anesthesia	0	0	1	0	0	1
Inhalation anesthesia	0	0	1	0	0	1
Intravenous anesthesia	0	0	2	0	0	2
Vertebral/epidural anesthesia	0	0	3	0	0	3
Anesthesia, others	0	2	1	0	0	3
Caesarean section	0	0	1	0	0	1
Delivery and artificial abortion, others	1	0	0	2	0	3
Blood purification (including hemodialysis)	1	0	3	1	1	6
IVR (ex. angiocatheter)	7	8	21	2	0	38
Radiotherapy	1	0	1	1	0	3
Rehabilitation	0	1	8	2	1	12
Invasive dental treatment	0	0	2	0	0	2
Endoscopic treatment	1	2	7	4	1	15
Treatment, others	1	6	19	5	0	31

Situation X Severity of Event	Death	Residual disability (likely)	Residual disability (unlikely)	Unknown	No choice(Note)	Total
Central venous line	0	1	10	1	0	12
Peripheral venous line	1	0	4	1	0	6
Catheter for blood purification	1	0	2	1	0	4
Feeding tube (NG, ED)	1	0	3	1	0	5
Urethral catheter	1	0	0	0	0	1
Drainage procedure	1	1	3	2	0	7
Wound care	0	0	0	3	0	3
Tube placement, others	3	0	6	4	0	13
Tracheal intubation	1	1	1	1	0	4
Tracheotomy	0	1	1	0	0	2
Cardiac compression	0	1	0	0	0	1
Oxygen therapy	0	0	0	1	0	1
Emergency procedure, others	5	0	2	1	0	8
Related to use/management of medical equipment (device)						49
Mechanical ventilator	3	3	4	2	1	13
Oxygen therapy equipment	1	0	0	1	0	2
Oxygenator	2	1	1	0	0	4
Defibrillator	0	0	0	1	0	1
Pace maker	0	0	0	1	0	1
Infusion/transfusion pump	0	0	2	1	0	3
Blood purification device	0	0	1	0	0	1
ECG, blood pressure monitor	2	0	0	0	0	2
Pulse oxymeter	0	1	0	0	1	2
Use/management of medical equipment (device), others	0	3	7	10	0	20
Related to use/management of drainage tube or other tube						89
Central venous line	1	1	6	3	0	11
Peripheral venous line	0	1	2	0	0	3
Tracheal tube	0	0	10	0	0	10
Tracheal cannula	2	1	2	2	0	7
Feeding tube (NG, ED)	0	1	7	0	1	9
Urethral catheter	0	0	1	2	0	3
Chest drainage tube	0	1	4	0	0	5
Abdominal drainage tube	0	1	7	2	1	11
Ventricular/cisternal drainage tube	0	0	2	1	0	3
Subcutaneous continuous suction drainage tube	0	0	1	1	0	2
Epidural catheter	0	1	0	0	0	1
Catheter/line for blood purification	1	0	2	1	0	4
Use/management of drainage tube or other tube, others	1	2	12	5	0	20
Related to examination						63
Blood drawing	1	1	5	1	0	8
Sample collection, others	2	1	6	1	0	10
General imaging	0	0	1	1	0	2
MRI	1	0	1	1	1	4
Angiocatheter-aided imaging	1	4	4	1	0	10
Lower gastrointestinal imaging	0	1	1	0	0	2

Situation X Severity of Event	Death	Residual disability (likely)	Residual disability (unlikely)	Unknown	No choice(Note)	Total
Imaging, others	1	0	1	1	0	3
Upper gastrointestinal	2	1	2	0	0	5
Lower gastrointestinal	0	0	2	3	1	6
Bronchoscopy	0	1	1	0	0	2
Endoscopic examination, others	0	0	1	1	0	2
Pathological examination	0	2	1	3	0	6
Examination, others	0	0	2	1	0	3
Related to nursing care						319
Endotracheal/oral suctioning	0	1	0	0	0	1
Changing position	0	2	5	0	0	7
Bed bath	0	1	0	0	0	1
Help with changing clothes	0	0	2	0	0	2
Help with eating	2	1	2	1	0	6
Help with bathing	1	0	2	2	0	5
Help with elimination	0	1	6	2	0	9
Help with moving	0	3	7	2	1	13
Transportation	0	0	2	0	0	2
Tending patient’s belongings	0	1	1	0	0	2
Meal serving	0	1	2	0	0	3
Patient observation	5	6	9	2	1	23
Nursing care, others	1	3	23	8	0	35
Oral intake	4	3	0	1	0	8
While taking a walk	1	0	5	3	0	9
While moving from one place to another	3	13	59	12	1	88
While going out/sleeping out	0	0	2	0	0	2
While eating	1	4	5	0	0	10
While bathing	4	2	3	1	0	10
While excreting	2	6	17	2	1	28
While sleeping	1	1	14	3	0	19
Recuperation, others	7	3	21	4	1	36
Others	29	11	25	23	4	92
No choice(Note)	30	36	106	30	7	209
Total	169	192	664	211	29	1,265

(Note) “No choice” means no “situation” or “severity of event” was selected.

Fig. II-1-69 Details of Event and Severity of Event

Details of Event X Severity of Event	Death	Disability (likely)	Disability (unlikely)	Unknown	No choice(Note)	Total
Related to drug						77
Dose error	1	1	6	0	0	8
Overdose	1	0	11	6	0	18
Dosing speed too fast	1	0	1	2	0	4
Patient misidentification	0	0	6	1	0	7
Drug mix-up	0	0	5	2	0	7
Wrong dosing method	0	1	5	1	0	7
Drug prescription/administration, others	1	4	12	2	1	20
Dispensing error (wrong dose/number)	0	0	1	0	0	1
Dispensing/drug management, others	2	0	0	0	0	2
Drug/blood product management, others	1	1	1	0	0	3
Related to blood transfusion						6
Cross-match error	0	1	0	0	0	1
Error in documentation/recording of results	0	0	1	0	0	1
Transfusion testing, others	0	0	1	1	0	2
Irradiation of blood products, blood transfusion, others	0	1	1	0	0	2
Related to treatment/procedure						354
Patient misidentification	0	0	2	0	0	2
Wrong site treatment/procedure	0	1	10	1	0	12
Wrong examination/treatment/procedure, others	0	2	2	0	0	4
Wrong method (technique)	9	8	34	13	3	67
Neglected/forgotten treatment/procedure	0	0	2	1	1	4
Unnecessary treatment/procedure	0	1	5	0	0	6
Wrong patient position	0	1	0	0	0	1
Wrong examination/treatment, others	2	3	10	7	0	22
Aspiration	1	0	3	0	0	4
Retained foreign object	0	0	23	6	0	29
Treatment/procedure, others	36	39	103	23	2	203
Use/management of medical equipment (device)						49
Assembly	1	0	0	0	0	1
Forgot to set up/turn on power	0	0	2	0	0	2
Malfunction	0	0	0	1	1	2
Lack of knowledge	0	1	1	0	0	2
Forgot to set up alarm	0	0	0	0	1	1
Range of alarm setup	1	0	0	0	0	1
Neglect in inspection/management before or during device operation	1	1	0	2	0	4
Error in sterilization/clean technique	0	2	0	0	0	2
Breakage	0	0	1	4	0	5
Use/management of medical equipment (device), others	5	4	11	9	0	29
Related to use/management of drainage tube or other tube						89
Infusion leakage	0	1	2	1	0	4
Self-removal	1	0	10	2	0	13
Spontaneous dislodgment	1	0	7	1	0	9
Disconnection	0	1	7	1	1	10
Blockage	1	1	1	0	0	3

Details of Event X Severity of Event	Death	Disability (likely)	Disability (unlikely)	Unknown	No choice(Note)	Total
Breakage/severance	0	1	5	3	0	9
Wrong connection	0	0	2	0	0	2
Air bubble in tube	0	0	0	1	0	1
Use/management of drainage tube or other tube, others	2	5	22	8	1	38
Related to examination						63
Patient misidentification	0	1	3	0	0	4
Wrong examination/evaluation technique	1	0	5	1	0	7
Error in sample collection	1	1	2	0	0	4
Sample misidentification	0	1	0	0	0	1
Lost sample	0	0	0	0	1	1
Sample contamination	0	0	0	1	0	1
Management of analytical device/equipment	0	0	1	0	0	1
Preparation of examination device/equipment	0	0	1	0	0	1
Result reporting	0	0	0	3	0	3
Examination, others	6	8	16	9	1	40
Related to nursing care						329
Fall	5	22	113	23	2	165
Fall from bed	0	6	19	4	0	29
Collision	0	2	2	0	0	4
Restraint	0	0	1	1	0	2
Severe decubitus (involving muscle layer, Stage III/IV)	0	6	18	2	0	26
Aspiration	7	5	7	1	0	20
Accidental ingestion	1	0	0	0	0	1
Nursing care/recuperation, others	10	10	23	4	1	48
Transportation, others	0	0	7	3	1	11
Going out/staying out without notice	0	0	2	0	1	3
Self medication, others	6	1	3	4	0	14
Meal/nutrition, others	2	1	2	1	0	6
Others	29	11	25	23	4	92
No choice(Note)	33	36	98	32	7	206
Total	169	192	664	211	29	1,265

(Note) "No choice" means no "details of event" or "severity of event" was selected.

Fig. II-1-70 Place of Occurrence and Summary of Event

Place of occurrence x summary of event	Ordering	Drug	Blood transfusion	Treatment /procedure	Medical equipment, etc.			Examination	Nursing care	Others	No choice(Note 2)	Total
					Medical device	Drainage tube or other tube	Dental equipment					
Outpatient examination room	1	5	0	8	0	0	2	0	1	6	1	24
Outpatient treatment room	0	1	0	7	0	1	0	1	0	1	0	11
Outpatient lobby	0	0	0	1	0	0	0	0	2	0	0	3
Emergency room	0	2	0	2	0	2	0	0	0	3	0	9
Critical care center	1	1	1	0	0	1	0	1	1	1	1	8
Patient room	2	41	2	78	18	56	1	8	189	119	26	540
Ward treatment room	0	2	0	12	0	1	0	0	0	0	0	15
Operation room	1	1	4	141	17	5	0	3	0	15	8	195
ICU	0	4	0	15	1	11	0	0	1	4	2	38
CCU	0	1	0	2	2	1	0	0	2	1	0	9
NICU	0	1	0	3	0	3	0	0	0	1	2	10
Examination room	0	0	0	7	0	0	0	10	0	2	1	20
Catheterization laboratory	0	0	0	27	4	3	0	12	0	3	2	51
Radiotherapy room	0	0	0	4	0	0	0	0	0	1	0	5
Radiography room	0	1	1	9	0	5	0	7	0	1	0	24
Radioactive scanning room	0	1	0	1	0	0	0	1	0	0	1	4
Dialysis room	0	0	0	5	0	0	0	0	0	0	1	6
Delivery room	0	1	0	2	0	0	0	0	0	3	0	6
Rehabilitation room	0	0	0	7	0	0	0	0	1	0	0	8
Restroom	0	0	0	2	0	1	0	0	24	5	2	34
Hallway	0	0	0	2	0	0	0	0	35	7	1	45
Bathroom	0	0	0	0	0	1	0	0	13	6	0	20
Stairway	0	0	0	0	0	0	0	0	4	0	0	4
Unknown	0	0	0	2	1	1	0	0	2	2	1	9
Others	0	9	0	39	2	11	1	16	26	52	2	158
No choice(Note)	1	0	0	2	0	1	0	1	1	2	1	9
Total	6	71	8	378	45	104	4	60	302	235	52	1,265

(Note) "No choice" means no "place of occurrence" or "summary of event" was selected.

Fig. II-1-71 Clinical Department

Clinical Department (Note 1)	Number of events	%
Internal medicine	161	10.2
Anesthesiology	60	3.8
Cardiovascular medicine	92	5.8
Neurology	39	2.5
Respiratory tract medicine	58	3.7
Gastrointestinal medicine	91	5.8
Hematology	24	1.5
Circulatory surgery	23	1.5
Allergy	0	0.0
Rheumatism	5	0.3
Pediatrics	46	2.9
General surgery	143	9.1
Orthopedics	138	8.7
Plastic surgery	14	0.9
Cosmetic surgery	0	0.0
Neurosurgery	91	5.8
Respiratory surgery	29	1.8
Cardiovascular surgery	66	4.2
Pediatric surgery	10	0.6
Pain clinic	0	0.0
Dermatology	23	1.5
Urology	52	3.3
Venereology	0	0.0
Proctology	1	0.1
Gynecology/Obstetrics	23	1.5
Obstetrics	7	0.4
Gynecology	19	1.2
Ophthalmology	24	1.5
Otolaryngology	32	2.0
Psychosomatic medicine	3	0.2
Psychiatry	90	5.7
Rehabilitation	17	1.1
Radiology	33	2.1
Dentistry	5	0.3
Orthodontics	0	0.0
Pediatric dentistry	0	0.0
Dental/oral surgery	18	1.1
Unknown	1	0.1
Others	104	6.6
No choice (Note 2)	37	2.3
Total	1,579	100

(Note 1) More than one “clinical department” may have been involved in one event.
(Note 2) “No choice” means no “clinical department” was selected.

[Reference] Reports Made between October and December 2004

Since the project started on October 1, 2004, medical adverse event information was collected only during 3 months, between October 1 and December 31 in 2004. Although this annual report does not intend to cover the said 3-month period, tabulation data are shown herein as reference.

Fig. II-1-72 Number of Reports

Medical institutions subject to reporting requirement	224 reports
Registered medical institutions	17 reports
Total	241 reports

Fig. II-1-73 Summary of Event

Summary of event	October to December 2004	
	Number of events	%
Ordering	1	0.4
Drug	14	5.8
Blood transfusion	0	0.0
Treatment/procedure	72	29.9
Medical equipment, etc.	20	8.3
Medical device	7	2.9
Drainage tube or other tube	12	5.0
Dental equipment	1	0.4
Examination/test	7	2.9
Nursing care	53	22
Others	53	22
No choice(Note)	21	8.7
Total	241	100

(Note) "No choice" means no "summary of event" was selected.

Fig. II-1-74 Severity of Event

Severity of Event (Note 1)	October to December 2004	
	Number of events	%
Death	38	15.8
Potential residual disability (likely)	31	12.9
Potential residual disability (unlikely)	108	44.8
Unknown(Note 2)	54	22.4
No choice(Note 3)	10	4.1
Total	241	100

(Note 1) "Severity of event" is not necessarily associated with occurrence of event or negligence.

(Note 2) "Unknown" includes indefinite outcome at the time of reporting (within 2 weeks) and events of warning that did not affect patients' conditions in any way.

(Note 3) "No choice" means no "severity of event" was selected.

Fig. II-1-75 Place of Occurrence

Place of Occurrence	October to December 2004	
	Number of events	%
Outpatient examination room	3	1.2
Outpatient treatment room	2	0.8
Outpatient lobby	1	0.4
Emergency room	3	1.2
Critical care center	0	0.0
Patient room	110	45.6
Ward treatment room	2	0.8
Operation room	37	15.4
ICU	7	2.9
CCU	1	0.4
NICU	2	0.8
Examination room	3	1.2
Catheterization laboratory	9	3.7
Radiotherapy room	2	0.8
Radiography room	4	1.7
Radioactive scanning room	0	0.0
Dialysis room	0	0.0
Delivery room	2	0.8
Rehabilitation room	3	1.2
Restroom	12	5.0
Hallway	4	1.7
Bathroom	3	1.2
Stairway	0	0.0
Unknown	1	0.4
Others	25	10.4
No choice(Note)	5	2.1
Total	241	100

(Note) "No choice" means no "place of occurrence" was selected.

Fig. II-1-76 Place of Occurrence and Severity of Event

Place of Occurrence X Severity of Event	Death	Residual disability (likely)	Residual disability (unlikely)	Unknown	No choice(Note)	Total
Outpatient examination room	2	0	1	0	0	3
Outpatient treatment room	0	0	1	0	1	2
Outpatient lobby	1	0	0	0	0	1
Emergency room	0	1	2	0	0	3
Critical care center	0	0	0	0	0	0
Patient room	20	16	45	28	1	110
Ward treatment room	1	0	0	0	1	2
Operation room	3	4	22	7	1	37
ICU	1	3	2	1	0	7
CCU	0	0	0	1	0	1
NICU	0	1	1	0	0	2
Examination room	1	0	1	1	0	3
Catheterization laboratory	2	3	2	1	1	9
Radiotherapy room	0	0	1	1	0	2
Radiography room	1	0	1	1	1	4
Radioactive scanning room	0	0	0	0	0	0
Dialysis room	0	0	0	0	0	0
Delivery room	1	0	0	1	0	2
Rehabilitation room	0	0	1	2	0	3
Restroom	1	1	7	3	0	12
Hallway	0	0	3	1	0	4
Bathroom	0	0	3	0	0	3
Stairway	0	0	0	0	0	0
Unknown	0	1	0	0	0	1
Others	4	1	14	5	1	25
No choice(Note)	0	0	1	1	3	5
Total	38	31	108	54	10	241

(Note) "No choice" means no "place of occurrence" or "severity of event" was selected.

Fig. II-1-77 Situation and Severity of Event

Situation X Severity of Event	Death	Residual disability (likely)	Residual disability (unlikely)	Unknown	No choice(Note)	Total
Related to drug						16
Drug preparation	0	0	0	1	0	1
Subcutaneous/intramuscular injection	0	0	0	0	0	0
Intravenous injection	0	0	3	2	0	5
Arterial injection	0	0	0	0	0	0
Peripheral intravenous drop	0	0	2	0	0	2
Central venous injection	0	0	1	2	0	3
Oral administration	0	1	1	0	0	2
Nose drop/eye drop/ear drop	0	0	0	0	0	0
Other drug prescription/administration	0	0	2	1	0	3
Oral drug dispensing/management	0	0	0	0	0	0
Injection dispensing/management	0	0	0	0	0	0
Dispensing/management, others	0	0	0	0	0	0
Related to blood transfusion						0
Pre-transfusion testing	0	0	0	0	0	0
Blood transfusion	0	0	0	0	0	0
Blood transfusion, others	0	0	0	0	0	0
Related to treatment/procedure						66
Craniotomy	0	0	0	0	0	0
Thoracotomy	0	1	0	1	0	2
Cardiotomy	0	0	2	1	0	3
Laparotomy	1	1	8	2	1	13
Extremities	0	0	0	0	0	0
Endoscopic surgery	1	0	0	0	0	1
Surgery, others	0	0	2	4	0	6
Preparation for surgery	0	0	2	0	0	2
Preoperative procedure	0	0	0	0	1	1
Postoperative procedure	0	1	0	1	0	2
Surgery, others	2	0	3	0	0	5
General anesthesia (inhalation anesthesia and intravenous anesthesia)	0	0	0	0	0	0
Local anesthesia	0	0	0	0	0	0
Inhalation anesthesia	0	0	0	0	0	0
Intravenous anesthesia	0	0	0	0	0	0
Vertebral/epidural anesthesia	0	1	0	0	0	1
Anesthesia, others	0	0	0	0	0	0
Caesarean section	0	0	0	0	0	0
Delivery and artificial abortion, others	1	0	1	0	0	2
Blood purification (including hemodialysis)	0	0	0	0	0	0
IVR (ex. angiocatheter)	0	2	1	0	1	4
Radiotherapy	0	0	1	0	0	1
Rehabilitation	0	0	1	1	0	2
Invasive dental treatment	0	0	0	0	0	0
Endoscopic treatment	2	0	1	0	0	3
Treatment, others	1	1	1	0	1	4

Situation X Severity of Event	Death	Residual disability (likely)	Residual disability (unlikely)	Unknown	No choice(Note)	Total
Central venous line	2	0	4	2	1	9
Peripheral venous line	0	0	0	1	0	1
Catheter for blood purification	0	0	0	0	0	0
Feeding tube (NG, ED)	0	0	0	0	0	0
Urethral catheter	0	0	0	0	0	0
Drainage procedure	0	0	0	1	0	1
Wound care	0	0	1	0	0	1
Tube placement, others	0	0	1	0	0	1
Tracheal intubation	0	0	0	0	0	0
Tracheotomy	0	0	0	0	0	0
Cardiac compression	0	0	0	0	0	0
Oxygen therapy	0	0	0	0	0	0
Emergency procedure, others	0	1	0	0	0	1
Related to use/management of medical equipment (device)						12
Mechanical ventilator	0	1	1	1	0	3
Oxygen therapy equipment	0	0	0	0	0	0
Oxygenator	0	1	0	0	0	1
Defibrillator	0	0	0	0	0	0
Pace maker	0	0	0	0	0	0
Infusion/transfusion pump	0	0	0	1	0	1
Blood purification device	0	0	0	0	0	0
ECG, blood pressure monitor	0	0	0	4	0	4
Pulse oxymeter	0	0	0	0	0	0
Use/management of medical equipment (device), others	0	0	1	2	0	3
Related to use/management of drainage tube or other tube						17
Central venous line	1	0	2	0	0	3
Peripheral venous line	0	0	0	0	0	0
Tracheal tube	0	0	2	2	0	4
Tracheal cannula	0	0	0	0	0	0
Feeding tube (NG, ED)	0	0	0	0	0	0
Urethral catheter	0	0	1	0	0	1
Chest drainage tube	0	0	0	0	0	0
Abdominal drainage tube	0	0	0	0	0	0
Ventricular/cisternal drainage tube	0	0	0	0	0	0
Subcutaneous continuous suction drainage tube	0	0	0	0	0	0
Epidural catheter	0	0	1	0	0	1
Catheter/line for blood purification	0	0	0	0	0	0
Use/management of drainage tube or other tube, others	1	0	6	1	0	8
Related to examination						6
Blood drawing	0	0	0	0	0	0
Sample collection, others	0	0	0	0	0	0
General imaging	0	0	1	0	0	1
MRI	0	0	0	0	0	0
Angiocatheter-aided imaging	0	1	0	0	0	1
Lower gastrointestinal imaging	0	0	0	0	0	0

Situation X Severity of Event	Death	Residual disability (likely)	Residual disability (unlikely)	Unknown	No choice(Note)	Total
Imaging, others	0	0	0	0	0	0
Upper gastrointestinal	1	0	1	0	0	2
Lower gastrointestinal	1	0	0	1	0	2
Bronchoscopy	0	0	0	0	0	0
Endoscopic examination, others	0	0	0	0	0	0
Pathological examination	0	0	0	0	0	0
Examination, others	0	0	0	0	0	0
Related to nursing care						63
Endotracheal/oral suctioning	0	0	0	0	0	0
Changing position	0	0	1	0	0	1
Bed bath	0	0	0	0	0	0
Help with changing clothes	0	1	0	0	0	1
Help with eating	2	1	1	0	0	4
Help with bathing	0	0	1	0	0	1
Help with elimination	0	0	2	0	0	2
Help with moving	0	0	2	0	0	2
Transportation	0	1	0	0	0	1
Tending patient’s belongings	0	0	0	1	0	1
Meal serving	0	0	0	0	0	0
Patient observation	1	0	2	0	0	3
Nursing care, others	0	0	3	1	0	4
Oral intake	0	1	0	0	0	1
While taking a walk	0	0	0	0	0	0
While moving from one place to another	0	3	11	2	0	16
While going out/sleeping out	0	0	2	0	1	3
While eating	1	0	0	0	0	1
While bathing	0	0	0	0	0	0
While excreting	1	2	3	1	0	7
While sleeping	1	1	2	1	0	5
Recuperation, others	2	0	4	4	0	10
Others	5	3	5	5	0	18
No choice(Note)	11	6	15	7	4	43
Total	38	31	108	54	10	241

(Note) “No choice” means no “situation” or “severity of event” was selected.

2. Report on Project to Collect, Analyze, and Provide Medical Near-Miss Information

Medical near-miss information is provided by designated medical institutions and other registered medical institutions. Summary of the project as of December 31, 2005 is reported herein.

[1] Registered Participating Medical Institutions

The number of registered participating medical institutions in Project to Collect Medical Near-Miss Information is shown below.

Fig. II-2-1 Number of registered Participating Medical Institutions

Total number of registered participating medical institutions	1,274
Designated medical institutions (among registered participating medical institutions)	249

Designated medical institutions are those participating in Project to Collect Medical Near-Miss Information and agreed to cooperate to provide "general coded information." Designated medical institutions have been selected by avoiding biases in institution size and location. The number of beds at designated medical institutions and their locations are shown below.

Fig. II-2-2 Designated Medical Institutions by Number of Beds and Location

Number of beds	Number of medical institutions
0 to 99	27
100 to 199	40
200 to 299	25
300 to 399	50
400 to 499	23
500 to 599	25
600 or more	59
Total	249

Location	Number of medical institutions
Hokkaido	15
Tohoku	26
Kanto/Koshinetsu	59
Tokyo	16
Tokai/Hokuriku	39
Kinki	34
Chugoku/Shikoku	33
Kyushu/Okinawa	27
Total	249

The total number of beds at registered medical institutions participating in Project to Collect Medical Near-Miss Information as of December 31, 2005 is 103,970.

[2] Changes in Number of Reports

Fig. II-2-3 Changes in Number of Reports

		15th survey	16th survey	17th survey	18th survey	Remarks
Month of occurrence		January to March	April to June	July to September	October to December	
Collection period		February 15 to May 16	May 17 to August 15	August 16 to November 14	November 15 to February 13, 2006	
Registered participating medical institutions	Total number of registered participating medical institutions	1,269	1,275	1,277	1,274	
	Registered participating medical institutions that made reports	422	383	343	344	
	Designated medical institutions(Note 1)	250	249	249	249	
	Designated medical institutions that made reports	241	247	246	233	Institutions with reporting difficulty in the 15th survey: 9 institutions Institutions with reporting difficulty in the 16th survey: 2 institutions Institutions with reporting difficulty in the 17th survey: 3 institutions Institutions with reporting difficulty in the 18th survey: 13 institutions
Number of reports(Note 2)	Total number of reports	46,565	52,450	48,894	45,732	
	General coded information	43,780	50,576	47,642	44,267	
	Descriptive information	10,584	5,167	3,082	3,525	
Number of evaluable reports	General coded information	40,417	50,573	47,642	44,266	
	Descriptive information	432	718	455	1,641	

(Note 1) Designated medical institutions are those participating in Project to Collect Medical Near-Miss Information and agreed to cooperate to provide "general coded information." As of December 31, 2005, 249 institutions have been designated by avoiding biases in institution size and location.
See Attachment 5 "Designated Medical Institutions for Collection of Medical Near-Miss Information."

(Note 2) Reports from medical institutions are classified into (A) general coded information, (B) general coded information and descriptive information, and (C) descriptive information. "Total number of reports" shown in the table represents aggregated number of (A), (B), and (C); "number of general coded information" represents aggregated number of (A) and (B); and "number of descriptive information" represents aggregated number of (B) and (C).

[3] Details of Reports

Fig. II-2-4 Month of Occurrence

Month of occurrence	Number of reports
January	13,156
February	13,011
March	13,990
April	16,614
May	17,208
June	16,717
July	17,379
August	16,185
September	14,040
October	15,583
November	15,052
December	13,610
Month unknown	353
Total	182,898

Fig. II-2-5 Time of Occurrence

Time of occurrence	Number of events				
	15th	16th	17th	18th	Total
0:00 – before 2:00	2,163	2,590	2,576	2,537	9,866
2:00 – before 4:00	1,752	1,968	1,921	1,896	7,537
4:00 – before 6:00	1,594	1,905	1,817	1,667	6,983
6:00 – before 8:00	2,972	3,596	3,456	3,160	13,184
8:00 – before 10:00	4,703	5,945	5,389	5,159	21,196
10:00 – before 12:00	5,083	6,760	6,109	5,697	23,649
12:00 – before 14:00	3,871	5,196	4,793	4,472	18,332
14:00 – before 16:00	3,642	5,002	4,638	4,321	17,603
16:00 – before 18:00	3,649	4,987	4,484	4,328	17,448
18:00 – before 20:00	3,559	4,388	4,046	3,847	15,840
20:00 – before 22:00	2,752	3,195	3,127	2,970	12,044
22:00 – before 24:00	2,294	2,613	2,618	2,399	9,924
Time unknown	2,383	2,428	2,668	1,813	9,292
Total	40,417	50,573	47,642	44,266	182,898

Fig. II-2-6 Place of Occurrence

Place of Occurrence	Number of events				
	15th	16th	17th	18th	Total
Outpatient examination room	739	966	906	790	3,401
Outpatient lobby	95	143	109	103	450
Outpstient, facility others	538	646	547	505	2,236
Emergentcy room	203	206	241	256	906
Nurse station	4,050	5,469	4,977	4,515	19,011
Patient room	22,859	28,418	26,087	24,801	102,165
Treatment room	626	894	745	755	3,020
Bathroom	167	190	206	187	750
Ward facility, others	1,564	1,942	2,322	1,941	7,769
Operation room	1,181	1,399	1,272	1,142	4,994
Delivery room	33	51	50	45	179
ICU	1,165	1,504	1,430	1,371	5,470
CCU	269	293	242	246	1,050
NICU	621	577	477	551	2,226
ICU, others	356	371	419	469	1,615
Examination room	649	790	798	704	2,941
Rehabilitation room	151	218	212	218	799
IVR room	6	17	13	29	65
Radiography/examination room	752	867	849	910	3,378
Radioactive scanning room	25	32	44	28	129
Radiotherapy room	21	42	37	38	138
Dialysis room	452	588	478	428	1,946
Pharmacy/blood transfusion unit	1,383	1,668	1,573	1,472	6,096
Nutritional management/ room/kitchen	294	355	355	311	1,315
Restroom	633	676	724	689	2,722
Hallway	579	741	779	693	2,792
Stairway	12	15	14	20	61
Unknown	150	286	731	144	1,311
Other place (within institution)	727	1,014	819	760	3,320
Other place (outside institution)	117	195	186	145	643
Total	40,417	50,573	47,642	44,266	182,898

Fig. II-2-7 Cause of Event

Cause of Event (Note 1)	15th		16th		17th		18th		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Inadequate check	24,041	27.5	31,746	27.4	29,776	24.8	27,489	25.1	113,052	26.1
Inadequate observation	12,545	14.3	15,057	13.0	15,264	12.7	14,617	13.3	57,483	13.3
Misjudgment	7,093	8.1	8,958	7.7	8,958	7.5	8,485	7.7	33,494	7.7
Lack of knowledge/wrong knowledge	2,180	2.5	3,614	3.1	3,788	3.2	2,922	2.7	12,504	2.9
Deficiency of technique (skill)/erroneous technique (skill)	1,742	2.0	2,616	2.3	2,950	2.5	2,355	2.1	9,663	2.2
Reporting, etc. (forgotten, inadequate/incorrect, inappropriate)	1,304	1.5	2,013	1.7	2,260	1.9	1,865	1.7	7,442	1.7
Physical condition (ex. lack of sleep, being sick)	1,180	1.3	1,637	1.4	2,027	1.7	1,683	1.5	6,527	1.5
Psychological condition (ex. rushed, action based on false assumption)	10,134	11.6	15,330	13.2	15,092	12.6	13,864	12.6	54,420	12.6
System	1,359	1.6	2,003	1.7	2,293	1.9	1,825	1.7	7,480	1.7
Coordination	4,098	4.7	5,352	4.6	5,380	4.5	4,994	4.6	19,824	4.6
Record documentation	844	1.0	1,126	1.0	1,579	1.3	1,158	1.1	4,707	1.1
Similarity in patient's appearance (face, age) or name	160	0.2	203	0.2	193	0.2	171	0.2	727	0.2
Working condition	8,563	9.8	10,091	8.7	10,936	9.1	10,687	9.7	40,277	9.3
Environment	676	0.8	877	0.8	1,294	1.1	919	0.8	3,766	0.9
Medical/dental equipment (device), tool, material	720	0.8	944	0.8	1,426	1.2	1,005	0.9	4,095	0.9
Drug	781	0.9	1,101	1.0	1,504	1.3	1,146	1.0	4,532	1.0
Other items	363	0.4	503	0.4	562	0.5	470	0.4	1,898	0.4
Facility	170	0.2	257	0.2	642	0.5	316	0.3	1,385	0.3
Education/training	1,974	2.3	3,295	2.8	3,075	2.6	2,209	2.0	10,553	2.4
Explanation to patient/family	5,613	6.4	6,221	5.4	6,961	5.8	6,753	6.2	25,548	5.9
Others	1,970	2.3	2,864	2.5	3,987	3.3	4,761	4.3	13,582	3.1
Total	87,510	100.0	115,808	100.0	119,947	100.0	109,694	100.0	432,959	100.0

(Note 1) "Cause of event" may be more than one.

Fig. II-2-8 Cause of Event (Details)

Cause of Event (Note)	Detailed cause of event	Number of events				
		15th	16th	17th	18th	Total
Check	Inadequate checking	23,618	31,205	29,208	27,009	111,040
	Others	423	541	568	480	2,012
Observation	Inadequate observation	12,317	14,794	14,781	14,325	56,217
	Others	228	263	483	292	1,266
Psychological condition	Rushed	2,331	3,578	3,261	3,159	12,329
	Irritated	213	257	340	239	1,049
	Nervous	205	648	370	338	1,561
	Preoccupied with other thing	1,684	2,472	2,366	2,229	8,751
	Acted based on false assumption	3,864	5,637	5,620	5,264	20,385
	Acted unwittingly	1,081	1,681	1,913	1,670	6,345
	Others	756	1,057	1,222	965	4,000
Working condition	Busy	3,962	4,892	4,659	4,789	18,302
	Inadequate personnel management	36	77	183	86	382
	Interrupted procedure	354	459	431	460	1,704
	On duty	166	192	178	188	724
	After duty	34	47	68	42	191
	Worked on night shift	3,619	3,860	4,281	4,372	16,132
	After working on night shift	155	182	349	250	936
	Others	237	382	787	500	1,906
Judgment	Misjudgment	6,629	8,397	8,204	7,948	31,178
	Others	464	561	754	537	2,316
Explanation to patient/family	Inadequate explanation	2,588	2,958	3,082	3,033	11,661
	Incorrect explanation	55	86	77	75	293
	Insufficient understanding of patient/family	2,703	2,927	3,153	3,255	12,038
	Others	267	250	649	390	1,556
Coordination	Insufficient coordination between doctor and nurse	996	1,332	1,227	1,267	4,822
	Insufficient coordination between doctor and technical staff	44	94	115	84	337
	Insufficient coordination between doctor and administrative staff	18	24	15	20	77
	Insufficient coordination between doctors	85	106	89	110	390
	Insufficient coordination between nurses	2,242	2,936	2,693	2,617	10,488
	Insufficient coordination among technical staff	134	149	181	143	607
	Insufficient coordination among staff with different responsibilities	386	478	480	442	1,786
	Insufficient coordination between dentist and dental staff	0	0	0	0	0
	Others	193	233	580	311	1,317
Knowledge	Lack of knowledge	1,794	3,023	2,833	2,222	9,872
	Incorrect knowledge	179	322	372	332	1,205
	Others	207	269	583	368	1,427
Total		74,267	96,369	96,155	89,811	356,602

(Note 1) "Cause of event" may be more than one.

Fig. II-2-9 Patient Age

Age	Number of events				
	15th	16th	17th	18th	Total
0 to 10	2,854	3,503	3,095	2,981	12,433
11 to 20	737	1,003	1,073	860	3,673
21 to 30	1,268	1,603	1,530	1,381	5,782
31 to 40	1,669	2,110	2,021	1,931	7,731
41 to 50	1,850	2,483	2,487	2,272	9,092
51 to 60	4,373	5,560	5,497	5,265	20,695
61 to 70	7,418	9,044	8,705	8,101	33,268
71 to 80	9,862	12,233	11,429	10,730	44,254
81 to 90	5,058	6,421	5,955	5,637	23,071
91 or above	1,028	1,103	955	912	3,998
Multiple patients involved	446	532	463	450	1,891
Unknown	3,854	4,978	4,432	3,746	17,010
Total	40,417	50,573	47,642	44,266	182,898

Fig. II-2-10 Effect of Medical Near-Miss Incident

Effect	15th		16th		17th		18th		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Detected before taking action: slight effect on patient (no treatment necessary)	4,473	11.1	5,293	10.5	5,341	11.2	4,997	11.3	20,104	11.0
Detected before taking action: moderate effect on patient (treatment necessary)	1,637	4.1	1,586	3.1	1,506	3.2	1,375	3.1	6,104	3.3
Detected before taking action: major effect on patient (life-threatening)	423	1.0	429	0.8	649	1.4	259	0.6	1,760	1.0
Action taken but patient not affected	28,062	69.4	36,191	71.6	33,325	69.9	31,166	70.4	128,744	70.4
Unknown	1,869	4.6	2,447	4.8	2,326	4.9	2,131	4.8	8,773	4.8
Others	3,953	9.8	4,627	9.1	4,495	9.4	4,338	9.8	17,413	9.5
Total	40,417	100.0	50,573	100.0	47,642	100.0	44,266	100.0	182,898	100.0

Fig. II-2-11 Years of Experience of Person Involved

Years of Experience of Person Involved	Number of events				
	15th	16th	17th	18th	Total
0 year	4,822	6,133	7,554	6,427	24,936
1 year	3,762	5,211	4,448	3,980	17,401
2 years	3,371	3,929	3,760	3,740	14,800
3 years	2,644	3,666	3,276	2,901	12,487
4 years	2,231	2,801	2,413	2,340	9,785
5 years	1,905	2,359	2,140	2,020	8,424
6 years	1,594	1,899	1,712	1,539	6,744
7 years	1,398	1,775	1,515	1,448	6,136
8 years	1,126	1,437	1,204	1,070	4,837
9 years	1,018	1,259	1,142	1,125	4,544
10 years	1,114	1,445	1,304	1,261	5,124
11 to 20 years	5,765	7,126	6,612	6,565	26,068
21 to 30 years	3,069	3,813	3,532	3,434	13,848
30 years or longer	580	746	723	714	2,763
Multiple persons involved	1,473	1,843	1,740	1,508	6,564
Unknown	4,545	5,131	4,567	4,194	18,437
Total	40,417	50,573	47,642	44,266	182,898

Fig. II-2-12 Job Title of Person Involved

Job Title of Person Involved (Note)	Number of events				
	15th	16th	17th	18th	Total
Doctor	1,812	2,301	2,150	2,027	8,290
Dentist	16	29	26	33	104
Midwife	457	603	556	477	2,093
Nurse	32,522	40,547	38,421	35,604	147,094
Assistant nurse	665	768	754	707	2,894
Nursing assistant	266	338	298	297	1,199
Pharmacist	1,532	1,811	1,691	1,593	6,627
National registered dietitian	194	150	202	216	762
Dietitian	141	241	198	143	723
Cook/cooking staff	347	547	506	454	1,854
Radiological technologist	690	768	742	828	3,028
Clinical technologist	685	784	787	677	2,933
Medical technologist	7	10	16	6	39
Physical therapist (PT)	155	240	234	221	850
Occupational therapist (OT)	52	98	91	102	343
Speech therapist (ST)	11	18	12	14	55
Dental hygienist	3	8	15	12	38
Dental technician	0	2	2	2	6
Orthoptist	10	15	12	8	45
Psychiatric social worker	4	6	2	4	16
Clinical psychologist	2	3	3	3	11
Certified social worker	3	2	1	6	12
Certified care worker	55	75	63	69	262
Clinical engineering technologist	112	146	139	121	518
Children’s supervisor/child minder	16	21	21	13	71
Administrative staff	593	691	513	408	2,205
Unknown	674	1,132	2,172	3,199	7,177
Others	419	587	702	673	2,381
Total	41,443	51,941	50,329	47,917	191,630

(Note) More than one “job title” could be involved in a case.

Fig. II-2-13 Patient Physical/Psychological State

Patient Physical/Psychological State (Note)	Number of events				
	15th	16th	17th	18th	Total
Disturbance of consciousness	2,811	3,490	3,365	3,268	12,934
Visual impairment	777	1,005	950	884	3,616
Hearing impairment	649	840	865	752	3,106
Dysarthria	605	920	822	884	3,231
Mental disorder	1,682	2,152	2,361	2,363	8,558
Dementia/amnesia	3,473	4,193	4,027	4,006	15,699
Upper extremity disability	1,941	2,556	2,326	2,170	8,993
Lower extremity disability	3,419	4,383	4,081	3,939	15,822
Gait disorder	4,115	5,358	5,088	4,855	19,416
Bed rest	4,691	6,179	6,075	5,779	22,724
Sleeping	764	944	871	832	3,411
Delirious	1,670	1,800	1,888	1,691	7,049
Under drug influence	2,220	2,689	2,833	2,494	10,236
Anesthetized/pre- or post-anesthesia	1,066	1,260	1,176	1,048	4,550
No disorder	9,275	12,311	11,299	10,836	43,721
Unknown	9,991	11,557	11,925	11,443	44,916
Others	4,352	5,713	4,988	4,738	19,791
Total	53,501	67,350	64,940	61,982	247,773

(Note) More than one "patient physical/psychological state" could be selected.

Fig. II-2-14 Sex of Patients

Sex	Number of events				
	15th	16th	17th	18th	Total
Male	21,510	26,802	25,222	23,582	97,116
Female	16,823	21,105	20,119	18,669	76,716
Multiple patients involved	381	477	434	437	1,729
Unidentifiable	1,703	2,189	1,867	1,578	7,337
Total	40,417	50,573	47,642	44,266	182,898

Fig. II-2-15 Number of Years Person Involved Has Been Working at Current Department

Number of Years Person Involved Has Been Working at Current Department	Number of events				
	15th	16th	17th	18th	Total
0 year	8,906	11,844	13,006	11,561	45,317
1 year	6,411	8,741	7,581	6,880	29,613
2 years	5,033	5,991	5,570	5,592	22,186
3 years	3,427	4,514	3,925	3,559	15,425
4 years	2,188	2,824	2,553	2,553	10,118
5 years	1,464	1,890	1,660	1,685	6,699
6 years	942	1,242	1,094	983	4,261
7 years	730	749	682	745	2,906
8 years	404	609	500	473	1,986
9 years	358	380	332	311	1,381
10 years	307	407	443	380	1,537
11 to 20 years	1,132	1,423	1,296	1,334	5,185
21 to 30 years	497	430	422	421	1,770
30 years or longer	180	172	183	194	729
Multiple persons involved	1,471	1,842	1,742	1,512	6,567
Unknown	6,967	7,515	6,653	6,083	27,218
Total	40,417	50,573	47,642	44,266	182,898

Fig. II-2-16 Person Who Identified Incident

Person Who Identified Incident	Number of events				
	15th	16th	17th	18th	Total
Person himself/herself	20,623	24,331	22,921	21,689	89,564
Coworker of same job title	10,955	15,123	14,407	12,993	53,478
Coworker of another job title	4,213	5,422	4,857	4,452	18,944
Patient himself/herself	1,735	2,121	2,081	1,881	7,818
Patient’s family/caregiver	990	1,144	1,011	1,074	4,219
Other patient	1,060	1,024	1,159	1,068	4,311
Unknown	315	602	368	252	1,537
Others	526	806	838	857	3,027
Total	40,417	50,573	47,642	44,266	182,898

Fig. II-2-17 Situation in Which Medical Near-Miss Incident Occurred

Situation	15th		16th		17th		18th		Total	
	Number	%	Number	%	Number	%	Number	%	Number	%
Ordering/instruction	650	1.6	843	1.7	861	1.8	793	1.8	3,147	1.7
Communication process	1,248	3.1	1,485	2.9	1,296	2.7	1,209	2.7	5,238	2.9
Drug preparation	750	1.9	1,030	2.0	966	2.0	789	1.8	3,535	1.9
Prescription/drug administration	10,115	25.0	14,064	27.8	12,596	26.4	10,760	24.3	47,535	26.0
Dispensing, drug management, etc.	1,565	3.9	2,075	4.1	1,889	4.0	1,814	4.1	7,343	4.0
Blood transfusion	227	0.6	279	0.6	260	0.5	189	0.4	955	0.5
Surgery	615	1.5	746	1.5	730	1.5	571	1.3	2,662	1.5
Anesthesia	65	0.2	59	0.1	49	0.1	62	0.1	235	0.1
Delivery/mechanical abortion	26	0.1	40	0.1	29	0.1	26	0.1	121	0.1
Treatment, others	289	0.7	410	0.8	455	1.0	409	0.9	1,563	0.9
Procedure	317	0.8	395	0.8	374	0.8	302	0.7	1,388	0.8
Examination/interview	137	0.3	165	0.3	149	0.3	143	0.3	594	0.3
Use/management of medical equipment (device)	1,259	3.1	1,553	3.1	1,326	2.8	1,114	2.5	5,252	2.9
Use/management of drainage tube or other tube	6,865	17.0	7,839	15.5	7,770	16.3	7,180	16.2	29,654	16.2
Use/management of dental equipment (device)/material	3	0.0	9	0.0	8	0.0	15	0.0	35	0.0
Examination/test	3,079	7.6	3,926	7.8	3,554	7.5	3,287	7.4	13,846	7.6
Nursing care	4,216	10.4	5,308	10.5	4,662	9.8	4,790	10.8	18,976	10.4
Meal/nutrition	1,160	2.9	1,581	3.1	1,399	2.9	1,246	2.8	5,386	2.9
Nursing care, others	5,781	14.3	5,962	11.8	6,203	13.0	5,661	12.8	23,607	12.9
Supply transportation	50	0.1	59	0.1	51	0.1	52	0.1	212	0.1
Radiation control	5	0.0	25	0.0	15	0.0	15	0.0	60	0.0
Medical record and information management	528	1.3	685	1.4	548	1.2	460	1.0	2,221	1.2
Explanation to patient/family	285	0.7	378	0.7	356	0.7	340	0.8	1,359	0.7
Facility	94	0.2	99	0.2	116	0.2	112	0.3	421	0.2
Others	1,088	2.7	1,558	3.1	1,980	4.2	2,927	6.6	7,553	4.1
Total	40,417	100.0	50,573	100.0	47,642	100.0	44,266	100.0	182,898	100.0

Fig. II-2-18 Situation and Cause (15th Survey)

Situation and Cause (Note)	Check	Observation	Judgment	Knowledge	Technique (skill)	Reporting, etc.	Physical condition	Psychological condition	System
Ordering/instruction	526	38	68	40	9	33	16	137	61
Communication process	1,006	63	213	111	25	200	38	315	134
Drug preparation	614	60	78	37	45	35	16	228	37
Prescription/drug administration	8,745	1,366	1,489	728	394	379	357	3,141	388
Dispensing, drug management, etc.	1,371	120	117	63	65	27	51	503	47
Blood transfusion	166	29	38	34	20	19	7	81	10
Surgery	423	114	103	61	69	42	20	167	35
Anesthesia	33	17	6	5	11	1	5	14	2
Delivery/mechanical abortion	19	7	5	2	4	3	3	8	0
Treatment, others	191	104	79	32	15	15	18	65	11
Procedure	188	87	73	42	59	27	9	96	13
Examination/interview	79	23	39	9	4	16	13	37	6
Use/management of medical equipment (device)	913	279	159	138	111	35	30	286	26
Use/management of drainage tube or other tube	2,651	4,217	1,486	268	442	66	148	848	38
Use/management of dental equipment (device)/material	1	0	0	1	2	0	0	0	0
Examination/test	2,426	282	376	207	151	135	118	929	267
Nursing care	1,291	2,298	1,018	142	112	77	86	507	25
Meal/nutrition	996	126	103	46	36	37	12	261	40
Nursing care, others	1,100	3,089	1,331	61	57	38	116	443	34
Supply transportation	37	2	9	1	2	3	2	10	5
Radiation control	3	1	2	0	0	1	0	0	1
Medical record and information management	445	18	36	20	8	16	4	122	20
Explanation to patient/family	158	23	48	36	7	18	8	53	16
Facility	31	6	9	6	2	3	0	9	8
Others	535	151	110	41	32	33	28	124	39
Total	23,948	12,520	6,995	2,131	1,682	1,259	1,105	8,384	1,263

(Note) More than one "cause" could be selected.

Coordination	Record documentation	Similarity in patient's appearance (face, age) or name	Working condition	Environment	Medical/dental equipment, instrument, material	Drug	Other items	Facility	Education/training	Explanation to patient/family	Others	Total
124	30	6	85	5	5	13	2	2	28	20	40	1,288
377	96	7	219	15	7	10	5	6	95	39	23	3,004
97	24	2	125	10	4	59	5	0	30	14	16	1,536
1,199	294	51	2,026	50	50	357	30	6	531	438	220	22,239
116	21	5	254	15	23	239	11	4	79	14	33	3,178
40	6	0	43	1	2	3	1	1	13	1	9	524
139	24	1	65	14	30	2	15	2	35	22	37	1,420
10	2	0	11	2	4	2	4	0	3	4	9	145
4	0	0	5	1	0	0	0	0	0	2	0	63
38	5	1	47	7	8	5	4	4	15	17	19	700
45	9	0	68	12	12	4	7	0	24	25	22	822
21	3	5	40	1	1	0	1	3	6	14	14	335
96	4	0	158	18	230	2	18	5	85	7	50	2,650
303	4	1	1,459	76	151	18	45	3	239	922	256	13,641
0	0	0	0	0	2	0	0	0	0	0	0	6
413	76	38	558	35	65	8	29	13	153	128	226	6,633
273	10	11	856	118	45	15	67	28	176	975	242	8,372
122	19	5	158	11	3	2	10	5	59	47	25	2,123
197	9	3	1,060	219	37	16	73	39	158	1,829	411	10,320
10	1	1	7	1	0	0	1	2	7	1	3	105
1	1	0	1	0	0	0	1	0	0	0	0	12
56	126	16	62	3	3	0	9	3	23	6	21	1,017
48	4	1	42	2	0	0	0	1	15	130	13	623
4	0	0	14	7	7	0	6	27	4	7	16	166
75	18	6	93	44	31	26	19	15	46	80	265	1,811
3,808	786	160	7,456	667	720	781	363	169	1,824	4,742	1,970	82,733

Fig. II-2-19 Situation and Cause (16th Survey)

Situation and Cause (Note)	Check	Observation	Judgment	Knowledge	Technique (skill)	Reporting, etc.	Physical condition	Psychological condition	System
Ordering/instruction	687	52	119	79	27	85	33	215	106
Communication process	1,194	109	279	160	34	239	48	466	179
Drug preparation	876	88	122	103	101	56	36	353	56
Prescription/drug administration	12,134	2,190	2,061	1,347	681	622	511	4,666	589
Dispensing, drug management, etc.	1,811	142	150	101	99	26	56	736	56
Blood transfusion	192	35	46	53	23	18	7	93	23
Surgery	516	146	136	88	98	59	34	202	43
Anesthesia	28	19	9	4	12	3	4	10	1
Delivery/mechanical abortion	25	10	11	3	5	3	3	11	0
Treatment, others	257	136	103	37	43	27	22	123	19
Procedure	252	89	94	65	65	35	17	125	16
Examination/interview	88	25	29	5	2	10	5	31	8
Use/management of medical equipment (device)	1,136	370	212	194	175	57	35	399	51
Use/management of drainage tube or other tube	3,240	4,771	1,805	400	566	143	226	1,210	51
Use/management of dental equipment (device)/material	8	2	1	0	2	0	0	7	0
Examination/test	3,040	352	481	335	160	199	129	1,289	287
Nursing care	1,795	2,882	1,379	223	232	101	119	766	81
Meal/nutrition	1,380	183	143	64	68	69	32	446	80
Nursing care, others	1,345	3,133	1,287	85	48	52	156	481	28
Supply transportation	42	7	12	2	4	3	2	20	3
Radiation control	19	4	7	0	4	0	0	4	3
Medical record and information management	576	30	63	28	19	31	16	186	37
Explanation to patient/family	206	21	76	32	4	43	8	92	27
Facility	44	21	10	4	3	4	3	13	7
Others	702	207	149	88	60	52	29	208	69
Total	31,593	15,024	8,784	3,500	2,535	1,937	1,531	12,152	1,820

(Note) More than one "cause" could be selected.

Coordination	Record documentation	Similarity in patient's appearance (face, age) or name	Working condition	Environment	Medical/dental equipment, instrument, material	Drug	Other items	Facility	Education/training	Explanation to patient/family	Others	Total
191	76	2	126	18	10	22	11	7	63	31	27	1,987
451	118	14	282	19	6	12	8	5	150	63	28	3,864
130	44	5	193	17	9	78	13	5	85	28	24	2,422
1,725	453	57	2,615	74	62	572	52	9	1,084	544	441	32,489
114	46	3	338	17	28	299	11	4	98	17	47	4,199
56	8	0	61	5	7	2	2	1	26	1	15	674
157	21	0	91	14	45	10	17	9	46	24	42	1,798
11	0	0	8	3	3	4	2	1	3	4	8	137
5	0	0	5	0	2	0	0	0	3	3	1	90
54	14	2	63	14	13	4	7	4	36	22	16	1,016
53	11	1	81	7	18	5	5	1	36	20	30	1,026
26	2	8	36	1	1	0	1	0	4	19	20	321
152	7	0	203	27	293	6	41	6	137	19	70	3,590
369	15	1	1,524	88	218	18	67	5	372	947	361	16,397
1	0	0	4	0	3	0	1	0	0	0	0	29
476	71	51	703	27	70	9	30	3	254	142	283	8,391
328	18	15	981	165	43	16	75	47	215	1,211	335	11,027
165	33	14	193	13	6	2	11	6	102	49	77	3,136
185	8	4	1,013	288	40	17	100	75	167	1,849	512	10,873
5	1	0	11	2	4	0	1	2	4	1	6	132
7	0	2	1	0	0	0	0	0	0	0	0	51
66	58	15	63	7	6	1	12	2	44	12	46	1,318
76	10	2	54	3	4	1	1	1	19	170	17	867
6	0	0	8	1	8	1	9	26	9	9	11	197
111	31	7	112	54	45	22	26	25	95	119	447	2,658
4,920	1,045	203	8,769	864	944	1,101	503	244	3,052	5,304	2,864	108,689

Fig. II-2-20 Situation and Cause (17th Survey)

Situation and Cause (Note)	Check	Observation	Judgment	Knowledge	Technique (skill)	Reporting, etc.	Physical condition	Psychological condition	System
Ordering/instruction	706	56	97	68	22	55	28	212	114
Communication process	1,074	101	273	162	60	215	70	430	170
Drug preparation	840	81	123	93	75	57	45	329	70
Prescription/drug administration	11,070	2,155	2,096	1,249	760	687	576	4,736	662
Dispensing, drug management, etc.	1,670	167	167	121	109	64	102	710	92
Blood transfusion	206	34	49	49	28	18	12	89	21
Surgery	516	128	131	87	91	56	32	233	45
Anesthesia	29	16	11	4	7	4	0	11	4
Delivery/mechanical abortion	18	7	8	3	1	4	0	8	1
Treatment, others	290	158	143	55	59	54	30	135	40
Procedure	257	83	98	60	72	22	17	123	16
Examination/interview	96	23	25	8	6	10	10	41	10
Use/management of medical equipment (device)	1,018	375	202	196	153	55	47	421	72
Use/management of drainage tube or other tube	3,241	4,793	1,862	439	574	151	262	1,274	113
Use/management of dental equipment (device)/material	6	2	2	0	0	1	1	2	0
Examination/test	2,811	350	510	329	234	211	148	1,204	257
Nursing care	1,674	2,679	1,235	249	292	172	158	778	131
Meal/nutrition	1,206	199	138	76	72	54	32	400	77
Nursing care, others	1,395	3,450	1,262	104	77	39	177	534	35
Supply transportation	38	4	6	4	9	7	2	20	9
Radiation control	10	2	5	1	1	1	1	3	2
Medical record and information management	449	60	90	62	46	63	51	171	66
Explanation to patient/family	224	43	89	45	15	30	10	101	25
Facility	59	21	18	6	3	7	2	21	10
Others	754	251	212	137	105	110	95	307	112
Total	29,657	15,238	8,852	3,607	2,871	2,147	1,908	12,293	2,154

(Note) More than one “cause” could be selected.

Coordination	Record documentation	Similarity in patient's appearance (face, age) or name	Working condition	Environment	Medical/dental equipment, instrument, material	Drug	Other items	Facility	Education/training	Explanation to patient/family	Others	Total
177	75	4	121	17	19	29	5	12	50	26	79	1,972
449	138	6	276	44	34	48	10	29	128	75	83	3,875
125	56	4	224	16	13	88	5	9	61	22	51	2,387
1,639	542	49	2,836	171	170	667	58	93	932	656	644	32,448
204	79	6	394	52	56	298	16	36	136	51	118	4,648
50	11	1	48	5	9	6	4	4	29	5	15	693
168	29	3	94	23	56	8	16	7	54	31	60	1,868
6	0	0	6	0	3	1	1	0	4	1	9	117
6	0	0	4	0	0	0	1	0	2	1	0	64
69	25	0	86	20	24	17	12	17	38	45	39	1,356
50	7	1	73	5	21	12	10	5	30	18	24	1,004
36	4	14	37	4	4	1	1	4	9	19	21	383
139	21	2	228	30	297	14	44	19	123	36	95	3,587
382	57	4	1,854	143	340	59	84	48	336	1,053	487	17,556
2	0	0	2	0	0	0	0	0	0	0	1	19
469	123	54	665	51	79	26	36	25	222	167	275	8,246
408	86	18	963	213	91	71	76	90	269	1,218	353	11,224
144	40	5	182	14	10	11	21	14	82	48	84	2,909
183	12	5	1,145	316	45	21	108	77	130	1,995	507	11,617
16	4	1	8	1	2	5	2	0	5	1	4	148
4	1	0	1	1	2	1	0	1	2	1	2	42
98	86	12	113	43	34	32	12	29	76	41	70	1,704
82	6	0	55	4	5	4	2	4	29	147	16	936
7	2	0	9	12	6	1	9	34	8	12	10	257
166	103	4	186	93	106	84	29	77	112	162	940	4,145
5,079	1,507	193	9,610	1,278	1,426	1,504	562	634	2,867	5,831	3,987	113,205

Fig. II-2-21 Situation and Cause (18th Survey)

Situation and Cause (Note)	Check	Observation	Judgment	Knowledge	Technique (skill)	Reporting, etc.	Physical condition	Psychological condition	System
Ordering/instruction	622	47	90	71	25	71	29	172	100
Communication process	996	124	256	137	57	199	53	421	154
Drug preparation	703	68	86	56	57	22	36	288	33
Prescription/drug administration	9,431	1,730	1,727	896	508	491	425	3,959	495
Dispensing, drug management, etc.	1,586	163	164	90	114	44	89	702	67
Blood transfusion	144	36	44	35	20	14	10	67	12
Surgery	410	96	107	72	73	50	16	171	36
Anesthesia	39	22	11	8	11	6	5	18	1
Delivery/mechanical abortion	15	6	5	4	6	3	1	7	1
Treatment, others	257	150	137	46	60	42	24	118	32
Procedure	199	82	86	52	62	16	20	110	14
Examination/interview	96	18	34	14	3	18	5	42	8
Use/management of medical equipment (device)	816	319	174	154	128	44	44	370	40
Use/management of drainage tube or other tube	3,035	4,376	1,761	312	422	98	165	1,114	69
Use/management of dental equipment (device)/material	11	5	3	3	3	2	2	2	1
Examination/test	2,661	346	450	258	185	182	157	1,128	264
Nursing care	1,779	2,824	1,316	181	237	123	130	714	71
Meal/nutrition	1,080	202	118	52	51	48	31	325	67
Nursing care, others	1,287	2,968	1,145	68	39	28	163	460	28
Supply transportation	37	5	9	4	7	2	3	20	3
Radiation control	9	0	3	0	0	1	0	4	0
Medical record and information management	386	38	49	32	25	29	23	160	40
Explanation to patient/family	207	35	78	32	12	28	12	94	19
Facility	55	15	12	8	8	6	5	17	7
Others	1,523	929	533	258	187	214	118	661	133
Total	27,384	14,604	8,398	2,843	2,300	1,781	1,566	11,144	1,695

(Note) More than one “cause” could be selected.

Coordination	Record documentation	Similarity in patient's appearance (face, age) or name	Working condition	Environment	Medical/dental equipment, instrument, material	Drug	Other items	Facility	Education/training	Explanation to patient/family	Others	Total
173	69	8	120	8	11	21	7	5	73	25	87	1,834
363	100	8	264	24	25	21	5	14	93	56	78	3,448
104	19	3	177	9	9	78	7	2	56	25	42	1,880
1,466	412	41	2,459	87	69	507	42	21	655	556	499	26,476
130	45	0	391	21	25	308	12	8	73	13	132	4,177
39	11	1	45	6	4	5	3	2	20	3	12	533
159	19	3	76	16	34	9	16	3	33	26	45	1,470
10	1	0	12	5	5	3	2	2	3	6	6	176
6	1	0	5	1	1	0	0	0	2	3	2	69
64	17	1	75	16	13	11	7	8	19	33	47	1,177
41	11	0	78	6	12	7	5	4	21	18	29	873
28	4	6	37	2	2	3	1	2	9	14	16	362
107	12	0	202	20	248	3	26	4	102	20	85	2,918
373	31	1	1,694	99	274	37	57	17	230	1,121	458	15,744
1	1	0	1	1	7	1	0	1	2	2	1	50
464	117	52	653	36	61	18	33	20	166	140	211	7,602
344	29	11	1,087	159	67	24	87	33	211	1,349	334	11,110
123	26	8	138	7	6	4	13	5	59	36	97	2,496
163	9	0	1,075	269	35	14	101	58	95	1,635	453	10,093
17	1	0	6	1	2	1	2	1	4	2	3	130
2	0	1	0	0	5	0	0	0	0	1	2	28
73	34	7	68	15	14	11	5	13	46	23	25	1,116
71	9	3	43	3	5	2	4	1	18	153	14	843
5	2	0	12	10	7	0	6	34	9	13	9	240
274	98	17	667	87	64	58	29	49	123	323	2,074	8,419
4,600	1,078	171	9,385	908	1,005	1,146	470	307	2,122	5,596	4,761	103,264

Fig. II-2-22 Situation and Cause (Aggregated Table, 15th to 18th Surveys)

Situation and Cause (Note)	Check	Observation	Judgment	Knowledge	Technique (skill)	Reporting, etc.	Physical condition	Psychological condition	System
Ordering/instruction	2,541	193	374	258	83	244	106	736	381
Communication process	4,270	397	1,021	570	176	853	209	1,632	637
Drug preparation	3,033	297	409	289	278	170	133	1,198	196
Prescription/drug administration	41,380	7,441	7,373	4,220	2,343	2,179	1,869	16,502	2,134
Dispensing, drug management, etc.	6,438	592	598	375	387	161	298	2,651	262
Blood transfusion	708	134	177	171	91	69	36	330	66
Surgery	1,865	484	477	308	331	207	102	773	159
Anesthesia	129	74	37	21	41	14	14	53	8
Delivery/mechanical abortion	77	30	29	12	16	13	7	34	2
Treatment, others	995	548	462	170	177	138	94	441	102
Procedure	896	341	351	219	258	100	63	454	59
Examination/interview	359	89	127	36	15	54	33	151	32
Use/management of medical equipment (device)	3,883	1,343	747	682	567	191	156	1,476	189
Use/management of drainage tube or other tube	12,167	18,157	6,914	1,419	2,004	458	801	4,446	271
Use/management of dental equipment (device)/material	26	9	6	4	7	3	3	11	1
Examination/test	10,938	1,330	1,817	1,129	730	727	552	4,550	1,075
Nursing care	6,539	10,683	4,948	795	873	473	493	2,765	308
Meal/nutrition	4,662	710	502	238	227	208	107	1,432	264
Nursing care, others	5,127	12,640	5,025	318	221	157	612	1,918	125
Supply transportation	154	18	36	11	22	15	9	70	20
Radiation control	41	7	17	1	5	3	1	11	6
Medical record and information management	1,856	146	238	142	98	139	94	639	163
Explanation to patient/family	795	122	291	145	38	119	38	340	87
Facility	189	63	49	24	16	20	10	60	32
Others	3,514	1,538	1,004	524	384	409	270	1,300	353
Total	112,582	57,386	33,029	12,081	9,388	7,124	6,110	43,973	6,932

(Note) More than one “cause” could be selected.

Coordination	Record documentation	Similarity in patient's appearance (face, age) or name	Working condition	Environment	Medical/dental equipment, instrument, material	Drug	Other items	Facility	Education/training	Explanation to patient/family	Others	Total
665	250	20	452	48	45	85	25	26	214	102	233	7,081
1,640	452	35	1,041	102	72	91	28	54	466	233	212	14,191
456	143	14	719	52	35	303	30	16	232	89	133	8,225
6,029	1,701	198	9,936	382	351	2,103	182	129	3,202	2,194	1,804	113,652
564	191	14	1,377	105	132	1,144	50	52	386	95	330	16,202
185	36	2	197	17	22	16	10	8	88	10	51	2,424
623	93	7	326	67	165	29	64	21	168	103	184	6,556
37	3	0	37	10	15	10	9	3	13	15	32	575
21	1	0	19	2	3	0	1	0	7	9	3	286
225	61	4	271	57	58	37	30	33	108	117	121	4,249
189	38	2	300	30	63	28	27	10	111	81	105	3,725
111	13	33	150	8	8	4	4	9	28	66	71	1,401
494	44	2	791	95	1,068	25	129	34	447	82	300	12,745
1,427	107	7	6,531	406	983	132	253	73	1,177	4,043	1,562	63,338
4	1	0	7	1	12	1	1	1	2	2	2	104
1,822	387	195	2,579	149	275	61	128	61	795	577	995	30,872
1,353	143	55	3,887	655	246	126	305	198	871	4,753	1,264	41,733
554	118	32	671	45	25	19	55	30	302	180	283	10,664
728	38	12	4,293	1,092	157	68	382	249	550	7,308	1,883	42,903
48	7	2	32	5	8	6	6	5	20	5	16	515
14	2	3	3	1	7	1	1	1	2	2	4	133
293	304	50	306	68	57	44	38	47	189	82	162	5,155
277	29	6	194	12	14	7	7	7	81	600	60	3,269
22	4	0	43	30	28	2	30	121	30	41	46	860
626	250	34	1,058	278	246	190	103	166	376	684	3,726	17,033
18,407	4,416	727	35,220	3,717	4,095	4,532	1,898	1,354	9,865	21,473	13,582	407,891

Fig. II-2-23 Situation and Effect

Situation and Effect	Slight effect on patient					Moderate effect on patient					Major effect on patient				
	15th	16th	17th	18th	Total	15th	16th	17th	18th	Total	15th	16th	17th	18th	Total
Ordering/instruction	192	210	256	167	825	35	56	44	35	170	19	15	12	12	58
Communication process	291	206	187	165	849	61	64	52	52	229	18	19	18	13	68
Drug preparation	230	335	292	240	1,097	53	78	75	52	258	14	14	9	8	45
Prescription/drug administration	991	1,293	1,289	1,074	4,647	439	298	236	206	1,179	56	70	168	26	320
Dispensing, drug management, etc.	627	836	748	707	2,918	76	131	111	116	434	17	17	29	11	74
Blood transfusion	35	40	46	20	141	14	13	10	6	43	6	21	18	17	62
Surgery	98	88	96	68	350	64	74	55	45	238	15	28	21	13	77
Anesthesia	6	3	4	2	15	4	5	1	2	12	3	6	3	1	13
Delivery/mechanical abortion	2	1	4	5	12	1	0	0	2	3	0	0	0	0	0
Treatment, others	14	23	27	40	104	13	16	21	13	63	1	6	4	3	14
Procedure	24	37	27	24	112	12	13	9	13	47	2	8	15	5	30
Examination/interview	21	21	28	24	94	8	5	7	5	25	1	6	0	0	7
Use/management of medical equipment (device)	142	124	139	89	494	68	99	51	53	271	32	31	44	27	134
Use/management of drainage tube or other tube	291	278	273	320	1,162	299	262	261	203	1,025	75	76	130	28	309
Use/management of dental equipment (device)/material	0	3	1	0	4	1	0	0	1	2	0	0	0	1	1
Examination/test	488	528	460	425	1,901	82	83	116	81	362	21	16	20	17	74
Nursing care	257	310	320	447	1,334	193	191	210	191	785	56	43	37	22	158
Meal/nutrition	218	262	286	242	1,008	23	38	28	20	109	4	7	19	1	31
Nursing care, others	179	198	306	243	926	138	113	126	100	477	58	24	62	14	158
Supply transportation	7	15	12	9	43	1	1	2	2	6	1	0	0	1	2
Radiation control	2	4	3	1	10	0	1	1	2	4	0	0	0	0	0
Medical record and information management	76	112	110	76	374	12	11	32	17	72	5	6	5	5	21
Explanation to patient/family	41	47	59	51	198	10	7	12	5	34	4	2	6	2	14
Facility	9	13	26	16	64	5	4	5	5	19	3	1	1	5	10
Others	232	306	342	542	1,422	25	23	41	148	237	12	13	28	27	80
Total	4,473	5,293	5,341	4,997	20,104	1,637	1,586	1,506	1,375	6,104	423	429	649	259	1,760

Fig. II-2-24 Day of Occurrence and Weekday/Holiday Category

Day of occurrence	Weekday					Holiday				
	15th	16th	17th	18th	Total	15th	16th	17th	18th	Total
Monday	5,082	7,526	6,194	5,771	24,573	468	19	364	283	1,134
Tuesday	6,312	7,428	6,985	6,597	27,322	37	299	14	100	450
Wednesday	6,547	7,890	7,329	6,251	28,017	25	267	56	324	672
Thursday	6,490	7,793	7,210	6,004	27,497	13	277	51	410	751
Friday	5,789	7,585	7,427	5,884	26,685	250	315	247	406	1,218
Saturday	2,204	2,866	2,401	2,241	9,712	2,464	3,015	2,933	2,808	11,220
Sunday	209	245	209	134	797	3,895	4,502	4,376	4,009	16,782
Day unknown	35	62	58	38	193	11	17	13	7	48
Total	32,668	41,395	37,813	32,920	144,796	7,163	8,711	8,054	8,347	32,275

Error occurred but patient not affected					Unknown					Others					Aggregate total
15th	16th	17th	18th	Total	15th	16th	17th	18th	Total	15th	16th	17th	18th	Total	
322	490	438	390	1,640	44	27	41	40	152	38	45	70	149	302	3,147
760	1,032	910	877	3,579	58	60	51	39	208	60	104	78	63	305	5,238
396	523	516	426	1,861	25	40	29	31	125	32	40	45	32	149	3,535
7,849	11,142	9,858	8,559	37,408	351	609	502	483	1,945	429	652	543	412	2,036	47,535
641	825	755	760	2,981	38	97	88	64	287	166	169	158	156	649	7,343
138	161	152	126	577	19	26	16	8	69	15	18	18	12	63	955
313	406	405	340	1,464	35	59	41	25	160	90	91	112	80	373	2,662
33	35	28	41	137	2	3	2	4	11	17	7	11	12	47	235
17	29	17	14	77	1	3	1	0	5	5	7	7	5	24	121
214	287	337	281	1,119	13	16	14	13	56	34	62	52	59	207	1,563
216	264	256	195	931	20	24	15	19	78	43	49	52	46	190	1,388
75	92	88	84	339	17	21	9	5	52	15	20	17	25	77	594
844	1,077	936	808	3,665	62	85	59	39	245	111	137	97	98	443	5,252
5,199	5,963	5,843	5,405	22,410	287	315	273	229	1,104	714	945	990	995	3,644	29,654
0	4	3	6	13	0	1	1	2	4	2	1	3	5	11	35
2,049	2,767	2,463	2,204	9,483	211	228	204	193	836	228	304	291	367	1,190	13,846
2,878	3,814	3,383	3,444	13,519	246	272	150	146	814	586	678	562	540	2,366	18,976
800	1,123	964	845	3,732	48	65	59	46	218	67	86	43	92	288	5,386
4,152	4,489	4,428	4,123	17,192	219	225	211	229	884	1,035	913	1,070	952	3,970	23,607
26	30	27	31	114	2	3	4	1	10	13	10	6	8	37	212
2	20	11	9	42	0	0	0	2	2	1	0	0	1	2	60
366	457	323	300	1,446	31	55	36	22	144	38	44	42	40	164	2,221
165	251	235	229	880	26	29	11	9	75	39	42	33	44	158	1,359
46	52	54	60	212	16	8	10	5	39	15	21	20	21	77	421
561	858	895	1,609	3,923	98	176	499	477	1,250	160	182	175	124	641	7,553
28,062	36,191	33,325	31,166	128,744	1,869	2,447	2,326	2,131	8,773	3,953	4,627	4,495	4,338	17,413	182,898

Unknown					Aggregate total
15th	16th	17th	18th	Total	
52	51	240	421	764	26,471
33	62	276	453	824	28,596
33	62	278	483	856	29,545
35	58	278	472	843	29,091
37	51	280	442	810	28,713
26	48	185	373	632	21,564
0	2	3	139	144	17,723
370	133	235	216	954	1,195
586	467	1,775	2,999	5,827	182,898

III. Current Analysis of Medical Near-Miss/Adverse Event Information

Both medical adverse event information and medical near-miss information were collected in the project started in 2004. In 2005, medical adverse event information and medical near-miss information covered by individual themes were comprehensively analyzed.

1. Project Overview and Expert Division Activities

[1] Selection of Themes for Information to be Analyzed

Themes for information to be analyzed have been selected based on expert opinions and in light of (1) generality/universality, (2) event frequency, (3) effect on patients, (4) preventability/avoidability, and (5) nature as object lesson.

[2] Information to be Analyzed

Among medical adverse event information and medical near-miss information provided for the project, those covered by predetermined themes were selected and analyzed. Regarding medical near-miss information, individual Analysis Groups have determined relevant themes related to reported events and been collecting descriptive information.

[3] Analysis System

Analysis Groups consisting of medical safety experts have been reviewing all reported incidents/cases to understand their outlines and determine direction of analysis.

Individual Analysis Group meetings have been held separately to analyze cases covered by individual themes.

[4] Meetings

Management Committee (a subcommittee specified in the JCQHC act of endowment) meetings and Comprehensive Evaluating Panel meetings held between October 2004 and December 31, 2005 are shown below.

(1) Management Committee meeting

Management Committee meetings were held 4 times between October 2004 and December 31, 2005.

Fig. III-1-1 Management Committee Meeting

	Date	Agenda
1st	2004/12/02	• 2004 activities of Center for Medical Adverse Event Prevention • Future medical adverse event prevention activities
2nd	2005/02/03	• Current status of 2004 activities of Center for Medical Adverse Event Prevention
3rd	2005/04/15	• Medical Safety Support Center Comprehensive Support Project • Change of collection system in Project to Collect Medical Near-Miss Information • Future activities of Center for Medical Adverse Event Prevention
4th	2005/06/02	• Outcome of 2004 Medical Safety Support Center Comprehensive Support Project • Outcome of 2004 Project to Collect Medical Near-Miss/Adverse Event Information • 2005 timetable of Center for Medical Adverse Event Prevention • Future project of Center for Medical Adverse Event Prevention

(2) Comprehensive Evaluation Panel meeting

Comprehensive Evaluation Panel meetings were held 7 times between October 2004 and December 31, 2005.

Fig. III-1-2 Comprehensive Evaluation Panel Meeting

	Date	Agenda
1st	2004/12/15	• Operation of Project to Collect Medical Near-Miss/Adverse Event Information
2nd	2005/01/07	• Operation of Project to Collect Medical Near-Miss/Adverse Event Information
3rd	2005/02/18	• Current status of Project to Collect Medical Near-Miss/Adverse Event Information
4th	2005/03/25	• Project to Collect Medical Near-Miss/Adverse Event Information 1st report (proposal)
5th	2005/06/10	• Education/training for Project to Collect Medical Near-Miss/Adverse Event Information
6th	2005/07/04	• Project to Collect Medical Near-Miss/Adverse Event Information 2nd report (proposal)
7th	2005/10/05	• Project to Collect Medical Near-Miss/Adverse Event Information 3rd report (proposal)

[5] Expert Analysis Group Meeting

At meetings held once or twice a month, Expert Analysis Groups consisting of medical safety experts review all reported incidents/cases to understand their outlines and determine direction of analysis.

Also once or twice a month, individual Analysis Group meetings are held separately to analyze cases covered by individual themes.

Analysis Group meetings have been held on topics of “foreign objects retained during surgeries,” “medical adverse events associated with use of medical devices,” and “medical adverse events associated with drugs.” Other than meetings to analyze cases covered by individual themes, “Important Medical Near-Miss Case Database Development Group” has been established as another expert analysis group to select especially important medical near-miss cases and develop a relevant database.

[6] Collection of Follow-Up Information of Medical Adverse Event Cases

When an Analysis Group determines that further detailed case information from the medical institution is necessary for analysis, it makes written inquiries to the reporting medical institution or, if the institution agrees to cooperate, visits the institution to collect follow-up information. Follow-up information obtained is used as data at Expert Analysis Group meetings.

In 2005, follow-up information on 92 medical adverse events was requested in writing: 6 events related to retained foreign objects, 31 events related to medical devices, 18 events related to drugs, 7 events related to patient misidentification, 22 events related to treatment, and other 8 events including aspiration and fall.

Reporting institutions were visited to collect follow-up information on 14 events: 4 events related to retained foreign objects, 5 events related to medical device, 2 events related to drugs, 1 event related to patient misidentification, and 2 events related to treatment.

2. Individual Theme Review by Expert Division

[1] Foreign Objects Retained during Surgeries

(1) Report overview

Thirty-two medical adverse events associated with foreign objects retained during surgeries and other procedures were reported between October 2004 and December 2005. Further investigations were conducted for 7 events at individual reporting institutions to collect information. Details of the events are shown in Fig. III-2-1 and summaries of the events are shown in Fig. III-2-2.

(2) Medical adverse events associated with retained foreign objects

A. Overview

Some of the reported events associated with retained foreign objects were directly related to surgeries while others were not. Surgery-related events could be classified into following two types:

1. Objects (gauze, suture needle, forceps) used during surgical procedures performed in surgical sites were left unremoved although they should have been removed when or prior to completing the surgeries
2. Objects (part of retractor, metal plug, spoon, screw) used outside patients' bodies or surgical sites fell or partially disassembled and were left unremoved in surgical sites

Events associated with objects actually or almost retained during surgeries were categorized into stages; "during surgery and going back to patient room," "after going back to patient room and before discharge," and "after discharge." The types of foreign objects and number of events are summarized in Fig. III-2-3.

B. Cause of retained foreign object

Causes of retained foreign objects identified in the first report included inadequate gauze count or device count, inadequate postoperative X-ray check, and inconsistency of such X-ray check.

The second report summarized details of events occurred in the course of perioperative procedure (Fig. III-2-4). Perioperative procedure was classified into 5 processes: "cleaning, inspection, storage (of surgical tools)," "preparation for surgery," "preparation immediately before surgery," "during surgery," and "postoperation."

i. Cleaning, inspection, storage (of surgical tools)

No medical adverse event occurring in this process was reported. Reported medical near-miss incidents included "part of equipment broken," "missing part of equipment was identified in cleaning process," and "a set of surgical tools prepared in advance contained a tool that should not have been included."

ii. Preparation for surgery

No medical adverse event or near-miss incident occurring in this process was reported.

iii. Preparation immediately before surgery

Only 2 medical adverse events occurr in this process were reported in the second report. Both events occurred because "retained tool was not subject to counting(Note 1)." One event involved bulldog forceps and the other involved gauze. In these cases of superficial surgeries, the items were not expected to be retained and not subject to counting.

Some medical near-miss incidents involved surgical tools not subject to counting: radiolucent gauze, wet cotton, gauze with handle, and suture needle used in superficial surgery and not expected to be retained.

Medical near-miss incidents occurred in this process included "intraoperative gauze count was inconsistent with the original count but preoperative miscounting was eventually identified" and "forgot to count tools before surgery and correctness of later count could not be determined."

iv. During surgery

Ten medical adverse events occurred in this process were reported in the second report: 1 event of "object was broken and retained in the surgical site," 5 events of "tools were counted or checked but inconsistency in the count was unnoticed," 1 event of "first count was inconsistent but second was consistent," and 3 events of "tools were searched due to inconsistent count, which was never confirmed."

Five medical adverse events were reported in the third report. Causes of retained foreign objects occurred during surgery in all cases. Tools were counted during surgery but the retained tool was not noticed in 3 cases. Specified procedure was not followed in one case. Another case involved an object to be ligated was dislodged and migrated to an unexpected place. Retained foreign objects were detected by postoperative X-ray in all 5 cases.

In all events reported in the fourth report, the causes of retained foreign objects also occurred during surgery. Tools were counted during surgery but the retained tool was not noticed in 3 cases. Tools were searched due to an inconsistent count but never found in 2 cases. Tools were not subject to counting in 2 cases.

The retained foreign objects may be detected by x-ray. However, x-ray alone cannot or may not detect foreign objects in some cases depending on imaging condition or situation as discussed in the second report. The same can be said for tool counting.

(Note 1) "Counting" herein means (A) counting and documenting surgical tools to be used in advance and (B) counting and documenting surgical tools in use, used, or unused during or after surgery in order to keep pre- and postoperative count of surgical tools. "Consistent count" means count documented in (A) is consistent with that documented in (B). "Inconsistent count" means count documented in (A) is inconsistent with that documented in (B).

A larger number of medical near-miss incidents which occurred during surgery were reported compared with other processes. Many of such cases were associated with tool counting during surgery and can be classified as follows.

A) Caused by unestablished rule
E.g.)What tools to count, counting method, how to take gauze out of the operation room

B) Caused by unobserved rule
E.g.)Used gauze disposal

C) Mixing of hard-to-distinguish tools
E.g.)Mixing of normal gauze and radiolucent gauze

D) Error in communication or documenting
E.g.)Miscommunication between scrub nurse and circulating nurse concerning additional surgical tools, miscommunication at the time of staff change

E) Caused by size or condition of tools
E.g.)Lost suture needle for vascular anastomosis, miscounting of gauze that absorbed a large amount of blood

F) Caused by breakage or fall of tools

G) Others

v. Postoperation

Six medical adverse events which occurred in this process were reported in the second report. In fact, this process cannot cause events since foreign objects are retained as the result of surgical procedures. However, cases in which actual or potential retention of foreign objects were detected after surgery but causative process could not be identified or surgeries in question were performed at other institutions are classified in this process.

Radiolucent gauze not containing non-radiolucent steel wire was used in all events associated with retained foreign objects reported in the past. Excepting 1 case out of 8 in which an object was detected during surgery, retained objects were eventually detected by x-ray. X-ray check in the operation room did not detect retained objects but a review of the x-ray image or another x-ray performed after the patient returned to his/her room in 2 cases did detect retained objects.

Medical near-miss incidents included “a tool that should not have been used was missing in postoperative tool counting” and “pieces of tool used during surgery was found on the floor when cleaning up.”

C. Situation in which retained foreign object was detected

How retained foreign objects were identified in cases analyzed or referred are shown in Fig. III-2-2. How retained foreign objects were identified in most cases included the following:

A) Tool counting

B) Search of surgical site during surgery or before closing wound to check for retained tools

C) X-ray or fluoroscope

However, inconsistent counting despite no retained foreign object being identified was reported in some cases(Note 1). In other cases reported, foreign objects were retained despite search in surgical sites. X-ray or fluoroscope could not detect foreign objects due to its material (e.g.. resin) or its location (different structure) in some other cases. No method is perfect in avoiding retained foreign objects. Improving accuracy of these checking methods should be considered.

Fig. III-2-1 Medical Adverse Event Reports Involving Retained Foreign Objects

Retained foreign object	Number of reports October 2004 to December 2005	Remarks
Gauze	11	
Suture needle	7	
Bulldog forceps	2	
Metal plug	2	
Shunt tube	1	
Screw	1	
Retractor part	1	
Spoon	1	
Needle	2	
Orthodontic device (bracket)	1	
Gauze and vascular tape*	1	Vascular tape cut in short pieces was used.
Plate	1	
Cleaning nozzle	1	
Total	32	

*Vascular tape: narrow silicone rubber tape used to distinguish or handle blood vessels during surgery

Excerpt from: Fig. III-1 in the fourth report

(Note 1) Locations of foreign objects found outside patients' bodies in cases involving inconsistent tool count by tool are shown in Fig. III-2-5. Use the data as a reference for searching missing tools when tool count is inconsistent.

Fig. III-2-2 Summary of Medical Adverse Events Involving Retained Foreign Objects

No.	Retained foreign object	How retained object was identified	Check for retained object	Corresponding report
During operation and until returning to patient room (3 medical adverse events)				
1	Suture needle (breakage)	Identified when the needle broke.	Searched at the time of breakage and checked by x-ray before closing wound	Second report
2	Spoon	Unidentified until x-ray check	X-ray after closing wound	
3	Drill blade	Breakage during procedure	Checked at the time of breakage	Fourth report
After returning to patient room and before discharge (21 medical adverse events)				
1	Bulldog forceps	Not subject to counting and unnoticed	Postoperative x-ray check, biplane	Second report
2	Screw	Fallen screw was unnoticed during use	Abdominal x-ray after returning to ICU	
3	Suture needle	Counted but shortage was overlooked	Postoperative x-ray check, Day 3	
4	Gauze	Count was inconsistent in the middle of procedure but found to be consistent at the end	Postoperative x-ray check, biplane	
5	Metal plug	Noticed and searched during procedure	X-ray check on next day	
6	Suture needle	Inconsistent needle count reported during procedure	Chest x-ray after returning to patient room	
7	Shunt tube	Unreturned tube was unnoticed	Chest x-ray after returning to ICU	
8	Gauze	Not counted	During procedure performed 2 months postoperation (not detected by x-ray)	
9	Bulldog forceps	Inconsistent count	Chest x-ray after returning to ICU	
10	Retractor part	Missing parts unnoticed	Chest x-ray after returning to ICU	
11	Gauze(with thread)	X-ray	Intraoperative count was consistent. After the patient returned to his/her room, the retained object was identified in review of x-ray images taken immediately after surgery.	Third report
12	Needle for surgical site marking	X-ray, CT	Identified more than 1 week after surgery during postoperative check by reading x-ray and CT images taken immediately after surgery	
13	Gauze	X-ray	Intraoperative count was consistent. Retained object was identified by postoperative x-ray.	
14	Orthodontic device (bracket)	X-ray	Ligature became loose and part of device migrated to unexpected location. Detected by postprocedural x-ray.	
15	Suture needle	X-ray	Intraoperative count was consistent. X-ray image taken in the operation room immediately after surgery was checked on the monitor but the retained object was not identified. Identified when reviewing x-ray image after the patient returned to his/her room.	

No.	Retained foreign object	How retained object was identified	Check for retained object	Corresponding report
16	Metal plug	X-ray	Missing plug was identified during surgery but fluoroscope was not performed. Identified when reviewing x-ray image on the next day.	Fourth report
17	Plate	X-ray	Unreturned plate was unnoticed during surgery. Identified by postoperative x-ray.	
18	Gauze	X-ray	X-ray performed before closing wound but the retained object was not identified on the monitor in the operation room. Identified when reviewing the x-ray image on a high-resolution monitor on next day.	
19	Suture needle	X-ray	Intraoperative count(Note) was consistent. X-ray was performed immediately after surgery in the operation room but the retained object was not identified, and the patient returned to his ward. Identified by x-ray on next day.	
20	Cleaner nozzle	Angiography	The retained object containing metal was identified in angiography performed 2 weeks postoperation.	
21	Gauze	X-ray	Gauze count was consistent. Identified by x-ray on the next day.	
After discharge (8 medical adverse events)				
1	Gauze	Surgery performed 6 years ago. Radiolucent gauze was used back then.	Identified and removed during second operation	Second report
2	Gauze	Surgery performed 2 years ago.	Identified and removed during second operation	
3	Gauze	Surgery performed 15 years ago.	Identified and removed when visiting another institution after onset of symptom	
4	Gauze	Surgery performed a year ago. Not detected by x-ray.	Identified by CT and removed when visiting another institution for other disorder	
5	Suture needle	Surgery performed 10 years ago.	Identified and removed during inpatient close examination	
6	Suture needle	Surgery performed 5 years ago.	Identified by CT and removed when visiting another institution for other disorder	
7	Gauze (without steel wire) and vascular tape (one red and one blue)	Second surgery	A mass was identified during surgery at the same site. Contents were checked and the retained object was identified.	Fourth report
8	Gauze (without steel wire)	Surgery in approximate site	Identified during open surgery performed due to unimproved symptoms after endoscopic surgery. Pathological examination assumed the object was gauze left during a surgery performed more than 10 years ago.	

Note: "Count" in this table means counting of surgical tools and hygiene materials during surgical procedure to confirm consistency in number of prepared tools and number of used tools.

Excerpt from:
Table 2 in the second report
Table 2 in the third report
Fig. III-3 in the fourth report

Fig. III-2-3 Retained Foreign Objects and How They Were Identified

How retained object was identified	During surgery and until returning to patient room	After returning to patient room and before discharge	After discharge
	[How retained object was identified] ❍ As the result of counting tools, hygiene materials or disposable items ❍ By checking returned tools, hygiene materials or disposable items ❍ Postoperative x-ray or fluoroscope	**[How retained object was identified]** ❍ Postoperative x-ray ❍ By checking/counting returned tools, hygiene materials or disposable items ❍ By checking records/briefing~~reports~~	**[How retained object was identified]** ❍ Outpatient visit ❍ Patient sought treatment for symptoms associated with retained object ❍ Patient sought treatment for other symptoms

Number of reports	Medical adverse events	Medical adverse events	Medical adverse events
	Second report, 2 events Third report, 0 event Fourth report, 1 event	Second report, 10 events Third report, 5 events Fourth report, 6 events	Second report, 6 events Third report, 0 event Fourth report, 2 events

See Fig. 1 in the second report.

Fig. III-2-4 Surgical Process and Potential Cause of Retained Foreign Object

Surgical process	Cleaning, inspection, storage	Preparation for surgery	Preparation immediately before surgery	During surgery
	[Major activities] ❍ Purchase new medical device/equipment ❍ Repair/exchange broken medical device/equipment ❍ Dispose of inoperable medical device/equipment	**[Major activities]** ❍ Patient reception ❍ Check devices and tools to be used ❍ Arrange and prepare medical equipment~~tool~~s (surgical equipment, tools, hygiene materials) ❍ Preoperative planning ❍ Check	**[Major activities]** ❍ Assemble tool~~equipment~~ ❍ Check device/tool~~equipment~~ ❍ Prepare hygiene materials and disposable items ❍ Check hygiene materials and disposable items	**[Major activities]** ❍ Supply/exchange/supplement medical equipment~~tool~~s (tools~~equipment~~, hygiene materials, disposable items) ❍ Check returned medical equipment~~tool~~s (tools~~equipment~~, hygiene materials,

Potential cause of retained foreign object				
	[Inspection of medical device/equipment] ❍ Erroneous check of breakage, etc. **[Missing medical tools]** ❍ Missing tools in surgical tool set **[Selection/purchase of hard-to-distinguish medical equipment~~tool~~s]** ❍ Selection/purchase of radiolucent medical equipment~~tool~~s (tools~~equipment~~, hygiene materials)	**[Preparation of medical device/tool]** ❍ Lack of knowledge about parts and structure of medical device/equipment~~tool~~ **[Inadequate preoperative planning]** ❍ Insufficient information sharing among surgical team members ❍ Inadequate crosscheck/confirmation of removed items and x-ray images	**[Preparation of medical equipment~~tool~~s (tools~~equipment~~, hygiene materials)]** ❍ Items to be counted not predetermined ❍ Miscounting • Tools • Gauze, needle, etc. ❍ Miscommunication of count between counting person (person who prepared tools) and recording person	**[Counting]** ❍ No counting rule ❍ Miscounting ❍ Miscommunication of count between counting person and recording person ❍ Recording person hears count wrong or documents wrong count **[Checking additional tools~~equipment~~, hygiene materials, disposable items]** ❍ Counting person not knowing how many tools~~much equipment~~, ~~how many~~ hygiene materials, and/or disposable items were supplemented **[Checking returned tools, hygiene materials, disposable items from surgical sites]** ❍ Forget to check items returned from surgical site **[Lost items]** ❍ Broken and lost

See Fig. 2 in the second report.

Fig. III-2-5 Place Where Lost Item Was Found

	Gauze	Needle	Cotton ball, etc.	Device part	Small metallic items	Others	Remarks
Around surgical site	2	1	0	1	0	1	Pocket of cover
Equipment table	3	8	1	0	0	0	Between gauzes or drapes
Waste box	11	1	0	0	0	0	
Around scales	2	0	0	0	0	0	
On the floor	0	7	2	2	0	1	
Around patient	3	1	0	0	0	0	Under or between covers, under patient's body
Outside operation room	7	0	0	0	3	0	Pathological examination room, delivery room

(Note) Including medical adverse events and near-miss incidents

See Table 3 in the second report.

(3) Examples of retained foreign objects

The fourth report presents x-ray images of retained foreign objects provided by registered participating medical institutions. Use the data as a reference for educational materials in clinical training and medical/nursing education.

A. Retained gauze

Eight medical adverse events involving retained gauze were reported between October 2004 and December 2005. Many medical near-miss incidents also involved retained gauze or potential retention.

Retained gauze is usually shown in an x-ray image as in Fig. III-2-6 (enlarged image is shown in Fig. III-2-7).

Fig. III-2-6

Fig. III-2-7 Enlarged image of Fig. III-2-6

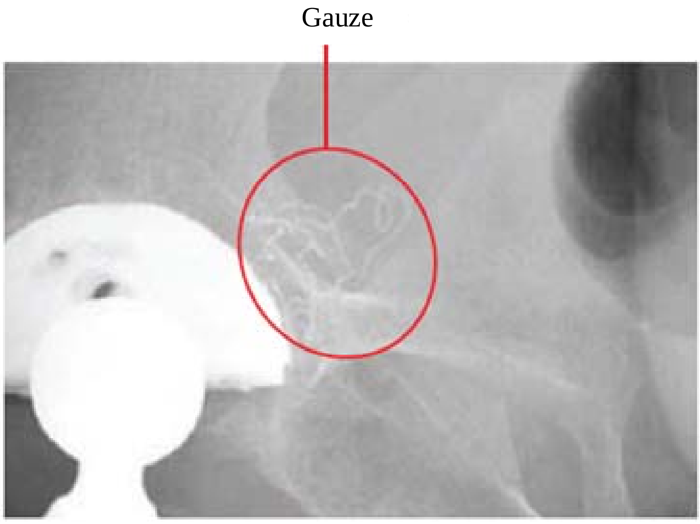


Image shown in Fig. III-2-6 was taken laterally several days after femoral head replacement. The enlarged image shows non-radiolucent steel wire woven into the gauze.

The retained gauze was identified in the x-ray image in this case.

A frontal x-ray had been performed separately immediately after surgery.

Fig. III-2-8　Frontal Image

Fig. III-2-9

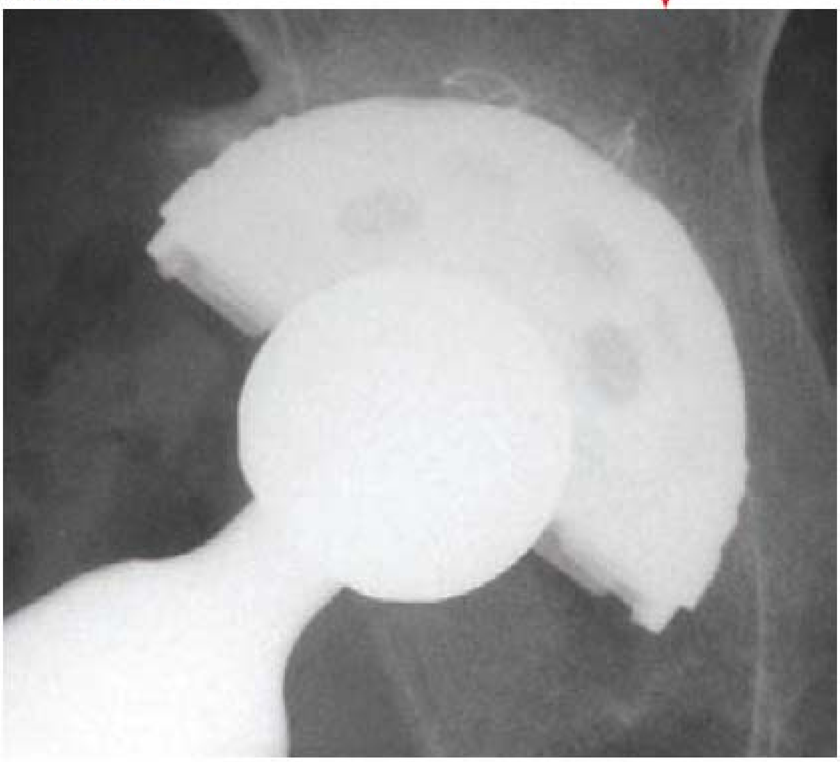


Fig. III-2-8 shows a frontal x-ray image of the same area.　The enlarged image in Fig. III-2-9 shows non-radiolucent steel wire woven into the gauze.

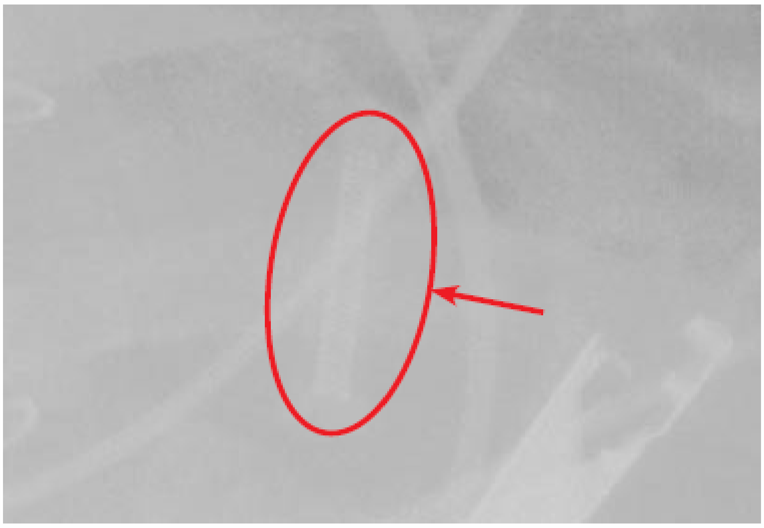
B. Retained forceps

Two medical adverse events involving retained forceps were reported between October 2004 and December 2005. Both events involved bulldog forceps used in vascular surgery. One medical near-miss incident involving forceps was also reported.

Bulldog forceps may be made of metal such as titanium or disposable plastics. Disposable bulldog forceps are shown in Fig. III-2-10. Only the spring part inside the retained disposable forceps will be shown in an x-ray image as in Fig. III-2-11.

Fig. III-2-10

Fig. III-2-11



Images shown in Figs. III-2-12 and III-2-13 were taken several days after surgery for follow-up, and retained forceps happened to be identified. The frontal image hardly shows the retained object. Fig. III-2-13 shows a lateral chest x-ray image taken on the same day, and Fig. III-2-14 shows an enlarged image of Fig. III-2-13 processed by changing contrast for easier viewing. These images show the spring. The retained forceps were identified in the lateral x-ray image.

Fig. III-2-12 Chest X-Ray Image Taken Several Days Postoperation for Follow-Up (Frontal)

Fig. III-2-13 Chest X-Ray Image (Lateral)

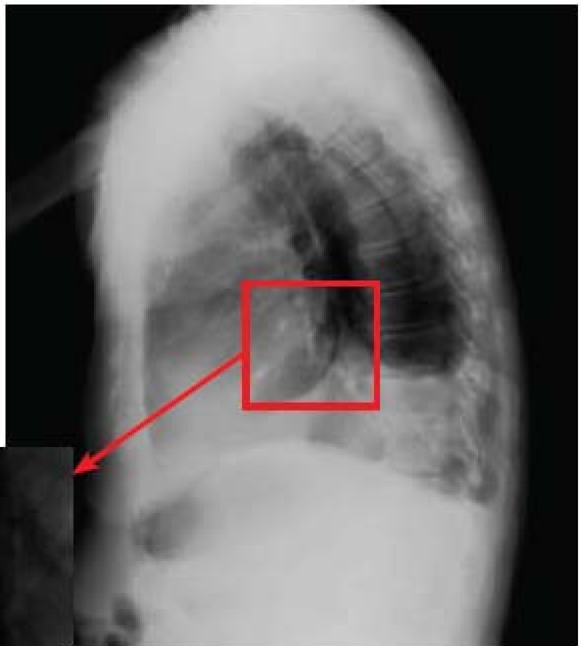


Fig. III-2-14 Enlarged Image

Fig. III-2-15 shows an x-ray image of the same patient taken immediately after surgery.

Wires and tubes actually placed in the patient's body are shown in the image. The enlarged image shows the spring of the retained forceps.

Fig. III-2-15 Chest X-Ray Image (immediately after surgery)

Fig. III-2-16 Chest X-Ray Image (same as that on the previous page – Fig. III-2-15)

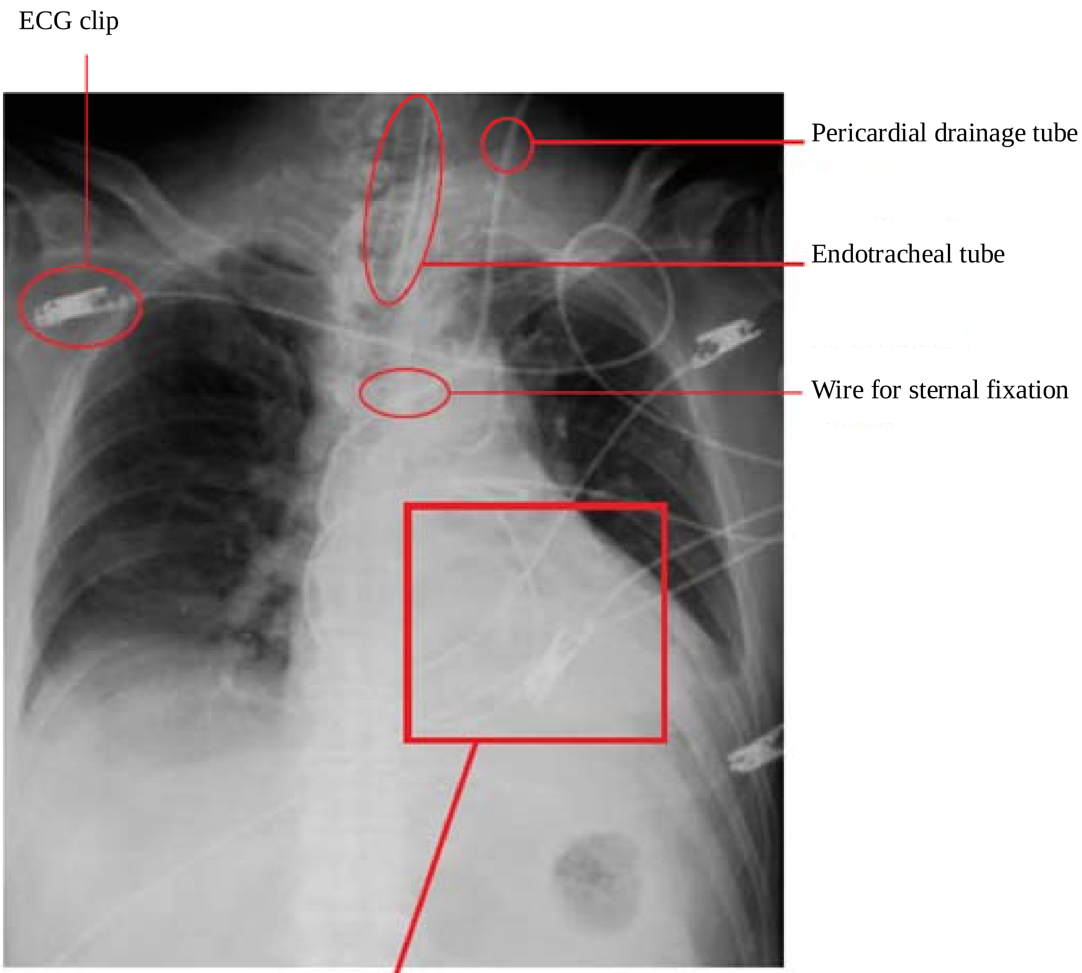


Fig. III-2-17 Enlarged Image

C. Retained screw of suction nozzle

One medical adverse event involving a retained screw from a surgical instrument was reported between October 2004 and December 2005. Relevant medical near-miss incidents included 2 cases of retained screw and 3 cases of lost but unretained screw.

Fig. III-2-18 shows a chest x-ray image taken immediately after emergency operation.

Another chest x-ray image taken after the patient returned from the operation room showed a screw and a washer (Fig. III-2-22).

Fig. III-2-18 Chest X-Ray Image

Fig. III-2-19 Same Image as That on Previous Page (Fig. III-2-18)

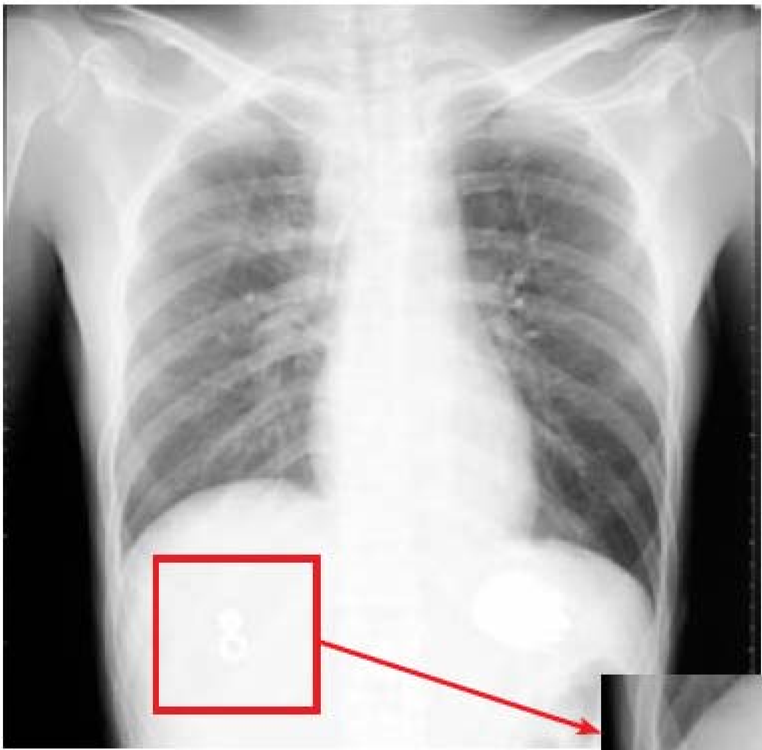


Fig. III-2-20 Enlarged Image

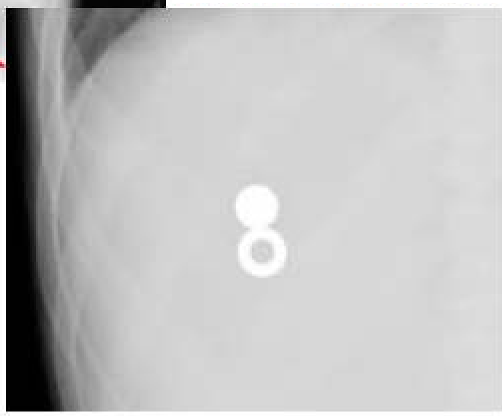


Fig. III-2-21 Suction Nozzle and Washer

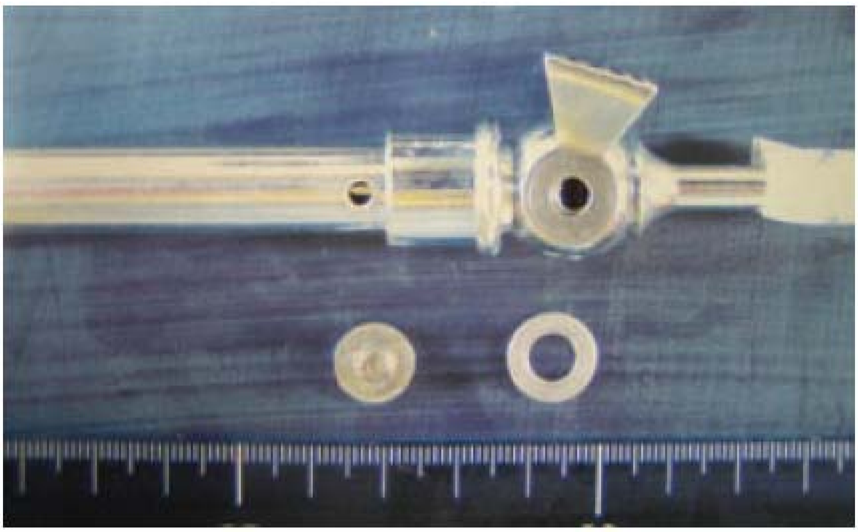


Fig. III-2-22 Abdominal X-Ray Image

(4) Issues to be addressed

In order to prevent retention of a foreign object during surgery, (A) procedures to minimize object retention and (B) procedures to detect a retained object before completing surgery need to be discussed.

Based on the analysis of reported events, any items used in surgical sites could be retained. It is therefore important to consider materials of surgical instruments. For example, small surgical items made of steel should be designed to minimize accidental fall and made of materials easily detectable by x-ray.

The JCQHC will conduct a questionnaire survey on medical institutions participating in the project and hold hearing sessions with relevant academic societies and industrial organizations to consider safer, surer, feasible and practical measures to prevent retention of foreign objects.

A downloadable Japanese translation of “Correct Maintenance of Instruments” published by German experts is available on the Japanese Society of Medical Instrumentation website(Note 1) as a reference for maintenance and handling of medical devices.

(Note 1) Japanese Society of Medical Instrumentation website (http://www.a-k-i-org/)

[2] Medical Adverse Events Related to Drugs

(1) Report summary

Medical adverse events reported between October 2004 and December 2005 included 110 events related to drugs with 87 events being analyzed. Events caused by adverse drug reactions known to be associated with pharmacological actions, events subject to inquiry, and events considered as medical near-miss incidents were excluded from the analysis. Summaries of medical adverse events are shown in Fig. III-2-23.

Individual medical institutions were visited for investigation to collect further information on 2 events.

(2) Details of medical adverse events related to drugs

Flow of drug therapy is summarized in a matrix with five processes; with “ordering,” “receiving order/briefing,” “preparation,” “drug administration,” and “observation and management after drug therapy” on the vertical axis and details of events on the horizontal axis (Fig. III-2-24).

A. Ordering

The second report included 24 events which occurred during this process. These events took up a half of those subject to analysis. Wrong dose was most commonly involved in these events. Specifically, documentation error was involved in 3 events, lack of knowledge about drug or inadequate check in 11 events, communication error in medical record documentation in 2 events, and similar drug name in 1 event.

The third report included 11 events occurring during this process. These events took up a half of those subject to analysis. Wrong dose was most commonly involved in 5 events. Two events were related to drug concentration, 1 event to dosing speed, 1 event to inadequate monitoring of drug’s effect, 1 event to collective packaging of multiple drugs, and 1 event to ordered starting date.

The fourth report included 4 events occurring during the ordering process. One event involved the wrong dose provided on the order sheet, 2 events involved unchecked allergy, and 1 event involved overdose due to error in prescription data entry.

B. Receiving order/briefing

The second report included 1 event occurring during this process. It involved similar drug names confused when copying the doctor’s order to an order slip.

The third report did not include any event occurred during this process.

The fourth report included 3 events occurring during this process. All events involved wrong dose. The unit was not clearly communicated or checked in orally-given orders in 2 events, and an order was not followed appropriately due to unobserved ordering rule in 1 event.

C. Preparation

The second report included 5 events occurring during this process. Three events involved wrong doses given to pediatric patients by nurses (error in copying labeled information, dilution error, and wrong dose), 1 event was related to confusion of insulin “unit” and “mL,” and 1 event involved wrong dose due to dispensing error.

The third report included 1 event involving dispensing of wrong dosage form.

The fourth report included 7 events occurring during this process. Three events involved drug mix-up; confusion of similar drug names in 1 event, and taking out wrong drug and giving to patients in 2 events. Four events involved wrong doses; 1 event was related to an orally-given order, and 2 events involved preparation of wrong intravenous insulin dose.

D. Drug administration

The second report included 10 events occurring during this process. Wrong route of administration was used by doctors (interns) in 2 events and by a doctor (intern) and nurse in 1 event. Two events involved medical devices (infusion pump line mix-up and dislodgment of syringe pump plunger).

The third report included 7 events occurring during this process. Drug mix-up at the time of dispensing in 1 event, wrong dosage form was involved in 1 event, patient misidentification in 1 event, misconception of ordered dosing speed was involved in 1 event, and dosing method was involved in 1 event.

The fourth report included 3 events occurring during this process. Two events involved inadequate communication of order concerning dosing speed, and 1 event involved device setup error. Medical devices such as infusion pump were involved in all these events.

E. Observation and monitoring after drug therapy

The second report included 7 events occurring during this process, four of which involved extravascular leakage of chemotherapy drugs.

The third report did not include any event occurring during this process.

The fourth report included 5 evenits occurring during this process, four of which involved extravascular leakage of drugs for IV drip. Tissue necrosis associated with extravascular leakage of “phenytoin” (nonproprietary name) occurred in 2 events. One event was related to oral drug management.

F. Others

The third report included one event associated with error in drug master file registration.

(3) Types of drugs involved in medical adverse events

Types of drugs involved in 87 events reported between October 2004 and December 2005 are summarized (Fig. III-2-25).

The second report included 11 events related to anti-tumor drugs, 2 events related to blood/fluid product (anticoagulant), 3 events related to insulin, and 1 event related to narcotic. Drugs were intravenously administered to patients with serious conditions in all cases. Two events involved mix-up of anti-tumor drugs notorious for their similar names: paclitaxel (brand name: Taxol) and docetaxel hydrate (brand name: Taxotere). Special caution needs to be exercised when using these drugs.

Three cases of administration site phlebitis followed by skin necrosis and ulceration in patients who received peripheral intravenous gabexate mesylate for treatment of disseminated intravascular coagulation (DIC) were reported. Special caution also needs to be exercised when using gabexate mesylate. In these cases, gabexate mesylate was used at higher concentrations than those recommended in precautions concerning peripheral intravenous use provided in the package insert of the drug, in which potential phlebitis and ulcer/necrosis were mentioned. The events seemed to be associated with the higher concentrations of gabexate mesylate.

The third report included 4 cases involving anti-tumor drugs, 1 case involving blood/fluid product (anticoagulant), and 1 case involving insulin.

The fourth report included 1 case involving anti-tumor drug, 5 cases involving cardiovascular drugs, and 2 cases involving anti-diabetics (insulin). Other drugs involved in reported cases included central nervous system drugs in 6 cases, antibiotics in 3 cases, and peripheral nervous system drug in 1 case.

(4) Medical near-miss incidents associated with drugs

One hundred and eleven medical near-miss incidents reported in the 15th and 16th surveys were subject to analysis. Details of these cases were summarized as were the medical adverse events associated with drugs. The flow of drug therapy is summarized in a matrix with five processes; with "ordering," "receiving order/briefing," "preparation," "drug administration," and "observation and management after drug therapy" on the vertical axis and details of events on the horizontal axis (Fig. III-2-26).

"Drug mix-up" was most commonly reported (32 cases) followed by "wrong dose" (13 cases). Of 57 cases classified as "others," 18 cases involved closed ports that should have been opened when preparing infusion solution.

Medical near-miss incidents occurred most frequently during the preparation process (62 cases), including errors in dispensing drugs at pharmacies and taking out wrong drugs.

Paclitaxel (brand name: Taxol) and docetaxel hydrate (brand name: Taxotere) were mixed up in 2 cases; however, the mix-up was identified by a pharmacist before the drug was given to the patient in both cases. Medical adverse events of the same nature were included in the third report as medical adverse event information to be shared to call attention.

As in the medical adverse events involving insulin, preparation of intravenous insulin at a wrong dose was reported in 1 medical near-miss incident. In this case, the person involved had a coworker check the dose, and the initially prepared dose was corrected before given to the patient.

(5) Issues to be addressed

Since cases involving drugs have been steadily accumulated, case analyses by drug type, situation, and area of use will be started in this order.

Also, hearing sessions with medical institutions and industrial organizations will be held to consider effective measures for (A) developing systems to minimize errors in ordering process and detect ordering errors during subsequent processes and (B) sharing knowledge and information of drugs within medical institutions.

Fig. III-2-23 Summaries of Medical Adverse Events Involving Drugs

No.	Process in which event occurred	Summary of event	Remarks	
[Drug mix-up]				
1	Ordering	Drugs and doses were mixed up and entered in the form	Anti-tumor drug	Second
2		Patient received a drug to which he was allergic		
3		Drugs with similar names were mixed up	Anti-tumor drug (nonproprietary name: paclitaxel; brand name: Taxol; nonproprietary name: docetaxel hydrate; brand name: Taxotere)	
4	Receiving order	Drugs with similar names were mixed up	Anti-tumor drug (nonproprietary name: paclitaxel; brand name: Taxol; nonproprietary name: docetaxel hydrate; brand name: Taxotere)	
5	Drug administration	A drug for testing and an injection drug were mixed up		
6	Drug administration	An oral dosage form and an intravenous dosage form were mixed up	No health hazard since the drug was sterile.	Third
7	Drug administration	Drug mix-up in dispensing		
8	Preparation	Drug mix-up in dispensing		Fourth
9	Preparation	Another drug kept in the same place was used	Surgical division	
10	Preparation	Drug mix-up when taking out	Emergency division	
[Wrong dose]				
1	Ordering	Patient was given a wrong dose of the drug he brought		Second
2		Wrong dose was used after switching drugs	Blood/fluid product (anticoagulant)	
3		Dose entry error		
4		Error in protocol	Anti-tumor drug	
5		Handwriting order with wrong dose	Anti-tumor drug	
6		Error in copying the previous order in the order entry system		
7		Entry error in the order entry system		
8		Wrong dose was given based on a false assumption	Blood/fluid product (anticoagulant)	
9		Wrong dose was given intravenously	Insulin	
10		Error in protocol preparation	Anti-tumor drug	
11	Preparation	Wrong unit was used		Second
12		Dispensing drug at a wrong dose		
13		Wrong unit was used		
14		Miscalculation of dilution ratio		
15		Prepared drug was used at a wrong dose		

No.	Process in which event occurred	Summary of event	Remarks	
16	Ordering	Wrong dosage form was used	Blood/fluid product (anticoagulant)	Third
17		Error in entering dose in the form		
18		Dose entry error		
19		Wrong dose specified in the protocol	Anti-tumor drug	
20		Wrong dose was given based on a false assumption	Anti-tumor drug	
21	Preparation	Drug was provided in a wrong dosage form		
22	Ordering	Error in entering dose in the form		Fourth
23	Receiving order	Unit of dose was confused (mg for mL) when receiving oral order		
24	Receiving order	Unit of dose was confused (mg for mL) when receiving oral order		
25	Receiving order	Whole diluted solution was administered when only part of the solution should have been		
26	Preparation	Error in checking dose order		
27	Preparation	Drug was prepared without using an exclusive syringe	Insulin (intravenous)	
28	Preparation	Drug was prepared without using an exclusive syringe	Insulin (intravenous)	
29	Preparation	Drug was prepared in a wrong post-dilution dose		
[Wrong method] (administration route, concentration, duration)				
1	Ordering	Drug was given at a higher concentration than that specified in the package insert	Gabexate mesylate	Second
2		Drug was given at a higher concentration than that specified in the package insert	Gabexate mesylate	
3		Drug was given at a higher concentration than that specified in the package insert	Gabexate mesylate	
4		Drug for IV drip was injected intravenously	Anti-tumor drug	
5		Patient was given a wrong dose of the drug he brought		
6	Drug administration	Drug was injected intravenously when it should have been administered by continuous epidural infusion		Second
7		Drug was injected intravenously when intramuscular injection was ordered		
8		Oral drug was given intravenously		
9	Ordering	Line connection was cracked due to incompatibility of drug concentration and IV tube	Etoposide	Third
10		Drug was given at a higher concentration than that specified in the package insert	Gabexate mesylate	
[Wrong dosing speed]				
1	Ordering	Dosing speed and duration of IV drip ordered were mixed up		Second
2	Drug administration	Delayed change of dosing speed		
3		Wrong dosing speed due to mixed up lines of 2 infusion pumps	Narcotic	
4	Observation/management	IV drug was given faster than ordered	Insulin	
5	Ordering	Order for pump flow setup was confused		Third
6	Drug administration	Order for dosing speed was misconceived, and drug was given faster than intended	Anti-tumor drug	

No.	Process in which event occurred	Summary of event	Remarks	
7	Drug administration	Pump flow setup was confused with that ordered for other drug	Vasopressor	Fourth
8		Order for dosing speed was misconceived, and drug was given faster than intended	Vasopressor	
9		Flow display of the device was misread, and drug was given faster than intended		
[Patient misidentification]				
1	Drug administration	Drug to be given to Patient A was given to Patient B		Second
2		Drug to be given to Patient A was given to Patient B		
3		Drug to be given to Patient A was given to Patient B		
4	Drug administration	Barcode usage procedure was not followed correctly, and drug to be given to Patient A was given to Patient B		Third
[Others]				
1	Ordering	Preoperative dosing was missed		Second
2		Dose was missed when changing regular drugs		
3		Preoperative dosing was missed		
4		Occurrence of hyperglycemia associated with use of contraindicated drug in patients with a history of diabetes		
5		Patient received a drug to which he was allergic		
6	Drug administration	Wrong usage of syringe pump		
7	Observation/management	Extravascular leakage of anti-tumor drug in peripheral intravenous chemotherapy	Anti-tumor drug	
8		Extravascular leakage of anti-tumor drug in peripheral intravenous chemotherapy	Anti-tumor drug	
9		Extravascular leakage of anti-tumor drug in peripheral intravenous chemotherapy	Anti-tumor drug	
10		Extravascular leakage of anti-tumor drug in peripheral intravenous chemotherapy	Anti-tumor drug	
11		Changes in patient's respiratory function		
12		Patient was readmitted to the hospital due to drug intoxication after discharge		
13	Master file registration	Wrong dosage form registration in drug master file		Third
14	Ordering	Scheduled test was not conducted during drug therapy	Antirheumatic	
15		Misconception of ordered starting date after drug switch	Insulin	
16		Collective packaging of multiple drugs with different daily dosages	Anti-tumor drug	
17	Drug administration	Oral drug was taken without being removed from the package (heat seal)		
18	Ordering	Patient received a drug to which he was allergic		Fourth
19	Ordering	Patient received a drug to which he was allergic		
20	Ordering	Overdose due to error in order entry		
21	Observation/management	Extravascular leakage of IV drug that required treatment	Anti-tumor drug	
22	Observation/management	Extravascular leakage of IV drug that required treatment	Phenytoin	

No.	Process in which event occurred	Summary of event	Remarks	
23	Observation/management	Extravascular leakage of IV drug that required treatment	Phenytoin	Fourth
24	Observation/management	Extravascular leakage of IV drug that required treatment	Maintenance fluid 500 mL and KCL(Note) 3A	
25	Observation/management	Patient with allotriophagy took a large dose of another patient's drug		

（Note）Potassium chloride

Fig. III-2-24 Occurrence of Medical Adverse Events Involving Drugs (October 2004 to December 2005)

		Drug mix-up	Wrong dose	Wrong method			Wrong dosing speed	Patient misidentification	Others	Total
				Route of administration	Concentration	Duration				
Process	Ordering	3	16	1	5	1	2	0	11	39
	Receiving order/ briefing	1	3	0	0	0	0	0	0	4
	Preparation	3	10	0	0	0	0	0	0	13
	Drug administration	3	0	3	0	0	6	4	2	18
	Observation and management after drug therapy	0	0	0	0	0	1	0	11	12
	Others	0	0	0	0	0	0	0	1	1
Total		10	29	4	5	1	9	4	25	87

Fig. III-2-25 Type of Drugs Involved in Medical Adverse Events (October 2004 to December 2005)

Type of drug	Number of reports
Blood product	0
Narcotic	1
Anti-tumor drug	16
Cardiovascular drug	5
Antidiabetic	6
Anxiolytic	0
Hypnotic	0
Other drugs	59
Total	87

Fig. III-2-26 Occurrence of Medical Near-Miss Incidents Involving Drugs

		Drug mix-up	Wrong dose	Wrong method			Wrong dosing speed	Patient misidentification	Others	Total
				Route of administration	Concentration	Duration				
Process	Ordering	6	0	0	1	1	0	0	4	12
	Receiving order/ briefing	3	2	0	0	0	1	0	2	8
	Preparation	23	9	1	1	0	0	0	28 (Note)	62
	Drug administration	0	2	1	0	0	0	0	13	16
	Observation and management after drug therapy	0	0	0	0	0	3	0	10	13
	Others	0	0	0	0	0	0	0	0	0
Total		32	13	2	2	1	4	0	57	111

(Note) Including 15 cases involving closed ports that should have been opened to mix drugs when preparing infusion solution.

[3] Medical Adverse Events Involving Medical Devices

(1) Report summary

Among medical adverse events involving medical devices, those associated with mechanical ventilator which occurred at the highest frequency were analyzed first.

Fourteen medical adverse events associated with mechanical ventilator were reported between October 2004 and December 31, 2005. Summaries of events published in the third report are shown in Fig. III-2-27.

Relevant medical institutions were visited for further investigation of 2 medical adverse events involving mechanical ventilator between October 1 and December 31, 2005.

(2) Medical adverse events involving mechanical ventilator

Medical adverse events and near-miss incidents included in the third report were summarized and analyzed as described below.

A. Summaries of events involving mechanical ventilator

Device parts involved in the reported medical adverse events included “electric line” in 7 cases (58.0%), “heater/humidifier” in 2 cases (17.0%), and “setup/operation panel” in 3 cases (25.0%). Place of occurrence included patient room in 8 cases, NICU in 2 cases, operation room in 1 case, and CCU in 1 case.

Device parts involved in medical near-miss incidents included “power” in 13 cases (4.8%), “oxygen supply” in 14 cases (5.1%), “electric line” in 117 cases (42.9%), “heater/humidifier” in 41 cases (15.0%), “setup/operation panel” in 49 cases (17.9%), and “ventilator body” in 39 cases (14.3%) (Fig. III-2-28).

“Electric line” was most commonly involved in both medical adverse events and near-miss incidents.

B. Analysis by device part

i. Power

- Medical adverse event

  None

- Near-miss incident

  Most near-miss incidents were related to basic device usage such as “power was out because emergency power was not in use,” “battery ran out,” and “power plug was almost pulled out of the outlet because it was not firmly inserted and locked.”

  These events could have been prevented by ensuring pre-usage inspection.

ii. Oxygen supply

- Medical adverse event

  None

- Near-miss incident

  Frequently reported incidents included “oxygen was not supplied,” “oxygen tank was not connected,” “oxygen tank was disconnected,” “lack of oxygen in the tank, forgot to open the valve,” and “oxygen leaked.” Patients were spontaneously breathing so that mechanical ventilators could be temporarily removed in all cases. The events occurred after the previously removed ventilator was reattached.

  Some of these events could have been prevented by pre-usage inspection, and early response could have been possible by conducting inspection during use in other cases.

iii. Line

- Medical adverse event

  Two cases involved “wrong connection during line assembly,” 1 case involved “line blockage,” and 4 cases involved “leakage due to line disconnection.” One case of “wrong connection during line assembly” and 2 cases of “line disconnection” resulted in patients’ death dut to delayed notice.

- Near-miss incident

  Frequently reported incidents included “wrong connection” during pre-usage assembly in 28 cases (10.2%) and “inadequate connection” in 35 cases (12.8%). Leakage-related incidents included “line disconnection” in 35 cases (12.8%), “disconnected line and cannula” in 10 cases (3.7%), and “line breakage” in 13 cases (4.8%).

iv. Heater/humidifier

- Medical adverse event

  Two events involving heater/humidifier were related to water supply: “use of wrong purified water” and “water supply by wrong method.”

- Near-miss incident

  Frequently reported incidents included “power blackout” in 19 cases (7.0%) and “wrong setup” in 5 cases (1.8%). These events could have been prevented by pre-usage inspection.

  Checking during device use would have been necessary to prevent incidents reported in 9 cases (3.3%) related to “water supply.”

v. Setup/operation panel

- Medical adverse event

  "Discontinued operation," "suspended operation," and "inactivated alarm of mechanical ventilator" were reported in separate cases.

- Near-miss incident

  "Wrong setup" was reported in most cases (40 cases). "Power blackout" in 6 cases. Patients were spontaneously breathing so that mechanical ventilators could be temporarily removed in these cases. Medical adverse events were prevented since there was enough time to appropriately set up the devicesagain. Persons handling mechanical ventilators need to acquire thorough knowledge about appropriate setup, operation, and checking of the devices.

vi. Ventilator body

- Medical adverse event

  None

- Near-miss incident

  Most cases involved device malfunction or defect.

(3) Issues to be addressed

In order to prevent mechanical ventilator accidents, it is important to (A) set up and operate the ventilator appropriately and (B) detect any abnormality and respond properly.

The MHLW Pharmaceutical and Food Safety Bureau Notification "Measures to Prevent Medical Adverse Events Involving Life-Support System (Mechanical Ventilator)" (PFSB Notification No. 248 dated March 27, 2001) and the MHLW Announcement "Criteria for Mechanical Ventilator Alarm" have been issued to address the problem.

Measures to prevent accidents will be further considered by conducting surveillance on mechanical ventilator use/management at medical institutions.

Fig. III-2-27 Classification of Medical Adverse Events Involving Mechanical Ventilator

Classification			Place of occurrence	Severity	Event summary
Line	Line assembly	Wrong connection	Operation room	Unknown	Wrong line connection led to no ventilation and set off the alarm indicating high airway pressure.
	Line assembly	Wrong connection	Patient room	Death	Connection of the expiratory port and the inspiratory port to the heater/humidifier was confused when changing the line.
	Line blockage		CCU	Residual disability likely	Line was blocked by a foreign object (a connection adaptor used during the cleaning process).
	Line blockage		NICU	Residual disability unlikely	A hole in the expiratory tube about 1 mm in diameter caused water retention in the tube.
	Leakage	Disconnection	Patient room	Death	Tracheal cannula and mechanical ventilator were disconnected after sputum suction.
	Leakage	Disconnection	Patient room	Death	Alarm went off after sputum suction. L-shaped connector and cannula were disconnected.
	Leakage	Disconnection	Patient room	No disability	Low pressure alarm went off after sputum suction. Cannula and connector of corrugated tube were disconnected.
Heater/ humidifier	Water supply		Patient room	No disability	Sterilized and purified water containing cleanser prepared for bronchoscope cleaning was used for heater/humidifier by mistake.
	Water supply		Patient room	Residual disability unlikely	IV drip set was used with a heater/humidifier without automatic water feeder, and too much water was supplied.
Setup/ operation panel	Setup	Discontinued operation	Patient room	Residual disability likely	Alarm went off after connecting the mechanical ventilator. The person involved thought he/she had opened the front cover and pushed “sound-off” button; however, he/she had turned off the power by mistake.
	Setup	Suspended operation	Patient room	Residual disability unlikely	High-pressure alarm went off frequently. The ventilator was removed temporarily and its operation was suspended. Activated status of the ventilator was not checked after connecting the ventilator line again.
	Setup	Mechanical ventilator alarm	NICU	Residual disability likely	Alarm did not go off.

Fig. III-2-28 Classificatsion of Medical Near-Miss Incidents Involving Mechanical Ventilator

<table>
<tr><th>Classification</th><th colspan="3">Details</th><th>Number of incidents (%)</th><th>Number of incidents by classification (%)</th></tr>
<tr><td rowspan="4">Power</td><td>1</td><td colspan="2">Inappropriate power supply</td><td>7 (2.6)</td><td rowspan="4">13 (4.8)</td></tr>
<tr><td>2</td><td colspan="2">Inadequate code connection</td><td>4 (1.5)</td></tr>
<tr><td>3</td><td colspan="2">Internal battery malfunction</td><td>1 (0.4)</td></tr>
<tr><td>4</td><td colspan="2">Connection cable breakage</td><td>1 (0.4)</td></tr>
<tr><td rowspan="5">Oxygen supply</td><td>1</td><td colspan="2">Not supplied</td><td>5 (1.8)</td><td rowspan="5">14 (5.1)</td></tr>
<tr><td>2</td><td colspan="2">Not connected</td><td>3 (1.1)</td></tr>
<tr><td>3</td><td colspan="2">Oxygen tank disconnected</td><td>2 (0.7)</td></tr>
<tr><td>4</td><td colspan="2">Inappropriate handling of oxygen tank</td><td>2 (0.7)</td></tr>
<tr><td>5</td><td colspan="2">Oxygen leakage</td><td>2 (0.8)</td></tr>
<tr><td rowspan="11">Line</td><td rowspan="3">1</td><td rowspan="3">Wrong connection</td><td>Confused expiration/inspiration ports</td><td>15 (5.5)</td><td rowspan="11">117 (42.9)</td></tr>
<tr><td>Location of pressure/temperature sensor</td><td>6 (2.2)</td></tr>
<tr><td>Location</td><td>7 (2.6)</td></tr>
<tr><td>2</td><td colspan="2">Inadequate connection</td><td>7 (2.6)</td></tr>
<tr><td>3</td><td colspan="2">Inappropriate use of items</td><td>10 (3.7)</td></tr>
<tr><td>4</td><td colspan="2">Line exchange required time</td><td>2 (0.7)</td></tr>
<tr><td>5</td><td colspan="2">Line blockage</td><td>7 (2.5)</td></tr>
<tr><td>6</td><td colspan="2">Breakage</td><td>5 (1.8)</td></tr>
<tr><td>7</td><td>Leakage</td><td>Disconnection</td><td>35 (12.8)</td></tr>
<tr><td>8</td><td>Leakage</td><td>Disconnected cannula</td><td>10 (3.7)</td></tr>
<tr><td>9</td><td>Leakage</td><td>Line breakage</td><td>13 (4.8)</td></tr>
<tr><td rowspan="5">Heater/humidifier</td><td>1</td><td colspan="2">Power was off</td><td>19 (7.0)</td><td rowspan="5">41 (15.0)</td></tr>
<tr><td>2</td><td colspan="2">Wrong setup</td><td>5 (1.8)</td></tr>
<tr><td>3</td><td colspan="2">Water supply</td><td>9 (3.3)</td></tr>
<tr><td>4</td><td colspan="2">Breakage</td><td>2 (0.7)</td></tr>
<tr><td>5</td><td colspan="2">Malfunction/defect</td><td>6 (2.2)</td></tr>
<tr><td rowspan="14">Setup/ operation panel</td><td>1</td><td colspan="2">Power blackout</td><td>6 (2.2)</td><td rowspan="14">49 (17.9)</td></tr>
<tr><td rowspan="10">2</td><td rowspan="10">Setup</td><td>Alarm</td><td>3 (1.1)</td></tr>
<tr><td>Oxygen concentration</td><td>6 (2.2)</td></tr>
<tr><td>Oxygen flow</td><td>3 (1.1)</td></tr>
<tr><td>Mode</td><td>14 (5.1)</td></tr>
<tr><td>Mode/pressure</td><td>1 (0.4)</td></tr>
<tr><td>Ventilation</td><td>2 (0.7)</td></tr>
<tr><td>Pressure</td><td>4 (1.5)</td></tr>
<tr><td>Expiratory time</td><td>2 (0.7)</td></tr>
<tr><td>Respiratory rate</td><td>4 (1.5)</td></tr>
<tr><td>Wrong setup method</td><td>1 (0.4)</td></tr>
<tr><td>3</td><td colspan="2">Inappropriate position of mode setup dial</td><td>1 (0.4)</td></tr>
<tr><td>4</td><td colspan="2">Tidal volume display/high value due to sputum and moisture drops</td><td>1 (0.4)</td></tr>
<tr><td>5</td><td colspan="2">Battery of graphic monitor was out</td><td>1 (0.4)</td></tr>
<tr><td rowspan="2">Ventilator body</td><td>1</td><td colspan="2">Inappropriately secured ventilator</td><td>1 (0.4)</td><td rowspan="2">39 (14.3)</td></tr>
<tr><td>2</td><td colspan="2">Malfunction/defect</td><td>38 (13.9)</td></tr>
<tr><td colspan="4">Total</td><td colspan="2">273 (100)</td></tr>
</table>

[4] Medical Adverse Event Related to Treatment (Glycerin enema)

Medical adverse event related to treatment was selected as a new theme in the second report.

Two of 6 cases of rectal perforation or injury potentially caused by glycerin enema reported in the year between October 1, 2004 and September 30, 2005 were investigated by visiting relevant medical institutions that had agreed to cooperate. Considering information concerning these events should be widely shared by Expert Analysis Groups and others, the Center for Medical Adverse Event Prevention summarized them in the third report.

[5] Important Medical Near-Miss Case Database Development Group

The Center for Medical Adverse Event Prevention owns Important Medical Near-Miss Case Database as part of current Project to Collect Medical Near-Miss/Adverse Event Information.

The "Important Medical Near-Miss Case Database Development Group" has been established as another expert analysis group to promote effective usage of collected near-miss information from the Fourth report. Important Medical Near-Miss Case Database Development Group picks up cases to be widely known as the result of analysis by Expert Analysis Groups for individual themes and important medical near-miss incidents reported by medical institutions as "warning" cases to be widely known regardless of the survey theme, determines information to be included in the database, and reviews relevant data.

Important medical near-miss incidents reported as "warning" cases not covered by survey themes are described in the following pages (Fig. III-2-29).

Fig. III-2-29 Important Medical Near-Miss Cases (Descriptive Information)

No.	Details	Background/cause
1	Patient's respiratory function deteriorated. Endotracheal intubation was performed, and a mechanical ventilator was attached. "Propofol" (general anesthesia) was given at a speed of 12 mL/h for sedation. The patient removed the endotracheal tube by himself/herself (removal). Arterial oxygen saturation temporarily dropped to some 40% but returned to 95% after re-intubation. "Propofol" was increased to 15 mL by doctor's order.	• Safety belt (restraining tool) was not used based on the ward policy even when staff left the patient room. • Sedative effect of "propofol" was not sufficiently ensured. • Staff left the patient room. • Inadequate prediction.
2	Ambubag could not be inflated during preparation for bronchial lavage. Air was hardly coming out from the humidifier adaptor (adaptor with humidifying function). Wrong placement of the rubber plug of adaptor was identified when changing adaptor. The adaptor was promptly replaced, inflated reservoir was checked, and lavage was performed.	• Documentation review revealed the previous bronchial lavage was performed before line change. • An accident was prevented since the rubber plug misplacement was detected during the preparation process for bronchial lavage.
3	Patient awoke during the surgery under general anesthesia. Intravenous anesthesia was supplemented to induce sleep. The anesthesia apparatus was checked but the cause was not identified. Other anesthesia apparatus was used for subsequent procedure. The surgery was completed without further problem. It was found on the next day that laughter gas or anesthetic gas could not be supplied to anesthesia apparatus in another operation room.	• Laughter gas and anesthetic gas that should have been flowing were not supplied to the patient, resulting in a low anesthetic level. • The maintenance company for the malfunctioned anesthetic apparatus was contacted immediately and requested for prompt response and investigation into the cause.
4	Prescription of injection solutions containing anticancer drugs was inspected. Injection solutions were delivered to the ward except for those to be prepared at the pharmacy. Pharmacy staff did not notice that "Serenace" not included in the original prescription was among the delivered drugs. Ward staff noticed it and contacted the pharmacy.	• There have been several accidents of wrong drugs delivered to wards caused by "Ampule Picker" (automated injection dispensing system). • Drugs were checked without removing them from the bag; this may have caused overlooking of the unprescribed drug.
5	During a brain surgery, a scrub nurse kept a piece of cranial bone the size of 3 x 3 cm taken from the patient on the instrument table (Mayo table). The scrub nurse wrapped the piece of cranial bone in normal saline gauze and placed it on the Mayo table to prepare for dural suture process in which the bone piece would be put back. The surgeon took the gauze with cranial bone inside once and put it back on the Mayo table (the scrub nurse did not see the surgeon's action). The scrub nurse thought the gauze on the Mayo table had been used in the surgical site and threw it away in a bucket without checking inside.	• The principles of sample storage place and method were not observed. • The nurse did not pay attention to the surgical site or the instrument table. • A piece of bone 3 to 5 mm thick and 3 x 3 cm in size wrapped in gauze should have been easily recognized by touch, but it wasn't. • Procedures specified in the surgical manual were not followed. The nurse acted based on false assumption. Placement of the bone piece was inappropriate.

No.	Details	Background/cause
6	A new test strip was used in the periodic blood glucose check in a patient because the remaining "Advantage Test Strip S" (exclusive measurement sensor) was not enough. The chip to register the code number in the measuring device should have been replaced and set up again then, but the person involved forgot to replace it and used the device for measurement. In the next glucose check 3 hours later, another person noticed the code numbers of the strip and the device were inconsistent before measurement and replaced the chip.	• It was a periodic blood glucose check; however, the person involved was pressed for time and preoccupied with several things since he/she had to tend a newly admitted patient who should have been covered by another nursing team. • Code numbers of the test strip and measuring device should be cross checked before each blood glucose measurement as well as when replacing test strip in principle. The person involved forgot the principle; he/she needs to modify his/her behavior.
7	The patient put the antiseptic (Gojo MHS; disinfectant/antiseptic gel with moisturizer) placed on the overbed table into his/her cup and drank during dinner. (The patient said he drank 2 cups of antiseptic.)	• A bottle of antiseptic is usually placed on every overbed table. • The patient had not received explanation about the antiseptic.
8	The pendant bar hanging from the ceiling to hold IV bottles fell during bottle change (the bar was hung by hooks screwed to the ceiling). The screws came off, and the bar hit the bedside cabinet and then fell on the patient lying on the bed on the other side. The bar hit the right cheek of the patient, causing only bruising and no change in vital signs. The accident was reported to the doctor, who ordered to follow up the patient's condition. The accident was also reported to the department director. IV bars were replaced with IV stands and have been no longer used since then.	• Load limit of pendant IV bar had never caught anyone's attention. • Durability of hooks had not been fully considered. There had been a lack of risk prediction.
9	Temperature/humidity indicator of the incubator showed a high value. Water in the heater/humidifier tank was removed to monitor the device condition. The condition did not improve, and the power of the incubator was turned off once and turned on again to see heating/humidifying status. Oxygen flow in the incubator was reset; it would not be activated without restart. An hour after when the person on the next shift was briefed by the person involved, oxygen was not flowing in the incubator. There was no significant change in vital signs of the patient during the time without oxygen flow. Oxygen level in the incubator should have been 30% with oxygen flow; however, it was 21%, or the same as room oxygen level, due to lack of oxygen flow.	• The person involved knew that every incubator had yellow tape with a warning "check oxygen flow/heating/humidifying status when restart" but did not pay attention. He/she did not know why the yellow tape was on the incubator. • The person involved did not remember if he/she checked oxygen flow after restarting the device. • Oxygen level was to be documented on the temperature chart every hour for the patient receiving oxygen supplement but the chart was not used during the shift change. • Temperature, probe, oxygen level, and temperature/humidity of incubator should be checked when restarting it in principle. However, check was neglected from time to time.

3. Medical Adverse Event Information to Be Shared

In the process of individual review by Expert Analysis Groups of medical adverse events reported by participating medical institutions and compiled in the third report or subsequent reports, publication of event summaries that should be widely shared was decided. The event summaries are shown below.

Fig. III-3-1

Summary	Details	Number of events	Corresponding report
Drug	Anti-tumor drugs with similar names, paclitaxel (brand name: Taxol) and docetaxel hydrate (brand name: Taxotere), were mixed up.	2	Third report
Drug	Skin necrosis and ulceration in administration site in patients who received peripheral intravenous gabexate mesylate for treatment of disseminated intravascular coagulation (DIC). Gabexate mesylate was used at higher concentrations than that recommended in precautions concerning peripheral intravenous use provided in the package insert of the drug, in which potential phlebitis and ulcer/necrosis were mentioned. For example, the recommended concentration for central venous administration was used for peripheral intravenous administration.	4	Third report
Drug	1) White blood cells decreased during antirheumatic (methotrexate) therapy, and patients died of infection. Testing was not conducted at the frequency recommended in the package insert. 2) Antirheumatic (methotrexate) overdose. Methotrexate was given daily by mistake when it should have been given once a week.	3	Third report
Medical device, etc.	A hemostatic device may be used for pressure hemostasis of puncture site when completing a cardiac catheterization. Air is injected into the hemostatic device to inflate for pressure hemostasis. In the reported cases, air was accidentally injected into the sheath (a tube inserted into blood vessel as catheter passage) inserted into the artery instead of the hemostatic device, causing air embolism.	2	Third report
Treatment	Glycerin enema performed as a preoperative or a pre-test procedure caused rectal perforation. Enema was performed in patients standing up in the toilet, not in the left lateral position, in all cases.	4	Third report
Drug	Wrong dose of intravenous insulin was prepared. Persons involved did not have correct understanding of units equivalent to insulin 1 mL in both cases. Exclusive syringe for insulin preparation was not used. Another case of similar nature has been reported by September 30, 2005. Total of 3 cases involving lack of knowledge about insulin dose (unit/mL) have been reported. Nurses involved in 2 cases had 1 year of working experience, and one involved in the remaining case had 3 years of working experience but had been working at the current department for 4 months.	2	Fourth report

IV 2005 Surveillance on Basic Information of Registered Participating Medical Institutions

The Center for Medical Adverse Event Prevention conducted surveillance on medical institutions participating in Project to Collect, Analyze, and Provide Medical Near-Miss/Adverse Event Information with their cooperation to obtain supplemental data for analysis and tabulation of medical near-miss/adverse event information. The surveillance was designed to enable comparison of obtained data with those from the national surveillance on medical institutions throughout Japan.

Data tabulation is shown below.

Summary of surveillance

1. Subject

   Practices/activities performed at medical institutions participating in Project to Collect, Analyze, and Provide Medical Near-Miss/Adverse Event Information in the month of September 2005

2. Medical institutions

   273 medical institutions subject to reporting requirement

   283 registered participating medical institutions

3. Surveillance items

   Number of beds, number of employees, number of surgeries performed/tests conducted(Note 1)

Results

1. Surveillance forms collected
   1) 250 medical institutions subject to reporting requirement (91.4%)
   2) 209 registered participating medical institutions (73.5%)

2. Results

   See Fig. IV-1 for details.

   The total number of beds reported by medical institutions participating in the project with cooperation in the surveillance was 193,224.

   Among them, the total number of beds reported by medical institutions subject to reporting requirement with cooperation in the surveillance was 132,618. The Center for Medical Adverse Event Prevention obtained number of beds at medical institutions subject to reporting requirement not participated in the surveillance from published data of individual institutions and added to the total number of beds obtained in the surveillance. The total number of beds at all medical institutions subject to reporting requirement was 143,636.

(Note 1) Surveillance Form is shown in Attachment 9.

Fig. IV-1 Results of Surveillance on Basic Information of Registered Participating Medical Institutions

Name of institution		National university hospital	National Hospital Organization	National Center	Municipal	Sanatorium for Hansen's Disease	School juridical person	Medical institutions subject to reporting requirement (total)	Registered participating medical institutions (total)
Number of registered institutions		46	146	8	11	13	49	273	283
Number of responding institutions		43	134	7	10	12	44	250	209
Total	Total number of inpatients	763,990	1,338,736	109,422	169,616	86,824	708,128	3,176,716	1,465,247
	Number of inpatients at month end	25,337	42,808	3,587	5,590	2,884	23,300	103,506	48,028
	Number of newly admitted patients	35,613	38,187	5,067	6,765	7	38,957	124,596	80,950
	Number of discharged patients	35,735	38,147	5,046	6,704	15	39,204	124,851	80,950
	Number of beds at month end	31,332	52,167	4,512	6,846	6,955	30,806	132,618	60,606
Psychiatric ward	Total number of inpatients	42,024	114,623	19,527	6,456	0	34,471	217,101	81,529
	Number of inpatients at month end	1,337	3,737	643	261	0	951	6,929	2,662
	Number of newly admitted patients	625	685	206	110	0	419	2,045	1,320
	Number of discharged patients	692	712	214	98	0	459	2,175	1,315
	Number of beds at month end	1,768	4,492	801	332	0	1,277	8,670	3,325
Infection ward	Total number of inpatients	16	0	0	0	0	332	348	648
	Number of inpatients at month end	0	0	0	0	0	13	13	19
	Number of newly admitted patients	3	0	0	0	0	32	35	48
	Number of discharged patients	4	0	0	0	0	31	35	44
	Number of beds at month end	16	12	4	4	0	20	56	144
Tuberculosis ward	Total number of inpatients	1,365	65,672	1,884	452	0	483	69,856	7,966
	Number of inpatients at month end	41	2,132	71	9	0	14	2,267	283
	Number of newly admitted patients	22	1,129	34	19	0	9	1,213	127
	Number of discharged patients	24	1,039	25	19	0	13	1,120	128
	Number of beds at month end	173	4,129	80	26	0	52	4,460	543
Long-term care ward	Total number of inpatients	0	4,485	0	0	670	926	6,081	103,145
	Number of inpatients at month end	0	147	0	0	0	30	177	3,196
	Number of newly admitted patients	0	0	0	0	0	0	0	336
	Number of patients transferred from another ward within institution	0	1	0	0	0	30	31	302
	Number of discharged patients	0	2	0	0	0	21	23	681
	Number of patients transferred to another ward within institution	0	2	0	0	0	7	9	85
	Number of beds at month end	0	156	0	0	0	80	236	3,879
General ward	Total number of inpatients	720,699	1,090,904	88,011	161,526	86,612	671,580	2,819,332	1,223,926
	Number of inpatients at month end	23,959	36,940	2,873	5,320	2,884	22,283	94,259	40,242
	Number of newly admitted patients	34,963	37,155	4,827	6,636	7	38,462	122,050	75,436

Name of institution		National university hospital	National Hospital Organization	National Center	Municipal	Sanatorium for Hansen's Disease	School juridical person	Medical institutions subject to reporting requirement (total)	Registered participating medical institutions (total)
	Number of discharged patients	35,015	37,136	4,841	6,587	14	38,639	122,232	75,468
	Number of beds at month end	29,340	43,751	3,591	6,484	6,722	29,311	119,199	50,397
Others	Total number of inpatients	0	28,243	0	0	0	0	28,243	14,850
	Number of inpatients at month end	0	555	0	0	0	0	555	490
	Number of newly admitted patients	0	27	0	0	0	0	27	434
	Number of discharged patients	0	30	0	0	0	0	30	489
	Number of beds at month end	0	560	0	0	0	0	560	683
Long-term care ward (relisted)	Total number of inpatients	0	0	0	0	0	0	0	24,627
	Number of inpatients at month end	0	0	0	0	0	0	0	684
	Number of newly admitted patients	0	0	0	0	0	0	0	80
	Number of patients transferred to another ward within institution	0	0	0	0	0	0	0	79
	Number of discharged patients	0	0	0	0	0	0	0	150
	Number of patients transferred to another ward within institution	0	0	0	0	0	0	0	28
	Number of beds at month end	0	0	0	0	0	0	0	911
Total number of outpatients		1,246,937	913,532	128,844	289,375	1,001	1,556,307	4,135,996	2,517,361
Doctor	Full-time	10,258	4,537	704	1,698	101	10,376	27,674	9,033
	Part-time (full-time equivalent)	4,327	1,232	531	639	13	2,067	8,809	1,396
	Total number of doctors	14,585	5,769	1,235	2,337	114	12,443	36,483	10,429
Dentist	Full-time	1,542	39	7	115	18	2,940	4,661	184
	Part-time (full-time equivalent)	600	39	10	25	1	678	1,353	35
	Total number of dentists	2,142	78	17	140	19	3,618	6,014	219
Pharmacist	Actual number	1,371	964	129	247	35	1,424	4,170	2,021
	(Full-time equivalent)	1,295	859	122	188	36	1,245	3,744	1,545
Public health nurse	Actual number	2	0	0	4	0	223	229	759
	(Full-time equivalent)	2	0	0	4	0	220	226	303
Midwife	Actual number	719	609	80	160	0	730	2,298	1,856
	(Full-time equivalent)	683	551	80	160	0	624	2,098	1,282
Nurse	Actual number	18,812	25,560	2,809	4,809	845	21,966	74,801	36,731
	(Full-time equivalent)	17,419	22,996	2,795	4,062	777	19,907	67,955	28,049
Assistant nurse	Actual number	162	1,840	38	115	328	458	2,941	3,199
	(Full-time equivalent)	150	1,532	38	104	303	384	2,512	2,623
Nursing assistant		765	1,842	150	179	1,461	2,024	6,421	4,772
Physical therapist		214	489	22	59	19	323	1,126	1,135
Occupational therapist		106	207	20	30	5	146	513	474
Orthoptist		90	30	7	14	0	171	312	208
Speech therapist		60	47	7	14	0	81	208	175
Prosthetist		0	0	0	0	9	0	9	1
Dental hygienist		147	24	3	19	1	589	783	227
Dental technician		100	11	2	12	10	243	378	50
Radiological technologist		1,153	992	154	287	16	1,363	3,964	2,097
Radiologist		1	3	0	1	0	6	11	72
Clinical technologist		1,752	1,353	156	410	41	2,370	6,082	3,056
Medical technologist		32	14	55	6	4	81	193	27
Clinical engineering technologist		202	110	16	26	0	381	735	658

Name of institution		National university hospital	National Hospital Organization	National Center	Municipal	Sanatorium for Hansen's Disease	School juridical person	Medical institutions subject to reporting requirement (total)	Registered participating medical institutions (total)
Traditional massage/massage/finger pressure, acupuncture, moxacautery practitioner		6	54	4	1	2	13	80	88
Judo-orthopedist		0	8	0	5	0	7	20	13
National registered dietitian		187	388	28	52	21	319	994	603
Dietitian		34	60	1	2	5	164	266	136
Psychiatric social worker		4	42	21	1	0	25	93	62
Certified social worker		10	14	0	3	1	19	47	183
Certified care worker		0	43	0	0	0	8	51	316
Other technical worker		375	776	37	71	8	371	1,639	617
Medical social worker		61	150	13	12	21	84	342	274
Administrative staff		4,574	3,128	382	501	248	4,100	12,933	7,881
Other staff		900	2,761	611	310	726	1,368	6,677	3,190
Remarks		0	0	0	0	0	0	0	0
General anesthesia	General anesthesia	10,551	6,669	1,185	2,259	0	10,807	31,471	13,689
Craniotomy	Craniotomy	481	263	60	89	0	361	1,254	513
Surgery under pump-oxygenator	Surgery under pump-oxygenator	358	148	62	63	0	256	887	325
Cancer operation	Cancer operation	2,422	1,922	530	635	0	2,126	7,635	3,116
	Gastrointestinal cancer operation (relisted)	520	480	83	132	0	509	1,724	1,136
	Lung cancer operation (relisted)	210	258	62	65	0	154	749	186
	Breast cancer operation (relisted)	285	269	63	89	0	282	988	480
	Uterine cancer operation (relisted)	207	143	15	50	0	150	565	171
	Hepatic, biliary or pancreatic cancer operation (relisted)	310	120	46	46	0	176	698	283
Prosthetic joint replacement		368	291	10	56	0	297	1,022	591
Open reduction of fracture		189	552	18	41	0	371	1,171	1,669
Pacemaker implant		167	156	17	27	0	187	554	322
Laparoscopic operation		543	406	41	111	0	701	1,802	1,141
Thoracoscopic operation		379	258	29	63	0	219	948	273
Gastrointestinal endoscopic surgery		1,114	932	389	207	0	2,033	4,675	3,565
Percutaneous transluminal coronary angioplasty		267	289	77	114	0	357	1,104	1,076
Percutaneous arterial embolization		567	152	4	136	0	481	1,340	422
Intraocular lens implant		1,559	919	70	310	5	1,846	4,709	3,287
Retinal photocoagulation		731	271	38	203	0	733	1,976	1,329
Extracorporeal shock wave lithotripsy	Extracorporeal shock wave lithotripsy	96	113	1	31	0	195	436	826
	Number of lithomyls	37	21	1	4	0	23	86	74
IABP	IABP	151	92	6	21	0	193	463	161
	Number of IABPs	91	64	3	18	0	82	258	174
Hyperthermia		1,237	1	0	2	0	8	1,248	34
Radiation therapy (External radiation)	Radiation therapy (external radiation)	28,109	19,823	3,740	11,683	0	24,657	88,012	21,695
	Number of radiotherapy units	92	73	13	16	0	53	247	68
	Gamma knife/stereotactic multi-orbital irradiation (relisted)	164	7	17	168	0	71	427	86
Radiation therapy (Small sealed source)	Radiation therapy (small sealed source)	312	138	32	37	0	301	820	46

Name of institution		National university hospital	National Hospital Organization	National Center	Municipal	Sanatorium for Hansen's Disease	School juridical person	Medical institutions subject to reporting requirement (total)	Registered participating medical institutions (total)
Hemodialysis	Hemodialysis	6,591	6,292	450	1,045	243	13,788	28,409	82,258
	Number of hemodialyzers	398	259	23	70	27	536	1,313	2,750
Delivery (Including normal delivery)	Delivery (including normal delivery)	1,088	1,890	183	249	0	1,141	4,551	4,332
	Caesarean section (relisted)	325	511	47	82	0	403	1,368	963
Upper gastrointestinal endoscopy		10,288	11,105	2,202	2,918	34	13,244	39,791	37,625
Bronchoendoscopy		976	1,578	99	155	0	1,233	4,041	1,626
Colorectal endoscopy		3,635	4,020	557	1,002	9	4,598	13,821	13,520
Angioseriography		4,822	4,335	581	1,061	0	4,344	15,143	6,616
X-ray CT scan	Number of examinations conducted	226,793	62,992	8,847	14,315	337	54,808	368,092	124,428
	Number of CT scanner	135	152	18	32	12	114	463	251
CT-guided biopsy		195	117	13	39	0	102	466	128
MRI	Number of examinations conducted	25,127	23,374	2,711	5,587	0	28,287	85,086	51,608
	Number of machines	96	113	14	22	0	86	331	195
RI (scintigram)	Number of examinations conducted	5,643	6,709	2,230	1,144	13	7,100	22,839	7,570
	Number of machines	102	83	19	20	1	72	297	105
Single photoemission CT (SPECT)	Number of examinations conducted	3,194	3,477	765	1,002	0	4,294	12,732	4,753
	Number of machines	105	68	16	21	0	80	290	105
Positron CT	Number of examinations conducted	919	1,229	364	109	0	674	3,295	2,730
	Number of machines	12	3	6	1	0	6	28	17
Bone mineral analysis	Number of examinations conducted	2,223	1,788	77	572	33	2,295	6,988	5,285
DSA		44	178	7	11	20	53	313	236
Computed radiography		43	159	7	10	15	45	279	228
Digital fluorography		52	182	8	10	18	56	326	270
Use of ordering system	1. Examination/testing	42	43	5	9	0	29	128	106
	2. Prescription	42	66	6	10	0	28	152	112
	3. Appointment	41	46	6	9	0	28	130	100
	4. Not used	0	65	1	0	11	12	89	88
Use of ICD code	1. ICD-10	41	99	6	10	0	31	187	155
	2. ICD-9	2	2	0	0	0	2	6	5
	3. ICD-9-CM	2	12	0	1	0	9	24	62
	4. ICD-0	1	3	0	0	0	2	6	10
	5. Not used	1	30	1	0	8	11	51	45
Hospital website		43	133	7	10	12	43	248	186

Attachment 1　Outline of Project to Collect Medical Adverse Event Information

I. Summary of Project to Collect Medical Adverse Event Information

1. Objective

Objective analysis of various factors involved in medical adverse events and developing corrective measures based on the analysis are necessary to establish effective medical safety measures.

Individual medical institutions have been developing systems to collect and analyze medical safety information on their own.　It is important to effectively collect information on factors common to medical institutions associated with medical adverse events and corrective measures, rather than information on factors unique to individual medical institutions, in order to understand the importance and characteristics of individual factors.

The project intends to collect, analyze, and provide medical adverse event information of which causes and backgrounds have been analyzed by medical institutions subject to reporting requirement and registered participating medical institutions and corrective measures developed based on such analysis for sharing of information useful to develop medical safety measures among medical institutions in general and to provide information to the general public in order to further promote medical safety measures.

2. Information to be collected

The following medical adverse event information will be collected.

A. Apparent error in treatment or management that resulted in the patient's death or mental or physical disability or required unexpected treatment, treatment to an unexpected extent, or other medical procedure

B. Unapparent error in treatment or management that resulted in the patient's death or mental or physical disability or required unexpected treatment, treatment to an unexpected extent, or other medical procedure (including events possibly associated with treatment or management provided; limited to unexpected events)

C. Other than those described in A and B, information conducive to prevention of medical adverse events and their recurrence at medical institutions

II. Medical Institutions

1. Medical institutions to be surveyed

In this project, surveys will be conducted at following medical institutions subject to reporting requirement and registered participating medical institutions.

- Medical institutions subject to reporting requirement
  1. National Centers and National Sanatoriums for Hansen's disease
  2. Hospitals run by the National Hospital Organization
  3. Hospitals affiliated with universities governed by the School Education Law (not including their branch hospitals)
  4. Advanced treatment facilities
- Registered participating medical institutions
  Medical institutions other than those subject to reporting requirement that wish to participate in the project

2. Procedure to be followed by medical institutions subject to reporting requirement

Medical institutions newly designated as those subject to reporting requirement will be requested to fill out a registration form for the medical institution subject to reporting requirement. Registration will be completed by submitting necessary information such as person responsible for project participation to the Center for Medical Adverse Event Prevention.

3. Application for registered participation

Medical institutions that wish to voluntarily participate in the project should fill out "Application for Registered Participation in Project to Collect Medical Adverse Event Information" with the necessary information and send it to the JCQHC by mail or fax.

4. Registration cancellation

1) Registered participating medical institutions may cancel their registration by contacting the Center for Medical Adverse Event Prevention should their participation in the project become difficult for some reason.

2) Medical institutions subject to reporting requirement may cancel their registration at discretion by contacting the Center for Medical Adverse Event Prevention should they lose the qualification as medical institutions subject to reporting requirement due to change of mother organization or other reasons.

III. Medical Adverse Event Reporting

1. Report from medical institutions

Medical adverse events should be reported on the exclusive reporting web page at the following address via the Internet (SSL communication).

https://www.accident.med-safe.jp

See “Guideline for Reporting” for details.

Case information submitted for reporting in Project to Collect Medical Adverse Event Information will not be returned.　Reporting medical institutions should take necessary steps (e.g. printing out) before document submission as necessary.

2. Reporting due date

Should a medical adverse event to which any of the criteria shown in I-2 herein applies occur at a medical institution subject to reporting requirement or a registered participating medical institution, such an event should be reported on the day of occurrence or within 2 weeks of identifying the occurrence in principle in accordance with the method specified in III-1 herein.

3. Exceptions for reporting due date/method

1) Events may be reported in a separately provided form, not in accordance with the method specified in III-1 herein, within 2 weeks if any of the following applies:
   1. Patient’s consent has not been obtained prior to reporting.
   2. Reporting by the specified method is impossible due to system trouble.
   3. Reporting by the specified method is impossible due to other special reasons.

   Medical institutions subject to reporting requirement may not submit reports in a separate form due to Reason 1.

2) After reporting in the form described in 1), another report should be submitted in accordance with the method described in III-1 herein within 45 days of the initial report if Reason 1 is applicable or as soon as reporting by the specified method is possible if Reasons 2 or 3 are applicable.

3) Reporting in the form described in 1) alone will not be considered as an official report for the project unless the event is reported by the method specified in III-1 herein.

4. Institution ID and password

1) Institution ID and password required for data entry are issued as described below.

- Medical institution subject to reporting requirement

  Institution ID, password, and registration form for the medical institution subject to reporting requirement will be automatically issued to the head of institution in writing at the time of its designation as a medical institution subject to reporting requirement.

- Registered participating medical institution

  Institution ID and password will be automatically issued to the head of institution after registration is completed.

2) Any change in information included in the registration form for the medical institution subject to reporting requirement or application for registered participation in Project to Collect Medical Adverse Event Information should be notified as soon as possible.

3) When institution ID or password needs to be reissued, re-issuance should be requested as soon as possible.

4) Medical institutions that canceled their registration should return their institution IDs and passwords to the Center for Medical Adverse Event Prevention.

IV. Confirmation of Adverse Event Information

1. Information receipt

A case receipt number will be issued on the web page when a report is received online.　The case receipt number is valid for 3 months after its issuance in principle and may be extended as necessary.

2. Collection of follow-up information

Follow-up information will be collected by the following methods.
Any and all inquiries will be made with a case receipt number in both methods.

1) Inquiry by mail

   Follow-up data will be requested by using a designated form sent by mail.

2) Interview at Center for Medical Adverse Event Prevention

   Follow-up data will be requested by using a designated form, and person(s) involved will be interviewed by Safety Management personnel at the Center for Medical Adverse Event Prevention to collect further information.

3) On-site inspection by expert

Follow-up data will be requested by using a designated form, and an on-site inspection will be conducted by experts to collect further information.

3. Submission of follow-up information

Follow-up information may be sent by mail to the Center for Medical Adverse Event Prevention, handed to administrative staff at the Center for Medical Adverse Event Prevention or submitted on the exclusive reporting web page via the Internet (SSL communication).

The reporting address specified in III-1 herein may be used for submission of follow-up information. See “Guideline for Reporting” for specific entry procedure.

V. Publication of Collected Information and Analysis Results

1. Analysis and publication

Collected information will be analyzed by experts at the Center for Medical Adverse Event Prevention, compiled in periodic reports, and published for medical institutions, general public, and administrative organizations.

2. Proposals and requests

Proposals and requests to improve medical safety may be made to administrative organizations, industrial organizations, and individual companies as necessary based on published reports.

VI. Information Handling

1. Confidentiality to be observed by Center for Medical Adverse Event Prevention

The following information is subject to confidentiality at the Center for Medical Adverse Event Prevention.

- Information on medical institution
- Case information
- Information on reported cases known in the process of relevant investigational activities
- Other personal information of patients, families or medical professionals involved

Confidentiality does not apply to the following information.

- Information already published or within the public domain
- Case information from which information to identify the medical institution or persons involved has been deleted through designated procedures after the information had been received

2. Use of information for purposes other than those specified

Information collected in the project will not be used for purposes other than development of medical safety measures.

3. Information handling at medical institution

Unless there is a justifiable reason, a reporting medical institution may not disclose information obtained in the process of communication with the Center for Adverse Event Information such as confirmation of reported case information described in IV herein to any parties other than its staff members.

4. Necessity of patient consent for case report in the project

Registered participating medical institutions are required to obtain patient consent prior to reporting adverse events.

Prepared on January 18, 2005

Revised on May 1, 2005

Attachment 2 Outline of Project to Collect Medical Near-Miss Information

I. Project to Collect Medical Near-Miss Information

1. Objective

Objective analysis of various factors involved in medical adverse events and developing measures based on the analysis are necessary to establish effective medical safety measures.

Individual medical institutions have been developing systems to collect and analyze medical safety information on their own. It is important to effectively collect information on common factors associated with medical adverse events and corrective measures, rather than information on factors unique to individual medical institutions, in order to understand the importance and characteristics of individual factors.

The project intends to collect, analyze, and provide medical near-miss information analyzed by individual medical institutions and corrective measures developed based on such analysis for sharing of information useful to develop medical safety measures among medical institutions in general and to provide information to the general public in order to further promote medical safety measures.

2. Project summary

"Medical near-miss information" will be collected from registered participating medical institutions throughout Japan for compilation, analysis, and publication of analysis results for the general public.

II. Medical Near-Miss Information to be Collected and Collecting Method

1. Cases and information to be collected

(1) Definition of medical near-miss incidence

Information on "medical near-miss incidences" is to be collected. "Medical near-miss incidences" in this project are defined as follows.

A. Erroneous medical procedures identified before actually performed for patients
B. Erroneous medical procedures performed but did not affect patients' conditions
C. Erroneous medical procedures performed, and patients required minor procedure/treatment as a result

(2) Information to be collected

"Descriptive information" and "general coded information" will be collected.

A. Descriptive information

Regarding near-miss incidents of which information should be provided to others in general in light of promoting medical safety measures, causes and proposed corrective measures will be reported in accordance with the "descriptive information" report form.

"Descriptive information" described below will be collected.

a) Medical near-miss incidents covered by themes specified for individual collection periods
b) Medical near-miss incidents to be collected regularly regardless of periodic themes

- Cases in which patients would have died or had serious conditions if actions in question had been done or occurrence of incidents in question had been unnoticed
- Cases involving names or dosage forms of drugs; cases involving drugs, medical devices/equipment such as errors in medical device operation (information such as names (brand names) and units of drugs involved will also be collected in cases involving drugs, medical devices or other items)
- Other cases that persons responsible for safety management at medical institutions examined thoroughly and determined that reporting of such cases would be conducive to improvement of medical safety

B. General coded information

Information on any and all medical near-miss incidents (e.g. situation and details) will be collected in accordance with the report form based on the code table in order to understand patterns of occurrence. Any and all medical near-miss incidents occurring during a given collection period will be collected as general coded information.

	Descriptive information	General coded information
Code table	[Appendix 1]	[Appendix 3]
Selection of items in code table, etc. (data entry guide)	[Appendix 2]	[Appendix 4]

2. Medical institutions to be surveyed

Registered medical institutions will be surveyed in the project.

A. Descriptive information

To be collected from all registered participating medical institutions

B. General coded information

To be collected from designated medical institutions among registered participating medical institutions

	Descriptive information	General coded information
Designated medical institutions	○	○
Other registered participating medical institutions	○	Not collected

3. Application for registration

Medical institutions that wish to participate in the project should fill out "Application for Registration in Project to Collect Medical Near-Miss Information" [Appendix 5] with the necessary information and send it to the JCQHC by mail or fax.

Project to Collect Medical Near-Miss Information
Center for Medical Adverse Event Prevention
Japan Council for Quality Healthcare
7th floor, Mitsui Sumitomo Kaijo Surugadai Building Annex
3-11 Kanda-Surugadai, Chiyoda-ku, Tokyo
101-0062
Tel 03-5217-0251　Fax 03-5217-0253

4. Institution ID and confirmation code

1) Institution ID and confirmation code required for data entry and downloading the designated format (CSV) system will be issued to the head of institution after registration is completed.
2) Any change in information included in "Application for Registration in Project to Collect Medical Near-Miss Information" should be notified (see [Appendix 6]) as soon as possible.
3) When institution ID or confirmation code needs to be reissued, re-issuance should be requested (see [Appendix 6]) as soon as possible.

5. Registration cancellation

Registered medical institutions may cancel their registration by contacting the Center for Medical Adverse Event Prevention (see [Appendix 6]) and return their institution IDs and confirmation codes should their participation in the project become difficult for some reason.

6. Reporting method

(A) Online reporting and (B) reporting in designated format (CSV format) are available. Reporting method will be selected by participating institutions at the time of registration.

(A) Online reporting

Medical near-miss incidents are reported on the exclusive reporting web page at the following address via the Internet (SSL communication).

http://www.hiyari-hatto.jp/

(B) Reporting in designated format (CSV format)

Information is entered into the system downloaded from the website to create a file in the designated reporting format (CSV format). The prepared file is saved on a floppy disc and sent by mail. The program and user's manual necessary for reporting in designated format (CSV format) should be downloaded from the website: Enter the main page by typing in the institution ID and confirmation code issued after registration and go to "Reporting" page.

Address of the system download site is:

http://www.hiyari-hatto.jp/

7. Collection period and timeline

A. Reports on medical near-miss incidents may be submitted anytime in principle. However, both descriptive information and general coded information are compiled every quarter.

B. The reporting due date for each quarter is the third Monday in the second month after the end of the quarter.

8. Return of information

Information reported to the JCQHC can be returned online after the reporting due date regardless of reporting method. Registered medical institutions wishing to have submitted information back may download the information from the "Reported Case Search" page. Go to the main page by typing in the institution ID and confirmation code.

9. Confirmation of case information

Should any questions arise concerning reported cases, the JCQHC may contact relevant registered medical institutions to make inquiries.

III. Publication of Collected Information and Analysis Results

1. Analysis and publication

Collected information will be analyzed by experts at the JCQHC, compiled in periodic reports, and published for medical institutions, the general public, and administrative organizations.

2. Post-publication

Requests to improve medical safety may be made to administrative organizations, industrial organizations, and individual companies as necessary based on published reports.

VI. Information Handling

1. Confidentiality to be observed by the Center for Medical Adverse Event Prevention

The following information is subject to confidentiality at the Center for Medical Adverse Event Prevention.

- Information on medical institution
- Case information
- Information on reported cases known in the process of relevant investigational activities
- Other personal information of patients, families or medical professionals involved

Confidentiality does not apply to the following information.

- Information already published or within the public domain
- Case information from which information to identify the medical institution or persons involved has been deleted through designated procedures after the report has been submitted

2. Use of information for purposes other than those specified

Information collected in the project will not be used for purposes other than development of medical safety measures.

3. Receipt of information

Reports that are apparently not “descriptive information” to be collected or information that may identify any individuals such as patients, medical professionals or reporting persons will not be collected. Reports containing such information may be rejected.

Prepared on March 1, 2005

Appendices omitted

Attachment 3　Medical Institutions Subject to Reporting Requirement (272 institutions)

English translation omitted

Attachment 4 Medical Adverse Event Report Form (items, choices, and description field)

1. Date of event occurrence and event summary

1	**Month of occurrence** ☐ January ☐ February ☐ March ☐ April ☐ May ☐ June ☐ July ☐ August ☐ September ☐ October ☐ November ☐ December
2	**Day of occurrence** ☐ Mon. ☐ Tue. ☐ Wed. ☐ Thu. ☐ Fri. ☐ Sat. ☐ Sun.
	Weekday/holiday category ☐ Weekday ☐ Holiday
3	**Time of occurrence** ☐ 0:00 - before 2:00 ☐ 2:00 – before 4:00 ☐ 4:00 – before 6:00 ☐ 6:00 – before 8:00 ☐ 8:00 – before 10:00 ☐ 10:00 – before 12:00 ☐ 12:00 – before 14:00 ☐ 14:00 – before 16:00 ☐ 16:00 – before 18:00 ☐ 18:00 – before 20:00 ☐ 20:00 – before 22:00 ☐ 22:00 – before 24:00 ☐ Unknown
4	**Severity of event** ☐ Death ☐ Potential residual disability (likely) ☐ Potential residual disability (unlikely) ☐ Unknown
5	**Place of occurrence (multiple answers acceptable)** ☐ Outpatient examination room ☐ Outpatient treatment room ☐ Outpatient lobby ☐ Emergency room ☐ Critical care center ☐ Patient room ☐ Ward treatment room ☐ Operation room ☐ ICU ☐ CCU ☐ NICU ☐ Examination room ☐ Catheterization laboratory ☐ Radiotherapy room ☐ Radiography room ☐ Radioactive scanning room ☐ Dialysis room ☐ Delivery room ☐ Rehabilitation room ☐ Restroom ☐ Hallway ☐ Bathroom ☐ Stairway ☐ Unknown ☐ Others ( )
6	**Event summary** ☐ Ordering ☐ Drug ☐ Blood transfusion ☐ Treatment/procedure ☐ Medical equipment ☐ Drainage tube ☐ Dental equipment ☐ Examination ☐ Nursing care ☐ Others ( )
7	**Clinical department (multiple answers acceptable)** ☐ Internal medicine ☐ Anesthesiology ☐ Cardiovascular medicine ☐ Neurology ☐ Respiratory tract medicine ☐ Gastrointestinal medicine ☐ Hematology ☐ Circulatory surgery ☐ Allergy ☐ Rheumatism ☐ Pediatrics ☐ General surgery ☐ Orthopedics ☐ Plastic surgery ☐ Cosmetic surgery ☐ Neurosurgery ☐ Respiratory surgery ☐ Cardiovascular surgery ☐ Pediatric surgery ☐ Pain clinic ☐ Dermatology ☐ Urology ☐ Venereology ☐ Proctology ☐ Gynecology/Obstetrics ☐ Obstetrics ☐ Gynecology ☐ Ophthalmology ☐ Otolaryngology ☐ Psychosomatic medicine ☐ Psychiatry ☐ Rehabilitation ☐ Unknown ☐ Radiology ☐ Dentistry ☐ Orthodontics ☐ Pediatric dentistry ☐ Dental/oral surgery ☐ Others( )

2. Information concerning patient involved

8	**Number of patient(s)** ☐ 1 ☐ Multiple
	Age (specify between 0 years 0 months to 120 years 11 months) ( ) years ( ) months
	Sex ☐ Male ☐ Female

9	**Patient category 1** ☐ Inpatient ☐ Outpatient (initial visit) ☐ Outpatient (follow-up visit)
	Patient category 2 ☐ Inpatient (0 to 31 days) ☐ Inpatient (32 days or longer) ☐ General outpatient ☐ Emergency outpatient ☐ Others ( )
10	**Disorder** Disorder directly associated with event ( ) Related disorder 1 ( ) Related disorder 2 ( ) Related disorder 3 ( )
11	**Patient condition immediately before event occurrence (multiple answers acceptable)** ☐ Disturbance of consciousness ☐ Visual impairment ☐ Hearing impairment ☐ Dysarthria ☐ Mental disorder ☐ Dementia/amnesia ☐ Upper extremity disability ☐ Lower extremity disability ☐ Gait disorder ☐ Bed rest ☐ Sleeping ☐ Delirious ☐ Under drug influence ☐ Anesthetized/pre- or post-anesthesia ☐ Others ( )

3. Information concerning medical professional involved

12	**Person who identified event** ☐ Person involved himself/herself ☐ Coworker with same job title ☐ Coworker with different job title ☐ Patient himself/herself ☐ Family/care giver ☐ Other patient ☐ Others ( )
13	**Job title of person involved** ☐ Doctor ☐ Dentist ☐ Nurse ☐ Assistant nurse ☐ Pharmacist ☐ Clinical engineering technologist ☐ Midwife ☐ Nursing assistant ☐ Radiological technologist ☐ Clinical technologist ☐ Physical therapist (PT) ☐ National registered dietitian ☐ Dietitian ☐ Cook/cooking staff ☐ Speech therapist (ST) ☐ Occupational therapist (OT) ☐ Medical technologist ☐ Dental hygienist ☐ Dental technician ☐ Others ( )
	Specialist, certified physician/surgeon, other professional/technical certification
	Years of experience (specify between 0 years 0 months to 50 years 11 months) ( ) years ( ) months
	Years of working at current department (specify between 0 years 0 months to 50 years 11 months) ( ) years ( ) months
	Number of night shift works in the week immediately before event occurrence ( ) times
	Shift work system ☐ 1-shift system ☐ 2-shift system ☐ 3-shift system ☐ 4-shift system ☐ Others ( )
	Working hours in the week immediately before event occurrence **(specify between 1 to 150 hours; enter "unknown" if information is unavailable)** ( ) hours
13-2	**Person involved 2** Same as 13
13-3	**Person involved 3** Same as 13
13-4	**Person involved 4** Same as 13

13-5	**Person involved 5** Same as 13
13-6	**Person involved 6** Same as 13
13-7	**Person involved 7** Same as 13
13-8	**Person involved 8** Same as 13
13-9	**Person involved 9** Same as 13
13-10	**Person involved 10** Same as 13
14	**Job title other than that of person involved (multiple answers acceptable)** ☐ Doctor ☐ Dentist ☐ Nurse ☐ Assistant nurse ☐ Pharmacist ☐ Clinical engineering technologist ☐ Midwife ☐ Nursing assistant ☐ Radiological technologist ☐ Clinical technologist ☐ Physical therapist (PT) ☐ National registered dietitian ☐ Dietitian ☐ Cook/cooking staff ☐ Speech therapist (ST) ☐ Occupational therapist (OT) ☐ Medical technologist ☐ Dental hygienist ☐ Dental technician ☐ Others ( )

4. Information concerning situation, place, and event details

Ordering and communication process

15	**Situation** ☐ Preparation of order ☐ Order in writing ☐ Order based on ordering system ☐ Oral order (with written memo) ☐ Oral order (without written memo) ☐ Frequent change in order ☐ Ordering/communication process, others ( )
16	**Details of event** ☐ Forgot to order ☐ Delayed order ☐ Inadequate ordering ☐ Giving wrong order ☐ Receiving order, misconception ☐ Receiving order, forgot to communicate ☐ Receiving order, delayed communication ☐ Receiving order, inadequate communication ☐ Receiving order, miscommunication ☐ Others ( )

Drug

15	**Situation** **Drug preparation** ☐ Drug preparation ☐ Other ( ) **Drug prescription/administration** ☐ Subcutaneous /intramuscular ☐ Intravenous injection ☐ Arterial injection ☐ Peripheral intravenous drip ☐ Central venous injection ☐ Oral administration ☐ Topical application ☐ Suppository ☐ Inhalation ☐ Nose drop/eye drop/ear drop ☐ Other ( ) **Drug dispensing/management** ☐ Oral drug dispensing / management ☐ Injection dispensing /management ☐ Blood product management ☐ Other ( )
	Type of drug/product ☐ Blood product ☐ Narcotic ☐ Anti-tumor drug ☐ Cardiovascular drug ☐ Antidiabetic ☐ Antidiabetic ☐ Hypnotic ☐ Other ( )

16	**Details of event** **Drug prescription/administration** ☐ Wrong dose ☐ Overdose ☐ Underdose ☐ Wrong time/date of administration ☐ Dose duplication ☐ Combination of contraindicated drugs ☐ Dosing speed too fast ☐ Dosing speed too slow ☐ Patient misidentification ☐ Drug mix-up ☐ Wrong unit ☐ Wrong dosing method ☐ Skipped dose ☐ Other (　　) **Drug dispensing/management** ☐ Erroneous inspection of prescription/injection order ☐ Erroneous weighing ☐ Dispensing in wrong number ☐ Wrong packaging ☐ Dispensing wrong dosage form ☐ Dispensing in wrong unit ☐ Drug mix-up in dispensing ☐ Package insert mix-up ☐ Patient misidentification ☐ Drug/product mix-up ☐ Dispensing expired drug ☐ Other (　　) **Drug/blood product management** ☐ Mixing error ☐ Bag/bottle labeling error ☐ Breakage ☐ Dispensing ABO incompatible product ☐ Contamination with foreign matter ☐ Bacterial contamination ☐ Other (　　)
17	**Drug involved** Product name (　　) Dosage form (　　) Unit (　　) Manufacturer (importer/distributor) (　　)

Blood transfusion

15	**Situation** ☐ Pretransfusion testing ☐ Irradiation ☐ Transfusion procedure ☐ Other (　　)
16	**Details of event** **Pretransfusion testing** ☐ Not conducted ☐ Sample mix-up ☐ Cross match error ☐ Result documentation/entry error ☐ Other (　　) **Irradiation** ☐ Not performed/forgotten ☐ Overirradiation ☐ Patient misidentification ☐ Product mix-up ☐ Other (　　)

Treatment/procedure

15	**Situation** **Surgery** ☐ Craniotomy ☐ Thoracotomy ☐ Cardiotomy ☐ Laparotomy ☐ Extremities ☐ Endoscopic surgery ☐ Surgery, others ☐ Preparation for surgery ☐ Preoperative procedure ☐ Postoperative procedure ☐ Other **Anesthesia** ☐ General anesthesia (inhalation and intravenous) ☐ Local anesthesia ☐ Inhalation anesthesia ☐ Intravenous anesthesia ☐ Vertebral/epidural anesthesia ☐ Other (　　) **Delivery/artificial abortion** ☐ Vaginal delivery ☐ Caesarean section ☐ Artificial abortion ☐ Other (　　) **Other treatment** ☐ Blood purification (including hemodialysis) ☐ IVR (angiocatheter, etc.) ☐ Radiotherapy ☐ Pain clinic ☐ Rehabilitation ☐ Invasive dental treatment ☐ Noninvasive dental treatment ☐ Endoscopic treatment ☐ Other (　　) **Other general procedure** ☐ Central venous line ☐ Peripheral intravenous line ☐ Arterial line ☐ Catheter for blood purification ☐ Feeding tube (NG, ED) ☐ Urethral catheter ☐ Other (tube placement) (　　) **Other emergency treatment** ☐ Drainage ☐ Wound care ☐ Tracheal intubation ☐ Tracheotomy ☐ Cardiac compression ☐ Oxygen therapy ☐ Securing IV access ☐ Other (　　)
16	**Details of event** ☐ Patient misidentification ☐ Wrong site treatment/procedure ☐ Medical material mix-up ☐ Mix-up of examination /treatment/procedure ☐ Wrong method (technique) ☐ Not performed/ forgotten ☐ Discontinuation/ postponement ☐ Wrong date/time ☐ Wrong procedural order

	☐ Unnecessary treatment/procedure ☐ Error in disinfection /cleaning technique ☐ Wrong patient position ☐ Treatment/procedure, others ☐ Aspiration ☐ Accidental ingestion ☐ Retained foreign object ☐ Error in examination /treatment, others ( )
17	**Medical material, dental material, other items** Product name ( ) Manufacturer (importer/distributor) ( ) Date of purchase ( )

Use/management of medical equipment (device)

15	**Situation** ☐ Mechanical ventilator ☐ Oxygen therapy equipment ☐ Anesthesia apparatus ☐ Oxygenator ☐ Defibrillator ☐ IABP ☐ Pace maker ☐ Infusion / transfusion pump ☐ Blood purification device ☐ Incubator ☐ Endoscope ☐ Low-pressure continuous suction device ☐ ECG, blood pressure monitor ☐ Pulse oxymeter ☐ High-pressure oxygen therapy device ☐ Other ( )
16	**Details of event** ☐ Assembly ☐ Error in condition setting ☐ Forgot to set up/turn on power ☐ Malfunction ☐ Inappropriate use of medical device ☐ Failure ☐ Inadequate maintenance /inspection ☐ Lack of knowledge ☐ Lack of skill ☐ Alarm setup forgotten ☐ Alarm setup range ☐ Alarm turned off for convenience ☐ Faulty memory ☐ Error in pre- or post-usage inspection/management ☐ Error in disinfection /cleaning technique ☐ Breakage ☐ Other ( )
17	**Medical device** Product name ( ) Manufacturer (importer/distributor) ( ) Date of manufacture ( ) Date of purchase ( ) Date of most recent maintenance/inspection ( )

Use/management of drainage tube or other tube

15	**Situation** ☐ Central venous line ☐ Peripheral venous line ☐ Arterial line ☐ Tracheal tube ☐ Tracheal cannula ☐ Feeding tube (NG, ED) ☐ Subcutaneous continuous suction drainage tube ☐ Urethral catheter ☐ Chest drainage tube ☐ Abdominal drainage tube ☐ Ventricular/cisternal drainage tube ☐ Epidural catheter ☐ Catheter/line for blood purification ☐ T-shape stopcock ☐ Other ( )
16	**Details of event** ☐ Infusion leakage ☐ Self-removal ☐ Spontaneous dislodgment ☐ Disconnection ☐ Not connected ☐ Blockage ☐ Breakage /severance ☐ Wrong connection ☐ Error in handling T-shape stopcock ☐ Route clamp error ☐ Air bubble in tube ☐ Other ( )
17	**Medical device** Product name ( ) Manufacturer (importer/distributor) ( ) Date of purchase ( )

Use/management of dental equipment (device)

15	**Situation** ☐ Rotation grinder ☐ Equipment for root canal treatment ☐ Dental prosthesis/filler ☐ Other ( )
16	**Details of event** ☐ Assembly ☐ Error in condition setting ☐ Forgot to set up/turn on power ☐ Malfunction ☐ Inappropriate use of medical device ☐ Failure ☐ Inadequate maintenance /inspection ☐ Lack of knowledge ☐ Lack of skill ☐ Alarm setup forgotten ☐ Alarm setup range ☐ Faulty memory ☐ Error in pre- or post-usage inspection/management ☐ Error in disinfection/cleaning technique ☐ Breakage ☐ Alarm turned off for convenience ☐ Other ( )

17	**Dental equipment** Product name ( ) Manufacturer (importer/distributor) ( ) Date of manufacture ( ) Date of purchase ( ) Most recent maintenance/inspection ( )
	Dental material, other items Product name ( ) Manufacturer (importer/distributor) ( ) Date of purchase ( )

Examination

15	**Situation** **Sample collection** ☐ Blood drawing ☐ Urine collection ☐ Stool collection ☐ Sputum collection ☐ Puncture fluid ☐ Other ( ) **Biological examination** ☐ Ultrasound examination ☐ Electrocardiography ☐ Treadmill test ☐ Holter monitor ☐ Electroencephalography ☐ Electromyography ☐ Pulmonary function test ☐ Other ( ) **Diagnostic imaging** ☐ General imaging ☐ Portable radiography ☐ CT ☐ MRI ☐ Angiocatheter-aided imaging ☐ Upper gastrointestinal imaging ☐ Lower gastrointestinal imaging ☐ Other ( ) **Endoscopic examination** ☐ Upper gastrointestinal ☐ Lower gastrointestinal ☐ Bronchoscopy ☐ Other ( ) **Other examination** ☐ Otolaryngological examination ☐ Ophthalmologic examination ☐ Dental examination ☐ Other function test ☐ Sample test ☐ Blood glucose check (at ward) ☐ Pathological examination ☐ Radioactive scan ☐ Other ( )
16	**Details of event** ☐ Patient misidentification ☐ Wrong examination/evaluation technique ☐ Error in sample collection ☐ Sample misidentification ☐ Lost sample ☐ Sample breakage ☐ Sample contamination ☐ Management of reagent ☐ Management of analytical device/equipment ☐ Preparation of examination device/equipment ☐ Data mix-up ☐ Lost data ☐ Calculation, data entry, memorization ☐ Result reporting ☐ Examination, others ( )
17	**Medical/dental device** Product name ( ) Manufacturer (importer/distributor) ( ) Date of manufacture ( ) Date of purchase ( ) Most recent maintenance/inspection ( )
	Medical/dental material, other items Product name ( ) Manufacturer (importer/distributor) ( ) Date of purchase ( )

Nursing care

15	**Situation** Nursing care involving patient assistance; meal/nutrition/recuperation involving patient's own act **Nursing care** ☐ Endotracheal /oral suctioning ☐ Changing position ☐ Bed bath ☐ Help with changing clothes ☐ Help with eating ☐ Help with bathing ☐ Help with elimination ☐ Stoma care ☐ Help with moving ☐ Transportation ☐ Temperature management ☐ Tending patient's belongings ☐ Meal serving ☐ Patient observation ☐ Other ( ) **Meal/nutrition** ☐ Oral intake ☐ Tube feeding ☐ Other ( ) **Recuperation** ☐ While taking a walk ☐ While moving from one place to another ☐ While going out/sleeping out ☐ While eating ☐ While bathing ☐ While changing clothes ☐ While excreting ☐ While sleeping ☐ Other ( )

16 Details of event

Nursing care/recuperation

☐ Fall ☐ Fall from bed ☐ Collision ☐ Restraint ☐ Severe decubitus (involving muscle layer, Stage III/IV)
☐ Aspiration ☐ Accidental ingestion ☐ Meal serving error ☐ Neglected order for bed rest ☐ Fasting order not followed
☐ Other ( )

Transportation

☐ Patient misidentification ☐ Delay ☐ Forgotten ☐ Wrong destination ☐ Going out/staying out without notice
☐ Other ( )

Self-medication

☐ Oral medication /injection forgotten ☐ Wrong dose ☐ Drug mix-up ☐ Other ( )

Meal/nutrition

☐ Wrong contents ☐ Wrong amount ☐ Forgotten meal suspension ☐ Forgotten meal postponement ☐ Contamination with foreign matter
☐ Other ( )

17 Medical/dental material, other items

Product name ( )
Manufacturer (importer/distributor) ( )
Date of purchase ( )

5. Information concerning event

18 Purpose of medical procedure performed

19 Cases conducive to prevention of recurrence (warning case)

☐ Death of low-risk mother/fetus/newborn
☐ Death or disability of patient due to hypoglycemia developed at institution
☐ Death or disability due to vascular (venous) embolism occurred during medical procedure (not including neurosurgical procedure)
☐ Malignant tumor associated with gene therapy
☐ Accident associated with use of contaminated drug/material/biological material
☐ Unknown infection associated with organ transplant
☐ Death or disability due to nosocomial infection to which none of the choices herein applies
☐ Suicide or suicide attempt of inpatient
☐ Escape of inpatient
☐ Accident associated with medical procedure performed by unskilled person without appropriate supervision
☐ Burn occurred in inpatient
☐ Electric shock occurred in inpatient
☐ Death or disability of patient due to fire at institution
☐ Handing over an infant to wrong parent
☐ Patient kidnap
☐ Sexual assault on patient at institution (within compound)
☐ Death or disability of patient due to violence at institution (within compound)
☐ Other ( )

20 Details of event

6. Necessary information concerning event

21 Situation

☐ Neglect to check ☐ Neglect to observe ☐ Misjudgment ☐ Lack of knowledge ☐ Technical inexperience/unskilled
☐ Delayed reporting ☐ Under unusual physical condition ☐ Under unusual psychological condition
☐ System failure ☐ Inadequate coordination ☐ Inadequate documentation ☐ Similarity in patient's appearance or name
☐ Busy working condition ☐ Problem in environment ☐ Problem in drug ☐ Problem in medical device ☐ Problem in other items
☐ Problem in facility ☐ Problem in education/training ☐ Lack of explanation ☐ Other ( )

22 Background/cause of event

23 Establishment of accident investigation committee

☐ Internal investigation committee established ☐ External investigation committee established ☐ Internal investigation committee to be established ☐ External investigation committee to be established
☐ Investigated by existing medical safety committee ☐ To be determined ☐ Other ( )

24 Corrective measures

25 Description of details of event

Attachment 5　Designated Medical Institutions for Project to Collect Medical Near-Miss Information

English translation omitted

Attachment 6 Medical Near-Miss Report Form (items, setting method, choices, and description field)

Information concerning time of occurrence

A	**Month of occurrence** ☐ January ☐ February ☐ March ☐ April ☐ May ☐ June ☐ July ☐ August ☐ September ☐ October ☐ November ☐ December ☐Month unknown
B	**Day of occurrence** ☐ Mon. ☐ Tue. ☐ Wed. ☐ Thu. ☐ Fri. ☐ Sat. ☐ Sun.
	Weekday/holiday category ☐ Weekday ☐ Holiday (including public holidays) ☐ Unknown
C	**Time of occurrence** ☐ 0:00 - before 2:00 ☐ 2:00 – before 4:00 ☐ 4:00 – before 6:00 ☐ 6:00 – before 8:00 ☐ 8:00 – before 10:00 ☐ 10:00 – before 12:00 ☐ 12:00 – before 14:00 ☐ 14:00 – before 16:00 ☐ 16:00 – before 18:00 ☐ 18:00 – before 20:00 ☐ 20:00 – before 22:00 ☐ 22:00 – before 24:00 ☐ Unknown
D	**Place of occurrence** ☐ Outpatient examination room ☐ Outpatient lobby ☐ Outpatient facility, others ( ) ☐ Emergency room ☐ Nurse station ☐ Patient room ☐ Treatment room ☐ Bathroom ☐ Ward facility, others ( ) ☐ Operation room ☐ Delivery room ☐ ICU ☐ CCU ☐ NICU ☐ ICU, others ( ) ☐ Examination room ☐ Rehabilitation room ☐ IVR room ☐ Radiography examination room ☐ Radioactive scanning room ☐ Radiotherapy room ☐ Dialysis room ☐ Pharmacy/blood transfusion unit ☐ Nutritional management room /kitchen ☐ Restroom ☐ Hallway ☐ Stairway ☐ Unknown ☐ Other place (within institution) ( ) ☐ Other place (outside institution) ( )

Patient information

E	**Sex** ☐ Male ☐ Female ☐ Multiple patients involved ☐ Unknown
F	**Age** ☐ 0 to 19 ☐ 20 to 39 ☐ 40 to 59 ☐ 60 to 79 ☐ 80 to 150 ☐ Multiple patients involved ☐ Unknown
G	**Physical/psychological condition (multiple answers acceptable)** ☐ Disturbance of consciousness ☐ Visual impairment ☐ Hearing impairment ☐ Dysarthria ☐ Mental disorder ☐ Dementia/ amnesia ☐ Upper extremity disability ☐ Lower extremity disability ☐ Gait disorder ☐ Bed rest ☐ Sleeping ☐ Delirious ☐ Delirious ☐ Under drug influence ☐ Anesthetized/pre- or post-anesthesia ☐ No disability ☐ Unknown ☐ Other ( )
H	**Person who identified incident** ☐ Person involved himself/herself ☐ Coworker with same job title ☐ Coworker with other job title ☐ Patient himself/herself ☐ Family/care giver ☐ Other patient ☐ Unknown ☐ Other ( )
I	**Job title of person involved (multiple answers acceptable)** ☐ Doctor ☐ Dentist ☐ Midwife ☐ Nurse ☐ Assistant nurse ☐ Nursing assistant ☐ Pharmacist ☐ National registered dietitian ☐ Dietitian ☐ Cook/cooking staff ☐ Radiological technologist ☐ Clinical technologist ☐ Medical technologist ☐ Physical therapist (PT) ☐ Occupational therapist (OT) ☐ Speech therapist (ST) ☐ Dental hygienist ☐ Dental technician ☐ Orthoptist ☐ Psychiatric social worker ☐ Clinical psychologist ☐ Certified social worker ☐ Certified care worker ☐ Clinical engineering technologist ☐ Children's supervisor/child minder ☐ Administrative staff ☐ Unknown ☐ Other ( )
J	**Years of experience of person involved (specify between 0 years 0 months to 50 years 11 months; specify if multiple persons were involved or years of experience is unknown)** ( ) years ( ) months

K	**Years of working at current department (specify between 0 years 0 months to 50 years 11 months; specify if multiple persons were involved or years of working is unknown)** ( ) years ( ) months

Information concerning situation and details of incident

Ordering/communication process

L	**Situation** **Ordering** ☐ Ordering **Communication process** ☐ Receiving written order ☐ Receiving oral order ☐ Receiving order in other form ☐ Written briefing ☐ Oral briefing ☐ Briefing in other form ☐ Other ( )
M	**Details** **Ordering/communication process** ☐ Forgot to order/receive order/communicate ☐ Delayed order/communication ☐ Inadequate ordering/communication ☐ Giving wrong order/miscommunication ☐ Other ( )

Drug prescription/administration

L	**Situation** **Drug preparation** ☐ Drug preparation **Drug prescription/administration** ☐ Subcutaneous /intramuscular ☐ Intravenous injection ☐ Arterial injection ☐ Peripheral intravenous drip ☐ Central venous injection ☐ Oral administration ☐ Topical application ☐ Suppository ☐ Inhalation ☐ Nose drop/eye drop/ear drop ☐ Other ( ) **Type of drug/product** ☐ Blood product ☐ Narcotic ☐ Anti-tumor drug ☐ Cardiovascular drug ☐ Antidiabetic ☐ Anxiolytic ☐ Hypnotic ☐ Other ( )
M	**Details of incident** **Drug prescription/administration** ☐ Wrong dose ☐ Overdose ☐ Underdose ☐ Wrong time/date of administration ☐ Dose duplication ☐ Combination of contraindicated drugs ☐ Dosing speed too fast ☐ Dosing speed too slow ☐ Dosing speed, other errors ( ) ☐ Patient misidentification ☐ Drug mix-up ☐ Wrong unit ☐ Wrong dosing method ☐ Skipped dose ☐ Other error ( )

Drug dispensing/management

L	**Situation** **Drug dispensing/management** ☐ Oral drug dispensing/management ☐ Injection dispensing/management ☐ Blood product management ☐ Other ( )

M	**Details of incident**

Drug dispensing/management

☐ Erroneous inspection of prescription/injection order		☐ Erroneous weighing	☐ Dispensing in wrong number	☐ Wrong packaging
☐ Dispensing wrong dosage form	☐ Dispensing in wrong unit	☐ Drug mix-up	☐ Drug dispensing/management, others ( )	
☐ Package insert mix-up	☐ Patient misidentification	☐ Drug/product mix-up		☐ Dispensing expired drug
☐ Dispensing ABO incompatible product		☐ Other ( )		
☐ Other error in dispensing drug/blood product				

Drug/blood product management

☐ Contamination with foreign matter	☐ Bacterial contamination	☐ Breakage	☐ Mixing error
☐ Other ( )	☐ Bag/bottle labeling error		☐ Drug bag mix-up

Others

☐ Lost drug ☐ Other errors ( )

Blood transfusion

L	**Situation**

Blood transfusion

☐ Pretransfusion test ☐ Irradiation ☐ Transfusion procedure ☐ Other ( )

M	**Details of incident**

Pretransfusion test

☐ Not conducted	☐ Sample mix-up	☐ Cross match error	☐ Result documentation/entry error
☐ Other ( )			

Irradiation of blood product

☐ Not performed/forgotten ☐ Overirradiation

Transfusion procedure

☐ Patient misidentification ☐ Product mix-up ☐ Other ( )

Examination, surgery, anesthesia, delivery, and other treatment/procedure

L	**Situation**

Surgery

☐ Craniotomy	☐ Thoracotomy	☐ Cardiotomy	☐ Laparotomy	☐ Extremities	☐ Endoscopic surgery
☐ Other surgery ( )		☐ Preparation for surgery	☐ Preoperative procedure	☐ Postoperative procedure	
☐ Other surgery-related situation ( )					

Anesthesia

☐ Local anesthesia	☐ Vertebral/epidural anesthesia	☐ Inhalation anesthesia	☐ Intravenous anesthesia	☐ Inhalation and intravenous anesthesia
☐ Other ( )				

Delivery/artificial abortion

☐ Vaginal delivery ☐ Caesarean section ☐ Medical induced abortion ☐ Other ( )

Other treatment

☐ Blood purification ☐ IVR ☐ Radiotherapy ☐ Pain clinic

M	**Details of incident**

Examination, surgery, anesthesia, delivery, and other treatment/procedure

☐ Patient misidentification	☐ Wrong site treatment/procedure	☐ Medical material mix-up	☐ Other ( )	
☐ Wrong method (technique)	☐ Neglected/forgotten treatment/procedure	☐ Discontinuation /postponement	☐ Wrong time/date	☐ Wrong procedural order
☐ Unnecessary treatment/procedure	☐ Error in disinfection/cleaning technique	☐ Wrong patient position	☐ Accidental ingestion	☐ Aspiration

	☐ Other errors

Use/management of medical equipment (device)

L	**Situation** **Use/management of medical equipment (device)** ☐ Mechanical ventilator ☐ Oxygen therapy device ☐ Anesthesia apparatus ☐ Oxygenator ☐ Defibrillator ☐ IABP ☐ Pace maker ☐ Infusion/transfusion pump ☐ Blood purification device ☐ Incubator ☐ Endoscope ☐ Low-pressure continuous suction device ☐ ECG, blood pressure monitor ☐ Pulse oxymeter ☐ Other ( )
M	**Details of incident** **Medical/dental equipment (device) operational error** ☐ Assembly ☐ Condition setup error ☐ Forgot to set up/turn on power ☐ Other operational error ( ) **Use/management of medical equipment (device)** ☐ Inappropriate use of medical/dental equipment (device) ☐ Medical/dental equipment (device) malfunction ☐ Failure of medical/dental equipment (device) ☐ Medical/dental equipment (device) repairing error ☐ Breakage of medical/dental equipment (device) ☐ Medical/dental equipment (device) inspection/management error ☐ Other error in use/management of medical/dental equipment (device) ( )

Use/management of drainage tube or other tube

L	**Situation** **Use/management of drainage tube or other tube** ☐ Central venous line ☐ Peripheral arterial line ☐ Arterial line ☐ Tracheal tube ☐ Tracheal cannula ☐ Feeding tube (NG, ED) ☐ Urethral catheter ☐ Chest drainage tube ☐ Abdominal drainage tube ☐ Ventricular/cisternal drainage tube ☐ Subcutaneous continuous suction drainage tube ☐ Epidural catheter ☐ Catheter/line for blood purification ☐ T-shape stopcock ☐ Other ( )
M	**Details of incident** **Use/management of drainage tube or other tube** ☐ Infusion leakage ☐ Self-removal ☐ Spontaneous dislodgment ☐ Disconnection ☐ Not connected ☐ Blockage ☐ Breakage /severance ☐ Wrong connection ☐ Error in handling T-shape stopcock ☐ Route clamp error ☐ Air bubble in tube ☐ Other ( )

Use/management of dental equipment (device) and material

L	**Situation** **Use/management of dental equipment (device) and material** ☐ Rotation grinder ☐ Equipment for root canal treatment ☐ Dental prosthesis/filler ☐ Other ( )
M	**Details of incident** **Medical/dental equipment (device) operational error** ☐ Assembly ☐ Condition setup error ☐ Forgot to set up/turn on power ☐ Other operational error ( ) **Use/management of medical equipment (device) and material** ☐ Inappropriate use of medical/dental equipment (device) ☐ Medical/dental equipment (device) malfunction ☐ Failure of medical/dental equipment (device) ☐ Medical/dental equipment (device) repairing error ☐ Breakage of medical/dental equipment (device) ☐ Medical/dental equipment (device) inspection/management error ☐ Other error in use/management of medical/dental equipment (device) ( )

Examination

L

Situation

Sample collection

☐ Blood drawing ☐ Urine collection ☐ Stool collection ☐ Sputum collection ☐ Puncture fluid ☐ Other ( )

Biological examination

☐ Ultrasound examination ☐ Electrocardiography ☐ Treadmill test ☐ Master ECG ☐ Electroencephalography
☐ Electromyography ☐ Pulmonary function test ☐ Other ( )

Diagnostic imaging

☐ General imaging ☐ Portable radiography ☐ CT ☐ MRI ☐ Angiocatheter-aided imaging
☐ Upper gastrointestinal imaging ☐ Lower gastrointestinal imaging ☐ Other ( )

Endoscopic examination

☐ Upper gastrointestinal ☐ Lower gastrointestinal ☐ Bronchoscopy ☐ Other ( )

Function test

☐ Otolaryngological examination ☐ Ophthalmologic examination ☐ Dental examination ☐ Other function test ( )
☐ Sample test ☐ Blood glucose check (at ward)

Examination

☐ Pathological examination ☐ Radioactive scan ☐ Other ( )

M

Details of incident

Examination

☐ Patient misidentification ☐ Wrong examination /evaluation technique ☐ Error in sample collection ☐ Sample misidentification ☐ Lost sample
☐ Sample breakage ☐ Sample contamination ☐ Other sample handling/management ( )
☐ Management of reagent ☐ Management of analytical device /equipment ☐ Preparation of examination device/equipment ☐ Data mix-up
☐ Lost data ☐ Other error in data management ☐ Calculation, data entry, memorization
☐ Result reporting ☐ Other examination error

Nursing care/recuperation

L

Situation

Nursing care

☐ Endotracheal/oral suctioning ☐ Changing position ☐ Bed bath ☐ Help with changing clothes ☐ Help with eating ☐ Help with bathing
☐ Help with eliminating

Nursing care/recuperation

☐ Stoma care ☐ Help with moving ☐ Transportation ☐ Temperature management ☐ Tending patient's belongings ☐ Meal serving
☐ Patient observation ☐ Other ( )

Recuperation, others

☐ While taking a walk ☐ While going out/sleeping out ☐ While changing clothes ☐ While moving from one place to other ☐ Other ( )

M

Details of incident

Nursing care/recuperation

☐ Fall ☐ Fall from bed ☐ Collision ☐ Aspiration ☐ Accidental ingestion ☐ Meal serving error
☐ Neglected order for bed rest ☐ Fasting order not followed ☐ Other ( )

Transportation

☐ Patient misidentification ☐ Delay ☐ Forgotten ☐ Wrong destination ☐ Other transportation error ( )

Self-medication

☐ Oral medication/injection forgotten ☐ Wrong dose ☐ Drug mix-up ☐ Other

☐ Going out/staying out without notice	☐ Other error in nursing care/recuperation ( )

Meal/nutrition

L	**Situation** **Meal/nutrition** ☐ Oral intake ☐ Tube feeding ☐ Other ( )
M	**Details of incident** **Meal/nutrition** ☐ Wrong contents ☐ Wrong amount ☐ Forgotten meal suspension ☐ Forgotten meal postponement ☐ Contamination with foreign matter ☐ Other error related to meal/nutrition ( )

Transportation of items

L	**Situation** **Transportation of items** ☐ Transportation of items
M	**Details of incident** **Transportation of items** ☐ Delay ☐ Forgotten ☐ Wrong destination ☐ Other error ( )

Radiation control

L	**Situation** **Radiation control** ☐ Radiation control
M	**Detail of incident** **Radiation control** ☐ Lost radioactive material ☐ Radiation leakage ☐ Other error ( )

Medical record and information management

L	**Situation** **Medical record and information management** ☐ (Medical record and information management) Doctor's or dentist's record ☐ Nursing record ☐ Other medical record ( ) ☐ Image data management ☐ Test data management ☐ Examination data management ☐ Examination/procedure/drug administration order form ☐ Other ( )
M	**Details of incident** **Medical record and information management** ☐ Documentation forgotten ☐ Misdocumentation ☐ Management error ☐ Other error ( )

Explanation to patient/family

L	**Situation** **Explanation to patient/family** ☐ Details of incident
M	**Details of incident** **Explanation to patient/family** ☐ Inadequate explanation ☐ Wrong explanation ☐ Other error ( )

Facility

L	**Situation** **Facility** ☐ Facility
M	**Details of incident** **Facility** ☐ Breakage of facility structure ☐ Facility management error ☐ Other ( )

Others

L	**Situation** **Others** ☐ Other
M	**Details of incident** **Others** ☐ Other

Information concerning cause of near-miss incident

(Multiple answers accepted except for questions concerning medical equipment (device), instrument, medical material, drug or other items)

Person involved

N	**Cause** **Check** ☐ Inadequate checking ☐ Other ( ) **Observation** ☐ Inadequate observation ☐ Other ( ) **Judgment** ☐ Misjudgment ☐ Other ( ) **Knowledge** ☐ Lack of knowledge ☐ Incorrect knowledge ☐ Other ( ) **Technique (skill)** ☐ Insufficient technique (skill) ☐ Wrong technique (skill) ☐ Other ( ) **Reporting** ☐ Forgot ☐ Inadequate ☐ Wrong report ☐ Inappropriate ☐ Other ( ) **Physical condition** ☐ Lack of sleep ☐ Feeling sick ☐ Took a drug that causes drowsiness ☐ Other ( ) **Psychological condition** ☐ Rushed ☐ Irritated ☐ Nervous ☐ Preoccupied with something else ☐ Acted based on false assumption ☐ Acted unwittingly ☐ Other ( )

Environment that affected person involved

N

Cause

System

☐ Inadequate communication/reporting system ☐ Inadequate ordering system ☐ Inadequate computer system
☐ Inadequate operation manual ☐ Other ( )

Coordination

☐ Insufficient coordination between doctor and nurse ☐ Insufficient coordination between doctor and technical staff ☐ Insufficient coordination between doctor and administrative staff ☐ Insufficient coordination between doctors
☐ Insufficient coordination between nurses ☐ Insufficient coordination among technical staff ☐ Insufficient coordination among staff with different responsibilities
☐ Insufficient coordination between dentist and dental staff ☐ Other ( )

Record documentation

☐ Illegible writing ☐ Letters were too small and difficult to read ☐ Inconsistent documentation form
☐ Difficult to understand documentation method ☐ Omission ☐ Other ( )

Similarity in patient's appearance (face, age) or name

☐ Similarity in patient's appearance (face, age) or name

Working condition

☐ Busy ☐ Inadequate personnel management ☐ Interrupted procedure ☐ On duty ☐ After duty ☐ Worked on night shift
☐ After working on night shift ☐ Other ( )

Environment

☐ At the time of natural disaster ☐ At the time of an emergency ☐ Computer system was down ☐ Dim lighting
☐ Wet floor ☐ Other ( )

Medical/dental equipment (device), drug, facility

N

Cause

Medical/dental equipment (device), instrument, medical material (multiple answers acceptable)

☐ Defective ☐ Failure ☐ Multiple specifications ☐ Difficult to handle
☐ Unfavorable placement ☐ Short in number ☐ Insufficient management ☐ Device malfunction
☐ Other ( )

Drug (multiple answers acceptable)

☐ Similar drug containers ☐ Similar colors or forms ☐ Similar drug names
☐ Multiple dosage forms ☐ Unfavorable placement ☐ Unfavorable management ☐ Problem in drug characteristic ☐ Similar therapeutic properties
☐ Similar drug abbreviations ☐ Other ( )

Other items (multiple answers acceptable)

☐ Defective ☐ Failure ☐ Multiple specifications ☐ Difficult to handle
☐ Unfavorable placement ☐ Short in number ☐ Insufficient management ☐ Other ( )

Facility

☐ (Insufficient maintenance) electric system ☐ Air conditioner ☐ Sanitary installation ☐ Communication facility
☐ Elevator machine ☐ Other problem in maintenance ( )
☐ Problem in facility structure ☐ Problem in facility other than facility structure ( )

Education/training

N

Cause

Education/training

☐ Insufficient education/training ☐ Inadequate manual ☐ Inadequate program ☐ Other ( )

Explanation/response

N

Cause

Explanation to patient/family

☐ Insufficient explanation ☐ Wrong explanation ☐ Insufficient understanding of patient/family
☐ Other ( )

Others

☐ Other ( )

Wrong procedure performed/not performed and effect of near-miss incident

O

Wrong procedure performed/not performed and effect of near-miss incident

Wrong procedure detected before performed

☐ Effect on patient would have been minimum (no treatment necessary) if it had been performed
☐ Effect on patient would have been moderate (treatment necessary) if it had been performed
☐ Effect on patient would have been significant (life-threatening) if it had been performed

Other incident

☐ Procedure performed but patient not affected
☐ Unknown
☐ Other

Remarks

P

Remarks

Provide description (up to xx words) if code selection and description provided in “Others” section are insufficient for reporting.

Attachment 7　Medical Adverse Event Prevention Center Committee Members

English translation omitted

Attachment 8 Medical Adverse Event Prevention Center Comprehensive Evaluation Panel Members

English translation omitted

Attachment 9　Registered Medical Institution Basic Information Survey Form

I. Patient Form

Provide the number of patients treated between September 1 and 30, 2005 (*provide the number as of October 1 as month-end number)

Category	Total number of inpatients	*Month-end number of inpatients	Number of new inpatients	Number of patients transferred from other wards within institution	Number of discharged patients	Number of patients transferred to other wards within institution	*Month-end number of beds
Total							
Psychiatric ward							
Infection ward							
Tuberculosis ward							
Long-term care ward							
General ward							
Other ward							
Convalescent ward (relisted)							
Total number of outpatients							

II. Employee Form

Provide number of employees as of October 1, 2005.

Job title		Number of employees	Job title	Number of employees	Job title	Number of employees
Doctor	Full-time		Nursing assistant		Judo-orthopedist	
	Part-time (full-time equivalent)		Physical therapist		National registered dietitian	
Dentist	Full-time		Occupational therapist		Dietitian	
	Part-time (full-time equivalent)		Orthoptist		Psychiatric social worker	
Pharmacist	Actual number		Speech therapist		Certified social worker	
	(Full-time equivalent)		Prosthetist		Certified care worker	
Public health nurse	Actual number		Dental hygienist		Other technical worker	
	(Full-time equivalent)		Dental technician		Medical social worker	
Midwife	Actual number		Radiological technologist		Administrative staff	
	(Full-time equivalent)		Radiologist		Other staff	
Nurse	Actual number		Clinical technologist		Remarks	
	(Full-time equivalent)		Medical technologist			
Assistant nurse	Actual number		Clinical engineering technologist			
	(Full-time equivalent)		Traditional massage/massage/finger pressure, acupuncture, moxacautery practitioner			

III. Institutional Function Form

Provide the number of procedures performed between September 1 and 30, 2005 (provide the number of devices and information management status as of October 1).

Anesthesia and surgery	Number of procedures performed in September (a series of procedures is counted as one procedure)
General anesthesia	
Craniotomy	
Surgery under pump-oxygenator	
Cancer operation	
Gastrointestinal cancer operation (relisted)	
Lung cancer operation (relisted)	
Breast cancer operation (relisted)	
Uterine cancer operation (relisted)	
Hepatic, biliary or pancreatic cancer operation (relisted)	
Prosthetic joint replacement	
Open reduction of fracture	
Pacemaker implant	
Laparoscopic operation	
Thoracoscopic operation	
Gastrointestinal endoscopic surgery	
Percutaneous transluminal coronary angioplasty	
Percutaneous arterial embolization	
Intraocular lens implant	
Retinal photocoagulation*	
Extracorporeal shock wave lithotripsy*	
(Number of lithomyls)	
IABP	
(Number of IABPs)	
Hyperthermia	
Radiation therapy (external radiation)*	
(Number of radiotherapy units)	
Gamma knife/stereotactic multi-orbital irradiation (relisted)	
Radiation therapy (small sealed source)*	
Hemodialysis	
(Number of hemodialyzers)	
Delivery (including normal delivery)	
Caesarean section (relisted)	

* Including those specified in the facility criteria for designated comprehensive perinatal intensive care unit

Examinations, etc.	Number of examinations conducted in September	Number of devices
Upper gastrointestinal endoscopy		
Bronchoendoscopy		
Colorectal endoscopy		
Angioseriography		
X-ray CT scan		
CT-guided biopsy		
MRI		
RI (scintigram)		
Single photoemission CT (SPECT)		
Positron CT		
Bone mineral analysis		
DSA	1. Conducted	2. Not conducted
Computed radiography	1. Conducted	2. Not conducted
Digital fluorography	1. Conducted	2. Not conducted

Medical record and information management	
Use of ordering system	
1. Examination	3. Appointment
2. Prescription	4. Not used
Use of ICD code	
1. ICD-10	4. ICD-0
2. ICD-9	5. Not used
3. ICD-9-CM	
Hospital website	
1. Available	
2. Not available	

Note: Excerpt from Medical Facility Static Surveillance