Project to Collect Medical Near-miss/ Adverse Event Information 2018 Annual Report

公益財団法人　日本医療機能評価機構
Japan Council for Quality Health Care

Division of Adverse Event Prevention

The current status of the project can be browsed at:
Website: http://www.med-safe.jp/
English page: http://www.med-safe.jp/contents/english/index.html

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*This Annual Report has been prepared as part of the Project to Collect Medical Near-miss/Adverse Event Information (project subsidized by the Ministry of Health, Labour and Welfare), based on information about medical adverse events gathered by the project and informed by the opinions of members of the Comprehensive Evaluation Panel, for the purpose of preventing the occurrence and recurrence of medical adverse events. Please refer to the project website for details about the purpose of the project. http://www.med-safe.jp/

*While the JQ takes all possible steps to ensure that the information carried in this report is accurate at the time of compilation, it does not guarantee that the content will remain accurate in the future.

*In preparing this information, the JQ intends neither to restrict the discretion of medical professionals, nor to impose any obligations or responsibilities on them.

Greeting

Hirobumi Kawakita
President
Japan Council for Quality Health Care

The Japan Council for Quality Health Care runs Hospital Accreditation and a variety of other projects aimed at providing third-party accreditation of medical institutions and supporting the provision of high-quality medical services by medical institutions, in order to improve the quality of medical care and ensure that the public have confidence in it. Today, with health care expected to be more advanced and diverse, we are aware that providing the public with accurate information concerning medical care, and promoting high-quality medical care are increasingly important tasks. We believe that the JQ has a major role to play in Japan, given this situation.

In FY2004, the Division of Adverse Event Prevention began implementing the Project to Collect Medical Near-miss/Adverse Event Information, which gathers information about medical adverse events and medical near-miss events, with the objective of promoting safety in medical care. The information gathered concerning medical adverse events is compiled into quarterly reports, in which the total figures for the events and an analysis thereof are also published. These regular quarterly reports and annual reports are made available to a wide range of individuals and organizations in society, including medical professionals, the public, and government bodies. In addition, Medical Safety Information is sent out by fax to medical institutions about once a month. As of December 2018, we have issued 145 Medical Safety Information bulletins. I would like to express my deepest gratitude to the medical institutions and other parties that cooperate with our project by reporting medical near-miss and adverse event information.

We are now publishing the 2018 Annual Report, which is based on the content of previously published quarterly reports. This report carries a large volume of information that can help to promote medical safety, including annual totals for medical near-miss and adverse event information, overviews of on-site visits, overviews of analysis themes and recurrent and similar event analyses, and an overview of workshops held. Accordingly, we hope that this Annual Report will be of use to those working in clinical practice, as well as helping the public to gain a deeper understanding of Japan's medical safety initiatives as they stand at present.

Having already received considerable feedback, including media coverage and inquiries about medical adverse event figures and the details thereof, we are keenly aware that public concern about the promotion of medical safety and the prevention of medical adverse events is high. We will strive to further enhance the content of our quarterly reports, annual reports, and Medical Safety Information, so that we continue to provide everyone with useful information.

In addition, we at the JQ intend to do our utmost to improve the quality of medical care and ensure that the public has confidence in it through such projects as Hospital Accreditation, thereby raising the standard of Japanese medical care. We would therefore be most grateful for your continued understanding and cooperation.

Foreword

Shin Ushiro
Director
Japan Council for Quality Health Care

Misa Sakaguchi
General Manager
Department of Adverse Event Prevention
Japan Council for Quality Health Care

We would like to express our deepest gratitude to everyone for your continued understanding and cooperation in regard to the running of this project.

This project provides various information based on medical near-miss/adverse event information reported by medical institutions. We are hereby pleased to publish our 2018 Annual Report, which summarizes the medical near-miss/adverse event information reported between January and December 2018. As well as providing the collated results for the year and an outline of the themes highlighted in the quarterly reports, this Annual Report offers details of on-site visits. We hope that staff at medical institutions, especially those in charge of medical safety management, will review this report thoroughly and share the parts which are most useful and relevant to the circumstances of their particular medical institution. The JQ also hopes that by reading this Annual Report, the general public—as recipients of medical care—will gain an understanding of the current state of medical adverse events and medical near-misses, as well as efforts by medical institutions and the medical community to prevent their recurrence.

A total of 1,502 medical institutions were participating in this project as of the end of 2018. By participating in this project and reporting events that can help to prevent medical adverse events or ensure that they do not recur, medical institutions provide us with information crucial to promoting medical safety nationwide, which we can share widely with medical institutions throughout Japan. While the number of voluntarily participating medical institutions has gradually increased, we would be grateful to secure the participation of even more medical institutions.

This project received 4,565 reports of medical adverse event information in 2018. As we continue to receive around the same number of reports as the previous year, if not more, we believe that the practice of reporting such events is becoming firmly established. We would like to express our heartfelt gratitude to all those who, while working in busy clinical environments at medical institutions, take the time to send their reports to us. The number of reports from voluntarily participating medical institutions remains lower than the number from medical institutions subject to reporting requirements. However, we know that the medical institutions that participate in this project assiduously strive to ensure medical safety in their routine practice. The focus of medical adverse event information reporting under this project is not dictated by whether or not the event was due to incorrect medical care or management, or even the extent of the impact, but also encompasses events that can help to prevent medical adverse events at medical institutions or ensure that they do not recur. Accordingly, we would greatly appreciate your cooperation in the appropriate reporting of events that fall within this scope.

Quarterly and annual reports and Medical Safety Information bulletins can be downloaded from the project website, which also has a function enabling users to search for events. Statistics that do not appear in this Annual Report can also be found on the website. We hope that you will read this Annual Report and the website, and use the information provided by this project to promote medical safety.

This project will continue to strive to provide useful information to prevent medical adverse events and ensure that they do not recur and would therefore greatly appreciate your understanding and cooperation in this endeavor.

I

2018 Annual Report

I 2018 Annual Report

1. Number of Registered Medical Institutions and Current Reporting Status

A total of 1,502 medical institutions were participating in this project as of the end of 2018. Diagrams providing a breakdown of the number of registered medical institutions can be found in "II-1 Status of Participation in the Project to Collect Medical Near-miss/Adverse Event Information," including the number of medical institutions reporting medical adverse event information and the number reporting medical near-miss events. These diagrams show basic data concerning the status of participation in this project and this information is updated on the website as required. It can be accessed via the "List of Registered Medical Institutions" link on the website.

A total of 4,565 reports of medical adverse event information were submitted between January and December 2018, the period covered by this Annual Report. Medical institutions subject to reporting requirements reported 4,030 of these, while voluntarily participating medical institutions reported 535. Fig. I-1 shows the number of reported events between 2005 and 2018. As the project continues to receive around the same number of reports as the previous year, if not more, we believe that the practice of reporting medical adverse events is becoming firmly established.

Fig. I-1 Number of Reports of Medical Adverse Event Information and Number of Medical Institutions

Year		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Number of Reports	Mandatory	1,114	1,296	1,266	1,440	1,895	2,182	2,483	2,535	2,708	2,911	3,374	3,428	3,598	4,030
	Voluntary	151	155	179	123	169	521	316	347	341	283	280	454	497	535
	Total	1,265	1,451	1,445	1,563	2,064	2,703	2,799	2,882	3,049	3,194	3,654	3,882	4,095	4,565
Number of Medical Institutions	Mandatory	272	273	273	272	273	272	273	273	274	275	275	276	276	274
	Voluntary	283	300	285	272	427	578	609	653	691	718	743	755	773	797
	Total	555	573	558	544	700	850	882	926	965	993	1,018	1,031	1,049	1,071

For reference, Fig. I-2 shows the scope of events reported as medical adverse event information. As can be seen from (3), the scope encompasses events that can help to prevent medical adverse events at medical institutions or ensure that they do not recur, irrespective of whether or not the event was due to incorrect medical care or management, or the degree of effect on the patient.

Fig. I-2 Scope of Events Reported as Medical Adverse Event Information

(1) Apparent errors 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.

(2) Unapparent errors 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).

(3) Other than those described in (1) and (2), information conducive to the prevention of medical adverse events and their recurrence at medical institutions.

In addition to the tables shown in the chapter "II Aggregate Reports" in this Annual Report, we recommend that you also refer to the website, which carries tables not published in the Annual Report, such as "Professional Experience of the Person Involved," "Clinical Department Involved," "Location of the Occurrence," and "Nature of Event × Severity of Event." Clicking on the "Statistics Menu (Web Data)" button on the project website brings up a list of quarterly and annual tables, which users can browse and download.

2. Collection of Follow-Up Information Concerning Medical Adverse Events: Overview of On-site Visits

Where we deem it necessary to obtain more detailed facts concerning reported events from the medical institutions concerned, we make written inquiries and, if cooperation is forthcoming, undertake on-site visits. In 2018, we made 158 written inquiries to medical institutions and received 117 responses. We asked six medical institutions for permission to carry out on-site visits regarding 11 events and carried out visits with the cooperation of five medical institutions regarding nine events. In particular, we believe that the on-site visits provide useful information for the promotion of medical safety, as it is possible to engage in more in-depth discussion of the details of the reported event by inquiring about the content of deliberations conducted within the institution after the report and to acquire information that it was not possible to glean at the time of the report. Section "III-2 Collection of Follow-Up Information via On-site Visits" in this Annual Report provides an overview of on-site visits. Fig. I-3 provides details of on-site visits carried out in 2018.

Fig. I-3 List of On-site Visits

Visit	The type of event	Summary of event
1	Drugs	Event in which Limas tab. was prescribed when issuing an internal prescription for the current medication Vemas combination tab.
2		Event in which the prescription for antiplatelet drugs was missed out when switching from medicines brought in at hospitalization to an internal prescription
3		Event in which an examination was halted because the rule that patients taking Takelda Combination Tablets must take a drug holiday before a bronchoscopy was not observed
4		Event in which an overdose occurred because of a misreading of the single dose and daily dosage of Oxycodone SR Capsules
5		Event in which all the Midazolam to be brought into the examination room was administered in the patient's room
6	Treatment/procedure	Event in which Mikulicz gauze was left in the body during surgery because it was not counted
7	Medical device, etc.	Event in which air entered the blood vessel because an infusion pump was used without setting the planned quantity and the bubble alarm failed
8	Drainage tubes or other tubes	Event in which pneumothorax occurred because suction pressure was applied without having put distilled water into the water seal chamber of the chest drainage bag
9	Others	Events in which an enteral nutrient containing dairy products was administered to a patient with a milk allergy

*The type of event is based on the item selected by the medical institution in its report.

3. Analysis of Events

1) Themes Analyzed

As shown in Fig. I-4, this project analyzes two types of theme: (1) themes selected for comprehensive analysis of both medical adverse event information and medical near-miss event information relevant to the theme collected over a six-month period; and (2) themes selected from medical adverse event information reported during the period under analysis in the quarterly report, which are then used in analyzing past events. In 2018, the themes selected for the first category were "Events Related to Intensive Care Unit Computer Systems," "Events Related to Drugs Administered to Pediatric Patients," and "Events Related to Medical Devices Used at Another Institution or at Home and Brought in at Admission"; details of relevant medical near-miss event information were collected and the results of analysis were published in the 53rd–56th Quarterly Reports. In the second category, eight themes were highlighted. Similar events in the past were highlighted and the analysis published along with the summary of each event, background and causal factors, and improvement measures reported by the medical institution concerned. Information such as the package inserts for the drugs or medical devices involved was also provided, as appropriate.

An overview of each theme is provided in "III-3 Themes Analyzed" in this Annual Report. Each quarterly report provides information about the number of reported events, details of the events, an analysis of the background and causal factors, and a summary of improvement measures taken to prevent recurrence, so please refer to the 53rd to 56th Quarterly Reports for details. We hope that you will make use of the project website, which enables users to peruse and download information by theme analyzed.

Fig. I-4 Themes Analyzed

Themes Analyzed	Quarterly Report No.
【1】 Themes selected for comprehensive analysis of both medical adverse event information and medical near-miss event information relevant to the theme collected over a six-month period	
[1] Events Related to Intensive Care Unit Computer Systems (2)	53rd
[2] Events Related to Drugs Administered to Pediatric Patients (1)	54th
[3] Events Related to Drugs Administered to Pediatric Patients (2)	55th
[4] Events Related to Medical Devices Used at Another Institution or at Home and Brought in at Admission (1)	56th
【2】 Themes selected from medical adverse event information reported during the period under analysis in the quarterly report and used in analyzing past events	
[1] Events Related to the Grinding of Drugs	53rd
[2] Events Related to Drug Holidays for Biguanide Oral Hypoglycemic Agents When Using Iodinated Contrast Media	
[3] Events Related to Damaged Guide Wires	54th
[4] Events Related to Injuries from a Wheelchair Footrest	
[5] Events Related to the Management of Drugs Prepared within the Institution	55th
[6] Events Related to Wrong-Site Procedures Due to Mix-ups between Left and Right During Examinations, Treatment and Other Procedures	
[7] Events Related to the Erroneous Administration of G-CSF Preparations	56th
[8] Events Related to Patient Mix-up When Using Electronic Medical Records	

2) Analysis of Recurrent and Similar Events

Some similar events continue to be reported even after information about medical adverse events has been provided in Quarterly Reports and Medical Safety Information, so repeated warnings are required. Accordingly, starting with the 18th Quarterly Report, we added a section entitled "Recurrence of Events and Occurrence of Similar Events" and, since the 50th Quarterly Report, have continued to analyze these events in the section "Analysis of Recurrent and Similar Events." This analysis highlights a number of themes that were the subject of reports after we had provided information about events of a similar nature and looks at trends in the reported number of recurrent or similar events after the provision of information, as well as providing details of the summary of event and specific improvement measures reported by the medical institutions concerned. Fig. I-5 shows the recurrent and similar events most commonly reported in 2018 in relation to themes previously highlighted in Quarterly Reports.

Fig. I-5 Most Commonly Reported Recurrent and Similar Events Previously Highlighted as Themes in Quarterly Reports

Summary	Number of Events
Events Involving Failure to Communicate the Content of the Diagnostic Imaging Report	63
Events Related to Burns (Excluding Burns Sustained During Nursing Care)	33
Event Involving Gauze Left Within the Body	32
Events Involving Administration of Allergic Drug to Patient with Previous Known Allergy History	22
Events Involving Suicide or Attempted Suicide in Hospital	16
Events Related to Wrongly Inserted Gastric Tube	16
Events Related to the Transfer of a Patient from One Bed to Another	14
Events Related to Pathology Specimens	13
Events Related to Drugs Subject to a Drug Holiday Before an Invasive Procedure	13
Events Related Wrong-site Treatment in Dental Consultations	11

Fig I-6 shows themes highlighted in the "Analysis of Recurrent and Similar Events" section of quarterly reports. An overview of each theme is provided in "III-4 Analysis of Recurrent and Similar Events" in this Annual Report. Each Quarterly Report sets out the number of events reported after information was provided, a summary of the events, details of the background and causal factors, and a summary of improvement measures taken, so please refer to the 53rd to 56th Quarterly Reports for details. We hope that you will make use of the project website, where users can peruse and download the Analysis of Recurrent and Similar Events for each theme.

Fig. I-6 List of Analysis of Recurrent and Similar Events

Title	Quarterly Report No.
Accidental Removal of a Drain/Tube during Transfer (Medical Safety Information No.85)	53rd
Delays in Urgent Contact Regarding Panic Values (Medical Safety Information No.111)	
Wrong Weight When Prescribing an Antineoplastic Agent (Medical Safety Information No.104)	54th
Event Involving Gauze Left Within the Body (14th Quarterly Report)	
Forgetting to Check the Pathologic Diagnosis Report (Medical Safety Information No.71)	55th
Misinterpretation of a Verbal Order (Medical Safety Information No.102)	
Wrong Quantity Prescribed When Switching from Medicines Brought in at Hospitalization to Internal Prescriptions (Medical Safety Information No.78)	56th
Events Related to the Transfer of a Patient from One Bed to Another (13th Quarterly Report) —Events in Which the Patient Fell during Transfer—	

4. Medical Safety Information

Since December 2006, the project has provided Medical Safety Information to promote the prevention of the occurrence/recurrence of medical adverse events through the provision of information that ought to be made common knowledge. Medical Safety Information is designed to be user-friendly for medical professionals in busy clinical environments. Specifically, the volume of information is narrowed down to keep the length to around two pages of A4, with illustrations and tables provided for maximum visual impact. Medical Safety Information is sent out once a month by fax to registered medical institutions participating in the Project to Collect, Analyze, and Provide Medical Adverse Event Information and the Project to Collect, Analyze, and Provide Medical Near-Miss Information, and is also published on the project website. In addition, to share this information with a wider audience, we also send it by fax free of charge to non-participating hospitals that ask to receive it. Medical Safety Information is faxed on the day of publication, enabling medical institutions to receive, circulate, and act on the information without delay.
In 2018, we compiled and published Medical Safety Information No. 134–145 (Fig. I-7). Fig. I-8 shows the recurrent and similar events most commonly reported in 2018 in relation to matters previously highlighted in Medical Safety Information No.1 to No.145.

Fig. I-7 Medical Safety Information released in 2018

Month of information supply	No.	Title
January	No.134	Erroneous Administration of Disinfectant in the Sterilized Area
February	No.135	Failure to Release Standby Mode When Resuming Ventilation (1st Follow-up Report)
March	No.136	Medical Safety Information released in 2017
April	No.137	Burns When Using a Heat Pack
May	No.138	Inadequate Checks Concerning Diagnostic Imaging Reports (1st Follow-up Report)
June	No.139	Medical Safety Information released from 2014 to 2016
July	No.140	Administration of an Antineoplastic Agent in Excess of the Total Dosage Limit
August	No.141	Falls from an Examination Table
September	No.142	Urethral Damage Caused by an Indwelling Bladder Catheter (1st Follow-up Report)
October	No.143	Error When Refilling a Prescription Due to Failure to Revise Prescription Details
November	No.144	Failure to Submit a Pathology Specimen
December	No.145	Administration of the Usual Dosage of Drugs for Patients with Impaired Renal Function

Fig. I-8 Most Commonly Reported Recurrent and Similar Events Previously the Subject of Medical Safety Information

No.	Title	Number of Events
No. 63 No.138	Inadequate Checks Concerning Diagnostic Imaging Reports Inadequate Checks Concerning Diagnostic Imaging Reports (1st Follow-up Report)	39
No. 71	Forgetting to Check the Pathologic Diagnosis Report	11
No. 7	Extravascular leakage in pediatric patients	10
No. 58	Rupture of the subcutaneous port and catheter	9
No. 59	Burns Due to Incorrect Handling of an Electrosurgical Pencil	9
No. 80 No.142	Urethral Damage Caused by an Indwelling Bladder Catheter Urethral Damage Caused by an Indwelling Bladder Catheter (1st Follow-up Report)	9
No.132	Patient Falls While Using the Overbed Table for Support	9
No. 39	Insufficient confirmation of medicines brought in at hospitalization	8
No. 47	Mix-up of the tooth extraction site	7
No. 54	Accidental removal of the endotracheal/tracheostomy tube when changing positions	7
No. 85	Accidental Removal of a Drain/Tube during Transfer	6

5. Current Status of the Project

The chapter “V Current Status of the Project” provides various information, including details of the project website overhaul that we carried out in March 2018, the number of times the website was accessed, and information about the publication of English-language editions of the Annual Report and Medical Safety Information. It also outlines academic conference presentations concerning this project and our dissemination of information overseas.

II

Aggregate Reports

II Aggregate Reports

1. Status of Participation in the Project to Collect Medical Near-miss/Adverse Event Information

The Project to Collect Medical Near-miss/Adverse Event Information consists of two projects, the Project to Collect, Analyze, and Provide Medical Adverse Event Information and the Project to Collect, Analyze, and Provide Medical Near-miss Event Information.

The medical institutions participating in each project as of December 31, 2018 are shown below.

Fig. II-1-1 Registration Status of Medical Institutions Participating in Each Project

Registration status			Project to Collect, Analyze, and Provide Medical Near-miss Event Information						Total	
			Participating				Not participating			
			Number of occurrences and medical near-miss event information		Only number of occurrences					
Project to Collect, Analyze, and Provide Medical Adverse Event Information	Required	Participating	123	489	83	313	68	269	274	1,071
	Voluntary	Participating	366		230		201		797	
		Not participating	165		266				431	
Total			654		579		269		1,502	
			1,233							

The current reporting status for each project is shown in 2. Project to Collect, Analyze, and Provide Medical Adverse Event Information and 3. Project to Collect, Analyze, and Provide Medical Near-miss Event Information.

2. Project to Collect, Analyze, and Provide Medical Adverse Event Information

The Project to Collect, Analyze, and Provide Medical Adverse Event Information gathers medical adverse event information from medical institutions subject to reporting requirements and also from voluntarily participating medical institutions that ask to participate in this project.

[1] Registered Medical Institutions

The number of medical institutions subject to reporting requirement and voluntarily participating medical institutions participating in the Project to Collect, Analyze, and Provide Medical Adverse Event Information as of December 31, 2018 is shown below. Reasons for the fluctuation in the number of medical institution include opening/closure and consolidation of hospitals as well as change of classification of the parent organization.

Fig. II-2-1 Number of Medical Institutions Subject to Reporting Requirement and Voluntarily Participating Medical Institutions

Parent organization		Medical institutions subject to reporting requirement(Note 1)	Voluntarily participating medical institutions(Note 2)
Government	National University Corporation, etc.	46	1
	National Hospital Organization	141	0
	National Research and Development Agencies	8	0
	National Hansen's Disease Sanatorium	13	0
	Japan Organization of Occupational Health and Safety	0	31
	Japan Community Health care Organization	0	41
	Other national organizations	0	0
Municipality	Prefecture	2	21
	City/village	0	86
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	9	2
	Local independent administrative institutions	1	24
Parent organization of public medical institution other than municipality	Japan Red Cross	0	55
	Saiseikai Imperial Gift Foundation	0	21
	Hokkaido Social Welfare Association	0	2
	National Welfare Federation of Agricultural Cooperatives	0	18
	National Health Insurance Association Federation	0	1
	Health Insurance Union and their associations	0	2
	Mutual Aid Associations and their associations	0	10
	National Health Insurance Society	0	0
Corporation	School juridical organization	53	14
	Healthcare corporation	0	332
	Charitable organization	1	49
	Company	0	11
	Other corporation	0	29
Individual practitioner		0	47
Total		274	797

(Note 1) As of the end of December 2018, details of the medical institutions subject to reporting requirement (274 institutions) are as follows:
A. National Research and Development Agencies and National Hansen's Disease Sanatorium 21 institutions
B. National Hospital Organizations 141 institutions
C. University hospitals governed by the School Education Act (not including branch hospitals) 108 institutions
D. Special Functioning Hospitals (including those categorized as A, B or C above) 85 institutions
(Note 2) Voluntarily participating medical institutions are those participating in the project other than medical institutions subject to reporting requirement.

[2] Number of Reports

(1) Number of Monthly Reports

The number of monthly reports made by medical institutions subject to reporting requirement and voluntarily participating medical institutions between January 1 and December 31, 2018 is shown below. There were 4,565 reports in 2018.

Fig. II-2-2 Number of Monthly Reports Made by Medical Institutions Subject to Reporting Requirement and Voluntarily Participating Medical Institutions

	2018												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of reports made by medical institutions subject to reporting requirement	366	229	368	248	316	383	371	386	336	355	364	308	4,030
Number of reports made by voluntarily participating medical institutions	59	15	51	83	39	32	81	32	37	48	22	36	535
Number of medical institutions subject to reporting requirement	276	276	276	276	276	276	274	274	274	274	274	274	-
Number of voluntarily participating medical institutions	772	776	778	781	784	783	784	787	788	790	793	797	-

(2) Medical Adverse Event Reporting Status

A. Reporting status of medical institutions subject to reporting requirement

Among 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, 2018 are shown in Fig. II-2-3, tabulated numbers of reports made since the launch of the project by the parent organization are shown in Fig. II-2-4, those by the number of beds are shown in Fig. II-2-5, and those by region are shown in Fig. II-2-6. In addition, tabulated numbers of reporting medical institutions in the same period by number of reports are shown in Fig. II-2-7. Figures for the number of medical institutions subject to reporting requirements may not correspond to those shown in other tables, due to changes during the collection period, such as the accreditation of medical institutions as Special Functioning Hospitals or the abolition of medical institutions. As of December 31, 2018, the number of medical institutions subject to reporting requirement was 274, and the total number of beds at those institutions was 140,188.

Fig. II-2-3 Number of Reporting Medical Institutions Subject to Reporting Requirement and Reports Made by the Parent Organization

Parent organization		Number of medical institutions (As of December 31, 2018)	Number of reporting medical institutions	Number of reports
			January to December, 2018	January to December, 2018
Government	National University Corporation, etc.	46	45	1,211
	National Hospital Organization	141	127	1,352
	National Research and Development Agencies	8	8	144
	National Hansen's Disease Sanatorium	13	10	54
Municipality	Prefecture	12	11	311
	City/village			
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities			
	Local independent administrative institutions			
Corporation	School juridical organization	53	33	933
	Charitable organization	1	1	25
Total		274	235	4,030

Fig. II-2-4 Number of Reports Made by Medical Institutions Subject to Reporting Requirement (Accumulated Total)

Parent organization		Number of reports
		October 2004 to December 2018
Government	National University Corporation, etc.	8,316
	National Hospital Organization	14,177
	National Research and Development Agencies	1,316
	National Hansen's Disease Sanatorium	397
Municipality	Prefecture	2,431
	City/village	
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	
	Local independent administrative institutions	
Corporation	School juridical organization	7,757
	Charitable organization	89
Total		34,483

Fig. II-2-5 Number of Reporting Medical Institutions Subject to Reporting Requirement and Reports Made by Number of Beds

Number of beds	Number of medical institutions (As of December 31, 2018)	Number of reporting medical institutions	Number of reports
		January to December, 2018	January to December, 2018
0-19 beds	0	0	0
20-49 beds	14	3	8
50-99 beds	5	2	3
100-149 beds	8	5	14
150-199 beds	7	5	39
200-249 beds	15	13	74
250-299 beds	15	13	112
300-349 beds	27	26	260
350-399 beds	18	13	123
400-449 beds	28	25	239
450-499 beds	18	15	264
500-549 beds	12	11	90
550-599 beds	8	8	126
600-649 beds	26	24	578
650-699 beds	6	6	179
700-749 beds	11	11	303
750-799 beds	4	4	46
800-849 beds	11	11	393
850-899 beds	5	5	153
900-999 beds	13	13	321
1000 beds or more	23	22	705
Total	274	235	4,030

Fig. II-2-6 Number of Reporting Medical Institutions Subject to Reporting Requirement and Number of Reports by Region

Region	Number of medical institutions (As of December 31, 2018)	Number of reporting medical institutions	Number of reports
		January to December, 2018	January to December, 2018
Hokkaido	10	9	62
Tohoku	25	21	226
Kanto/Koshinetsu	85	70	1,320
Tokai/Hokuriku	37	32	568
Kinki	36	32	413
Chugoku/Shikoku	35	33	732
Kyushu/Okinawa	46	38	709
Total	274	235	4,030

Fig. II-2-7 Number of Medical Institutions Subject to Reporting Requirement by Number of Reports

Number of reports	Number of reporting medical institutions
	As of December 31, 2018
0	40
1	19
2	11
3	12
4	11
5	10
6	16
7	13
8	14
9	5
10	9
11-20	56
21-30	23
31-40	11
41-50	14
51-100	5
101-150	2
151-200	3
200 or above	0
Total	274

B. Reporting status of voluntarily participating medical institutions

The number of voluntarily participating medical institutions as of December 31, 2018 and reports made by those institutions between January 1 and December 31, 2018 are shown in Fig. II-2-8 and tabulated number of reports made since the launch of the project by parent organization is shown in Fig. II-2-9.

Fig. II-2-8 Number of Reporting Voluntarily Participating Medical Institutions and Number of Reports

Parent organization	Number of medical institutions (As of December 31, 2018)	Number of reporting medical institutions	Number of reports
		January to December, 2018	January to December, 2018
Government	73	14	52
Municipality	133	26	164
Public medical institution	109	19	78
Corporation	435	57	240
Individual practitioner	47	1	1
Total	797	117	535

Fig. II-2-9 Number of Reports Made by Voluntarily Participating Medical Institutions (Accumulated Total)

Parent organization	Number of reports
	October 2004 to December 2018
Government	261
Municipality	1,124
Public medical institution	933
Corporation	2,041
Individual practitioner	8
Total	4,367

[3] Details of Reports Made by Registered Medical Institutions

This Annual Report carries some of the results compiled on the basis of medical adverse event information reports from registered medical institutions (medical institutions subject to reporting requirement and voluntarily participating medical institutions) between January 1 and December 31, 2018. Each table is compiled on the basis of the options available in the Medical Adverse Event Information Report Input Items.

Fig. II-2-10 Job Title of the Person Involved

Job title of the person involved	Number of event
Doctor	2,767
Dentist	54
Nurse	2,738
Assistant nurse	19
Pharmacist	50
Clinical engineer	29
Midwife	15
Nursing assistant	20
Radiological technologist	52
Clinical technologist	22
Registered dietitian	1
Dietitian	0
Cook/kitchen staff	0
Physical therapist (PT)	35
Occupational therapist (OT)	9
Speech -language –hearing therapist (ST)	1
Medical technologist	0
Dental hygienist	2
Dental technologist	0
Others	48
Total	5,862

* The 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.

Fig. II-2-11 Summary of Event

Summary of event	Number of event	%
Drug	418	9.2
Blood transfusion	7	0.2
Treatment/procedure	1,283	28.1
Medical device, etc.	142	3.1
Drainage tube or other tube	360	7.9
Examination	266	5.8
Nursing care	1,553	34.0
Others	536	11.7
Total	4,565	100.0

* Regarding percentages, the totals may not become 100.0 due to rounding to the first decimal place.

Fig. II-2-12 Severity of Event

Severity of event	Number of event	%
Death	356	7.8
High potential of residual disability	500	11.0
Low potential of residual disability	1,235	27.1
No potential of residual disability	1,179	25.8
No disability	1,151	25.2
Unknown	144	3.2
Total	4,565	100.0

* Severity of event is not necessarily associated with occurrence of event or negligence.
* "Unknown" includes indefinite outcome at the time of reporting (within 2 weeks).
* Regarding percentages, the totals may not become 100.0 due to rounding to the first decimal place.

Fig. II-2-13 Events Encouraged to Be Reported

Events encouraged to be reported	Number of event	%
Accident due to use of contaminated drug/material/ biologic product	7	0.2
Death or disability due to nosocomial infection	1	0
Suicide or suicide attempt of patient	66	1.4
Disappearance of inpatient	7	0.2
Burn of patient	49	1.1
Electric shock of patient	0	0
Death or disability of patient due to facility fire	0	0
Handling over of infant to wrong parent	1	0
No applicable option	4,434	97.1
Total	4,565	100.0

* Regarding percentages, the totals may not become 100.0 due to rounding to the first decimal place.

Fig. II-2-14 Clinical Department

Clinical department	Number of event	%
Internal medicine	369	6.6
Anesthesiology	168	3.0
Cardiovascular medicine	319	5.7
Neurology	139	2.5
Respiratory medicine	284	5.0
Gastrointestinal medicine	356	6.3
Hematology	84	1.5
Circulatory surgery	32	0.6
Allergy	9	0.2
Rheumatism	21	0.4
Pediatrics	284	5.0
General surgery	469	8.3
Orthopedics	665	11.8
Plastic surgery	42	0.7
Cosmetic surgery	0	0
Neurosurgery	272	4.8
Respiratory surgery	101	1.8
Cardiovascular surgery	198	3.5
Pediatric surgery	36	0.6
Pain clinic	2	0
Dermatology	60	1.1
Urology	192	3.4
Venereology	0	0
Proctology	3	0.1
Gynecology/Obstetrics	102	1.8
Obstetrics	18	0.3
Gynecology	59	1.0
Ophthalmology	55	1.0
Otolaryngology	141	2.5
Psychosomatic medicine	4	0.1
Psychiatry	268	4.8
Rehabilitation	52	0.9
Radiology	129	2.3
Dentistry	16	0.3
Orthodontics	2	0
Pediatric dentistry	1	0
Dental/oral surgery	50	0.9
Unknown	7	0.1
Others	622	11.0
Total	5,631	100.0

* "Clinical department" may be more than one.
* Regarding percentages, the totals may not become 100.0 due to rounding to the first decimal place.

3. Project to Collect, Analyze, and Provide Medical Near-Miss Event Information

The information collected in the Project to Collect, Analyze, and Provide Medical Near-Miss Event Information consists of the information on the number of occurrences and medical near-miss event information. The number of occurrences about them is collected by all medical institutions that wish to participate in the Project to Collect, Analyze, and Provide Medical Near-Miss Event Information. This Annual Report provides collated results for the number of medical near-miss events occurring and reported.

[1] Participating Medical Institutions

The number of medical institutions participating in the Project to Collect, Analyze, and Provide Medical Near-Miss Event Information as of December 31, 2018 is shown below.

Fig. II-3-1 Number of Participating Medical Institutions in the Project to Collect, Analyze, and Provide Medical Near-Miss Event Information

Parent organization		Participating medical institutions	Participating medical institutions for medical near-miss event information reporting
Government	National University Corporation etc.	29	18
	National Hospital Organization	117	68
	National Research and Development Agencies	5	3
	National Hansen's Disease Sanatorium	12	4
	Japan Organization of Occupational Health and Safety	31	26
	Japan Community Health care Organization	45	23
	Other national organizations	0	0
Municipality	Prefecture	27	15
	City/village	135	74
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	9	5
	Local independent administrative institutions	25	11
Parent organization of public medical institution other than municipality	Japan Red Cross	81	47
	Saiseikai Imperial Gift Foundation	21	11
	Hokkaido Social Welfare Association	1	1
	National Welfare Federation of Agricultural Cooperatives	21	8
	National Health Insurance Association Federation	2	0
	Health Insurance Union and their associations	1	0
	Mutual Aid Associations and their associations	21	12
	National Health Insurance Society	1	1
Corporation	School juridical organization	49	34
	Healthcare corporation	437	208
	Charitable organization	52	23
	Company	10	3
	Other corporation	44	21
Individual practitioner		57	38
Total		1,233	654

[2] Information on the Number of Occurrences

The reports of the information on the number of occurrences between January 1 and December 31, 2018 are shown below.

Fig. II-3-2 Information on the Number of Occurrences

Items	Erroneous medical procedures				Total
	Not performed			Performed	
	Effects (if actions in question had been done)				
	Patients would have died or had serious conditions	Patients would have required intensive procedure/treatment	Patients would have required minor procedure/treatment or would not have required any procedure/treatment		
(1) Drug	1,071	8,879	86,731	195,735	292,416
(2) Blood transfusion	90	244	1,669	3,275	5,278
(3) Treatment/procedure	355	2,197	13,538	38,308	54,398
(4) Medical device, etc.	264	1,113	10,338	18,469	30,184
(5) Drainage tube or other tube	292	2,283	26,882	105,554	135,011
(6) Examination	360	2,322	27,965	53,870	84,517
(7) Nursing care	505	4,144	56,751	142,533	203,933
(8) Others	605	4,155	52,190	58,453	115,403
Total	3,542	25,337	276,064	616,197	921,140
Re-posted					
[1] Events involving name or dosage form of drug	139	683	6,600	12,521	19,943
[2] Events caused by drug	617	5,120	29,413	77,557	112,707
[3] Events caused by medical device, etc.	207	640	4,501	18,752	24,100
[4] Current theme	64	302	1,531	5,155	7,052

Number of reporting medical institutions	611
Total number of beds	234,170

[3] Number of Medical Near-miss Event Information

(1) Status of Monthly Reports for Medical Near-miss Event Information

The number of monthly reports for medical near-miss event information between January 1 and December 31, 2018 is shown below.

Fig. II-3-3 Number of Monthly Reports for Medical Near-miss Event Information

	2018												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of medical near-miss event information	4,778	1,133	2,511	4,533	1,069	1,347	4,727	1,751	1,176	4,511	1,851	1,686	31,073
Number of participating medical institutions for medical near-miss event information reporting	648	649	649	652	653	652	652	653	652	652	653	654	-

(2) Summary of Event

Fig. II-3-4 Summary of Event

Summary of event	Number of event	%
Drug	11,770	37.9
Blood transfusion	152	0.5
Treatment/procedure	1,375	4.4
Medical device, etc.	958	3.1
Drainage tube or other tube	4,479	14.4
Examination	2,545	8.2
Nursing care	5,689	18.3
Others	4,105	13.2
Total	31,073	100.0

* Regarding percentages, the totals may not become 100.0 due to rounding to the first decimal place.

III

Current Analysis of Medical Near-miss/Adverse Event Information

III Current Analysis of Medical Near-miss/Adverse Event Information

Both medical adverse event information and medical near-miss event information have been collected in the project launched in 2004. Since 2005, medical adverse event information and medical near-miss event information covered by individual themes have been comprehensively analyzed.

1. Project Overview

[1] Information to be Analyzed

Events with information related to predetermined themes were selected from among the medical adverse event information and medical near-miss event information reported during the period under analysis in each quarterly report and then analyzed.

In addition, if additional analysis was deemed necessary, past events outside the period under analysis in the quarterly report were selected and analyzed in the same way, after first determining the period to be examined.

[2] Analysis System

At meetings held once a month or so, Expert Analysis Groups consisting of medical professionals involved in medical safety and experts in safety management review the main medical adverse event information reported through this project and consider the content of themes for analysis.

Theme-specific Expert Analysis Groups are established to conduct analysis, based on the field of expertise involved in the events. This department then compiles these analyses and, after review by the Comprehensive Evaluation Panel, publishes information about them.

[3] Workshop

The 10th Workshop on Process Flows and the Project to Collect Medical Near-miss/Adverse Event Information was held for medical institutions participating in this project, to inform them about the current status of the project and enhance the quality of reports.

(1) Overview of the Workshop

1) Workshop date: Sunday December 16, 2018
2) Workshop venue: Lecture Hall, JQ
3) Target participants: Staff from medical institutions, based on the following conditions i) – iv)

i) Multidisciplinary teams of 3 people.

ii) Teams must include someone who plays a part in medical safety at the medical institution, such as the person in charge of the Medical Safety Management Division, the Medical Safety Manager, or members of the Medical Safety Committee or Medical Safety Officers.

iii) At least 1 person with experience of using some kind of technique for analyzing medical adverse events at the medical institution should be included.

iv) As the workshop will involve preparing a process flow covering the process from prescribing an injection drug to an inpatient to dispensing, preparing, and administering that drug, participation by medical staff involved in those duties and by staff involved in preparing in-house procedure manuals is preferable.

4) Program

i) Lecture: 1) The Significance of Process Flows
2) Medical Safety and Process Flows
3) Drawing up Process Flows

ii) Practice: Drawing up Process Flows, Examining Problems and Revising Processes at Your Own Facility

(2) Participation Status

Number of participants: 45 people (15 medical institutions)

2. Collection of Follow-Up Information on Medical Adverse Events

When an Expert Analysis Group determines that more detailed information from the medical institution is required for analysis, it makes written inquiries to the reporting medical institution or, if the institution agrees to cooperate, conducts an on-site visit. The details of additional information provided are utilized in considering medical safety measures.

[1] Collection of Follow-Up Information in Writing

In 2018, 158 written inquiries concerning medical adverse events were made to medical institutions and 117 responses were received. Figure III-2-1 shows a breakdown of the events concerning which follow-up information was requested.

Fig. III-2-1 Breakdown of Written Requests for Follow-up Information

Overview of the event	Number of events
Drugs	49
Blood transfusions	1
Treatment/procedure	31
Medical device, etc.	11
Drainage tubes or other tubes	7
Examination	11
Nursing care	20
Others	28
Total	158

[2] Collection of Follow-Up Information via On-site Visits

After we made requests to six medical institutions that had reported medical adverse event information, five medical institutions granted their cooperation regarding nine events. A list of on-site visits conducted in 2018 is provided in Fig. III-2-2, while overviews of these visits are provided in Fig. III-2-3.

Fig. III-2-2 List of On-site Visits

Visit	The type of event	Summary of event
1	**Drugs**	Event in which Limas tab. was prescribed when issuing an internal prescription for the current medication Vemas combination tab.
2		Event in which the prescription for antiplatelet drugs was missed out when switching from medicines brought in at hospitalization to an internal prescription
3		Event in which an examination was halted because the rule that patients taking Takelda Combination Tablets must take a drug holiday before a bronchoscopy was not observed
4		Event in which an overdose occurred because of a misreading of the single dose and daily dosage of Oxycodone SR Capsules
5		Event in which all the Midazolam to be brought into the examination room was administered in the patient's room
6	**Treatment/ procedure**	Event in which Mikulicz gauze was left in the body during surgery because it was not counted
7	**Medical device, etc.**	Event in which air entered the blood vessel because an infusion pump was used without setting the planned quantity and the bubble alarm failed
8	**Drainage tubes or other tubes**	Event in which pneumothorax occurred because suction pressure was applied without having put distilled water into the water seal chamber of the chest drainage bag
9	**Others**	Events in which an enteral nutrient containing dairy products was administered to a patient with a milk allergy

*The type of event is based on the item selected by the medical institution in its report.

Fig. III-2-3 Overview of On-site Visits

Visit 5 **Event in which all the Midazolam to be brought into the examination room was administered in the patient's room**

Event as reported

Summary of event	Background and causal factors	Improvement measures
The patient was a man in his 70s who had been admitted for a bronchoscopy. When a bronchoscopy was to be performed, the physician usually issued an injection order for Midazolam (10 mg) 1A and 20 mL of normal saline as a set. The nurse would bring the two items to the examination room without mixing them when the patient was called for the examination and the physician would decide on the dosage before the examination began, taking into account such factors as the patient's respiratory condition, and would then administer the drug. When issuing an injection order for Midazolam, the physician was supposed to enter the comment "Bring to the bronchoscopy room," but forgot to do so. The primary nurse had no previous experience of preparing for a bronchoscopy at this hospital. In the morning, the primary nurse confirmed on the electronic medical record that there was an injection order for Midazolam and normal saline at 13:00 and thought that it was a premedication for the examination. At around 14:50, the patient was called for the bronchoscopy, so the primary nurse administered the whole of the Midazolam 1A + normal saline 20 mL in accordance with the injection order. The administration of the Midazolam caused the patient to suffer respiratory depression and spontaneous respiration stopped for a time. The nurse made an emergency call and the patient was ventilated using a bag valve mask after assistance arrived. Once spontaneous respiration was beginning to return, flumazenil was administered to the patient and his respiratory condition and level of consciousness quickly improved.	As the injection order did not have a comment about bringing the drug to the examination room, the nurse assumed that the order to inject Midazolam and normal saline meant that they should be administered on the ward. The nurse understood that the drug had sedative effects, but lacked knowledge about the concentration and rate of administration at which respiratory depression would occur. The nurse was hurrying because they did not want to be late taking the patient to the examination room once he had been called. The nurse did not tell anyone else that they were making preparations for a bronchoscopy for the first time. Nobody else knew this either. The physician forgot to enter the comment when issuing the injection order, but failed to notice this fact until this event occurred.	• When performing an examination or procedure for the first time, nurses will consult or check with their partner nurse or the lead nurse while carrying out the task in question. • Nurses will check with the physician if they feel anxious or doubtful about an injection order. • Nurses will reconfirm the level to which they are permitted to administer intravenous injections. • When issuing injection orders, physicians will check every time that they have not omitted anything. • Medical staff will work closely together as a matter of course, to ensure that nurses can readily check even trivial matters with physicians.

Details of the On-site Visit

Attendees from the Medical Institution

Deputy Hospital Director (in charge of medical safety); Medical Safety Management Division: pharmacist, nurse GRM, nurse; physician from the department of respiratory medicine (RM); physician from the department of respiratory surgery; 2 ward head nurses; clinical engineer; clerical staff

Findings

1. Lead-up to the event

- The patient was under the care of the department of respiratory medicine.
- The department of respiratory medicine mainly uses Ward Y, but also has 7 beds on Ward X.
- Ward X is a mixed ward containing patients from such departments as the department of respiratory medicine, the department of cardiovascular surgery, and the department of respiratory surgery.
- Patient was admitted to Ward X and was the only patient on Ward X that day who was to undergo a bronchoscopy.

2. Background and causal factors

○ Bronchoscopy
- The department of respiratory medicine has about one patient for bronchoscopy a week on Ward X.
- The department of respiratory medicine and the department of respiratory surgery sometimes carry out examinations on the same day. They also use the same examination room.

○ Use of sedatives for examinations
- The department of respiratory medicine had been using Pethidine and Midazolam for bronchoscopies, but until a year earlier, there were occasions when it did not use Midazolam.
- The content of orders for sedatives to be used in examinations had not been standardized between the department of respiratory medicine and the department of respiratory surgery, and the orders were not designed as a set.
- When a comment is entered on an injection order, the comment details are displayed in yellow on the screen on which nurses check the information in the order. Because no comment had been entered on this occasion, the ordinary injection order "Midazolam 10 mg/2 mL, normal saline 20 mL, IV procedure, intravenous injection" was displayed.
- There had been previous instances of failure to enter the comment "Bring to the bronchoscopy room," but the nurses on Ward Y, who were used to bronchoscopies, always brought the drug to the examination room even if the comment had not been entered, because that was the usual procedure for the examination.

○ Primary nurse (6 years of professional experience, 7 months assigned to the department)
- The primary nurse was confident that they were used to the procedure, because they had six years of experience on a department of respiratory medicine ward at another medical institution.
- The primary nurse had previous experience of preparing for a bronchoscopy and nursing patients at another medical institution.
- Although the primary nurse had been in this job for more than six months, they had not gained any experience of preparing for a bronchoscopy at this hospital.
- At the other medical institution, premedications for bronchoscopies were administered on the ward.
- The primary nurse had learned during this hospital's in-house intravenous injection training that Midazolam was a drug that nurses did not administer, but had forgotten this fact.
- Midazolam was a drug requiring a double-check, but the primary nurse did not perform a double-check when preparing or administering the drug, partly because they were in a rush.

○ Partner nurse (2 years of professional experience, 2 years assigned to the department)
- The nurse knew that Midazolam was a sedative and that it should be brought to the examination room.
- The partner nurse did not realize that the primary nurse had no previous experience of a bronchoscopy at this hospital.
- The partner nurse checked the drug with the primary nurse on the morning of the examination, but did not check the administration method. When doing so, the partner nurse thought that the primary nurse knew that the drug should be brought to the examination room, so did not confirm this verbally.

○ Bronchoscopy procedure manual
- The nursing department uses as its procedure manual the same online tool for nursing techniques as is used in nursing education programs.
- The online tool for nursing techniques can be viewed from a laptop computer and has a section on bronchoscopies.
- The Medical Safety Management Division has prepared safety management manuals for each department. These manuals describe characteristics of the department (names of treatments and examinations distinctive of the clinical department), the names of examinations, errors envisaged when conducting examinations, items to be checked, and measures for dealing with issues. The manual has a section on bronchoscopies.

○ Scope within which nurses administer intravenous injections
- The scope within which intravenous injections are administered is determined on a four-level scale. The levels are divided up on the basis of nurses' skills, with nurses permitted to administer injections classed as levels 1-3 .
- At level 2, nurses can administer intravenous drip infusions via a line secured in a blood vessel. To obtain level 2 clearance, a nurse must undergo in-house training and carry out practical exercises.
- Administration of a one-shot sedative is listed as a level 4 procedure; only physicians are permitted to perform level 4 procedures.
- The list showing the scope of intravenous injections that nurses can administer lists "one-shot sedatives," but does not give the brand name, etc. of any particular sedatives.

○ Education system for nurses hired mid-career
- Guidance is provided via the partnership nursing system, under which partners are determined for the whole year.
- As it is difficult to ensure that nurses are paired with their partner nurses in day-to-day duties, each ward is divided into teams and guidance is provided on a team basis.
- There was no guidance manual for nurses hired mid-career.
- While review interviews are held at the one- and three-month mark, there had been no reviews after the three-month interview.

3. Main improvement measures introduced after reporting the event

- The event was raised at a meeting of the medical institution's risk managers.
- The department of respiratory medicine now uses Midazolam for all bronchoscopies. The practice of bringing the drug from the ward has been stopped and Midazolam has been made available in the examination room. The procedure has been altered so that the physician only administers the drug after the physician and a nurse have carried out a pre-administration double-check.
- When department of respiratory medicine staff conduct a bronchoscopy, they now observe a time out before administering the premedication and then start the examination after verbally confirming the procedure.
- Level 4 (injections not to be administered by nurses) in "Scope and Content of Intravenous Injection Administration by Nurses" was raised at the meeting of head nurses, with instructions to ensure that departments were notified once more of the details.
- The ward in question decided to draw up and use the "Experience Checklist for Staff from Another Medical Institution."
- The online tool for nursing techniques is used to provide education about the importance of point-and-call.

Discussion during the visit, etc. (○: Visitor, ●: Attendees from the Medical Institution)

○ While Midazolam has now been made available in the examination room, it does raise the question of whether there are any other examinations requiring comments to be entered.

● There are still examinations for which drugs are brought from the ward. It seems that coordination with the pharmaceutical department is required to see whether drugs could be dispensed to the examination room for other examinations, as well. Drugs for bronchoscopies are dispensed directly to the examination room and kept there.

○ Although Midazolam was a drug requiring a double-check, no double-check was carried out. It would be advisable to have a mechanism capable of providing a warning about which drugs require a double-check.

○ The online tool for nursing techniques has been designated as the procedure manual for the nursing department, but the tool covers every topic exhaustively and is written in the style of a textbook. It would appear necessary to have a procedure manual that provides more specifics and is in keeping with front-line nursing.

○ The departmental safety management manuals summarize the examinations and treatments frequently carried out in each clinical department, but as they are specific to each clinical department, matters determined by the department of respiratory medicine have not been shared with other parts of the hospital. It would appear necessary to have a common procedure manual for the hospital, rather than departmental ones.

○ In "Scope and Content of Intravenous Injection Administration by Nurses," the entry for level 4 (injections not to be administered by nurses) mentions only sedatives and does not specify their names, such as brand names. As it is difficult to tell which drugs are sedatives, it would be advisable to specify the brand names.

○ The "Experience Checklist for Staff from Another Medical Institution " drawn up by the ward in question has check boxes marked "Experienced in another department" and "Experienced on this ward," but one wonders whether there are any rules about what happens after an item is checked.

● It is just used to check items where the nurse has no experience and no operational rules have been determined.

○ To ensure that the checklist is utilized effectively, it might be advisable to decide on some rules, such as permitting an individual to carry out a task singlehandedly once they have checks in both the "Experienced in another department" and "Experienced on this ward" boxes for the relevant item, for example.

○ On this occasion, it was apparently the first time that the nurse had carried out preparations for a bronchoscopy, but it would seem necessary to be clear, as "first time" could mean their first time being involved in the examination itself or just first time at this hospital.

Visit 6 **Event in which Mikulicz gauze was left in the body during surgery because it was not counted**

Event as reported

Summary of event	Background and causal factors	Improvement measures
During a shift change, the nurse was told at handover that the patient had a towel (Mikulicz gauze) remaining in their body. In fact, there were two towels inside the patient. The nurse saw the physician remove one towel from the patient's body before closing the abdomen and removed from the operative field the clip used as a marker to signify that there were still gauze sponges or towels inside the patient. Although the nurse counted the number of gauze sponges and instruments during the count when the abdomen was being closed, they did not count the number of towels, but nevertheless reported that the count was OK and the operation was completed. The remaining towel was found in the post-operative X-ray and when the towels were checked, it was discovered that one was missing. As the patient had not yet roused from the anesthetic, the lower abdomen was reopened and the towel removed.	The number of towels was not counted. The check of towels in the operative field before closing the abdomen was inadequate. As the clip used to prevent towels and gauze sponges being left in the body was removed, it was thought that no towels or gauze sponges remained in the body. The instruments, towels, and gauze sponges are not checked by their specific names during the count.	• A closing time out has been introduced, during which everyone stops what they are doing and checks such matters as towels, gauze sponges, instruments, and drain fixtures before closing the abdomen. Staff have been made fully aware of this procedure.

III

Details of the On-site Visit

Attendees from the Medical Institution

Medical Safety Promotion Center: Director (physician), Medical Safety Managers (2 nurses); theater head nurse; nurses

Findings

1. Lead-up to the event

Explained by the medical institution

2. Background and causal factors

○ Towels (Mikulicz gauze)
- The towels consisted of several gauze sponges placed on top of each other and sewn together; two towels had been sterilized together as a set.
- The scrub nurse confirmed that the first towel was in the peritoneal cavity and placed the second towel on the instrument tray behind the nurse.
- When taking an X-ray during surgery, the physician removed the towel from the instrument tray and draped it over the abdomen. It was unclear how the towel subsequently ended up inside the peritoneal cavity.
- The scrub nurse did not know that the physician had taken the second towel from the instrument tray and thought that only the first towel was being used in the operative field.

○ Clip
- The clip was an ordinary bulldog clip (10 cm wide) of the kind used in offices, which had been sterilized for the purpose.
- As there had been an event in which a laparoscopic sponge had been left inside a patient following laparoscopic surgery, the gastrointestinal surgery department alone was trialing the use of a clip on the bed cradle on the anesthesiologist's side to serve as a marker while gauze, etc. was inside the patient's body.
- The clip served as a marker, indicating whether or not there were any gauze sponges, etc. inside the patient's body, but only one clip was used while gauze of any kind was inside the body, irrespective of the actual number of gauze sponges, etc.
- There was no set procedure for who was supposed to attach the clip and when, so it was attached by whichever physician or nurse noticed that it should be used.

○ Counting
- A count sheet was used, on which the instruments and gauze sponges used in surgery were listed.
- The circulating nurse used a gauze counter caddy shaped like an egg case to count each individual gauze sponge dropped outside the sterilized area. In this operation, no towels had been dropped outside the sterilized area, but towels were also supposed to be counted.
- A count was carried out three times: before starting to close the abdomen, before finishing closing the abdomen, and before finishing closing the wound. A count was not usually carried out after finishing surgery.

• The scrub nurse saw the physician remove one towel and removed the clip, but did not check whether the one unused towel placed on the instrument tray was still there when carrying out the count that took place before closing the abdomen.
• For some time, it had been difficult to get physicians to cooperate in stopping what they were doing when counting gauze sponges, etc. Accordingly, it had not been possible to carry out a time out.

○ Circulating nurse
• While the circulating nurse did not have a lot of duties keeping them busy in this particular operating theater, they had to leave the room to check on progress in other operating theaters, as they were also the leader for the late shift.

○ X-ray imaging
• For about the last ten years, it had been the procedure to take an X-ray in the operating theater for all patients when finishing an operation. It is believed that this procedure was introduced after a gauze sponge was left inside a patient.
• In this particular case, the presence of the towel remaining in the peritoneal cavity was discovered because the contrast thread on the towel showed up on the X-ray image carried out as usual.

3. Main improvement measures introduced after reporting the event

• A clip was being used at the time this event occurred, but its use was discontinued, as staff were forgetting to attach or remove it.
• The hospital has revised the count sheet and switched to a layout that makes counting easier.
• Since this event occurred, the hospital has introduced a pre-wound closure time out before closing the incision. During the time out, staff stop what they are doing and carry out the following procedure.

Surgeon:	Says, "I am going to close the incision, so please observe the pre-wound closure time out."
Anesthesiologist:	Writes "Pre-wound closure time out" on the anesthesia record.
Nurse:	Checks with the surgeon the methods used to fix the drains, leads, and tubes.
Nurse:	After completing the aforementioned checks, the scrub nurse and circulating nurse together carry out a check following the count list and communicate the result of the count by saying, "The first count is OK."
Surgeon:	Starts to close the incision if the nurses' count comes back OK.

• A notice describing the aforementioned "Pre-wound closure time out" procedure was put up in the operating theaters for six months, to raise staff awareness of the procedure.

Discussion during the visit, etc. (○: Visitor, ●: Attendees from the Medical Institution)

○ On this occasion, the handover between nurses was just "there is a towel in the peritoneal cavity," but the task of checking the towels had not been carried out. As there were two towels in a set, there is a possibility that the scrub nurse would have noticed that there was a towel missing if they had checked the towel on the instrument tray and thereby confirmed that, with the other towel in the peritoneal cavity, there were two towels.

○ At Medical Institution A, a nurse who was not involved in the operation in question carries out the final check by counting the number of gauze sponges after the operation is completed. As this process only involves counting the number of gauze sponges, one possible method could be to secure the cooperation of a nursing assistant, etc.

● This is something which the hospital wishes to consider, as having a third party carry out the check is also a possible option.

○ At Medical Institution A, an RCA concerning gauze left in patients' bodies was carried out with the involvement of physicians from several clinical departments and compliance by departments that were not cooperating in carrying out the count improved after other departments commented that their failure to stop what they were doing was alarming. Perhaps all clinical departments that use operating theaters could consider the issue of gauze left in patients' bodies.

○ At Medical Institution B, the procedure manual states that if medical staff do not stop what they are doing during the pre-wound closure gauze count, the lead nurse in the operating theater must tell them that it is necessary to stop what they are doing. It has also taken the step of restricting operations by clinical departments that refuse to cooperate. Perhaps the institution could continue to display the "Pre-wound closure time out" notice to ensure that staff remain informed about it.

● Some consideration within the hospital will be required, as not all clinical departments cooperate in carrying out the count.

○ The count sheet has a space assigned for the signature of the "Nurse who checked whether the physician has looked at the X-ray," but it would also be advisable to clarify the locus of responsibility and procedure by redesigning the form to make it clear which physician actually checked the X-ray.

○ When changing or adding to procedures in future, it might be wise to add some kind of explanation of the reasons for the change or addition, as the background to the decision to take X-rays in all cases was vague. At Medical Institution B, a revision history page was added to the procedure manual, on which the reasons for any revisions are recorded.

Visit 8 **Event in which pneumothorax occurred because suction pressure was applied without having put distilled water into the water seal chamber of the chest drainage bag**

Event as reported

Summary of event	Background and causal factors	Improvement measures
The medical staff decided to leave a drain indwelling in the right thoracic cavity, for pleurodesis in a case of pleuroperitoneal communication. Resident A asked the nurse on Ward X to prepare the items required for the indwelling thoracostomy tube, but Ward X did not have the items required for thoracostomy tube insertion, so the nurse went to Ward Y to prepare the items. Resident A inserted the thoracostomy tube under the supervision of Supervising Physician B, with Nurse C on Ward X assisting. Supervising Physician B went away during the procedure after being called to another department. Resident A connected the thoracostomy tube to the MERA Aquaseal, but forgot to put distilled water into the water seal chamber. Although Nurse C looked at the thoracostomy tube once, this was their first time assisting with the procedure and they did not notice that there was no distilled water in the water seal chamber. Resident A applied suction pressure an hour later. Nurse C asked Resident A, "Should I check whether there's a bubbling sound?" Resident A replied, "You don't need to do anything." Nurse C observed the volume of fluid drained via the thoracostomy tube, the tube insertion site, and whether the patient had any pain or respiratory discomfort, and reported this to Lead Nurse D. Nurse C later handed over to Night Nurse E. Having noticed that there was no distilled water in the water seal chamber, Night Nurse E checked with Nurse C, who replied, "The physician said it was fine as it was," so Night Nurse E did not check again. Overnight, the patient complained of respiratory discomfort; the respiratory sounds in their right lung were weak and their oxygen saturation was at the upper end of the 80% range. A chest X-ray was taken and the patient was found to have a right pneumothorax. When the duty physician checked the chest drainage bag, they discovered that there was no sterile distilled water in the water seal chamber.	As Resident A had never made preparations for the insertion of a thoracostomy tube, they forgot to put distilled water into the water seal chamber of the chest drainage bag. Supervising Physician B was not in attendance all the way through to the end of the procedure, so they did not realize that distilled water had not been put into the water seal chamber of the chest drainage bag. Nurse C lacked any knowledge about thoracostomy tubes. The method used for checking and the content of those checks were also inadequate.	• Physicians and nurses will administer treatments only after checking the procedure and the items needed for it in the manual, etc. and ensuring that they understand what is required. • The supervising physician will carry out checks until the procedure is completed. • Medical staff who are uncertain about any devices will check with a knowledgeable staff member. • Medical staff will be specific in their communication with each other and check things with each other.

Details of the On-site Visit

Attendees from the Medical Institution

Deputy Hospital Director (in charge of medical safety); Medical Safety Management Division: pharmacist, nurse GRM, nurse; physician from the department of respiratory medicine (RM); physician from the department of respiratory surgery; 2 ward head nurses; clinical engineer; clerical staff

Findings

1. Lead-up to the event

- The patient was undergoing peritoneal dialysis due to diabetic nephropathy. The primary clinical department treating the patient was the nephrology department.
- The nephrology department asked the department of respiratory surgery to insert the thoracostomy tube, so Resident A from the department of respiratory surgery dealt with it on Ward X, to which the patient was admitted.
- Resident A went to Ward X after 08:00 and told the nurse that the thoracostomy tube would be inserted at around 09:00.
- Ward X is a mixed ward containing patients from such departments as the nephrology department, the endocrinology department, and the department of hematology and oncology. Thoracostomy tube insertion is hardly ever carried out there and electric low-pressure suction units rarely used.
- Ward Y is a mixed ward containing patients not only from the department of respiratory surgery, but also from such departments as the department of cardiovascular surgery, and the department of respiratory medicine.

2. Background and causal factors

○ Resident A
- Resident A prepared the trocar catheter, suture set, and other items required for inserting a thoracostomy tube on Ward Y.
- When inserting a thoracostomy tube in the operating theater, a nurse had already put sterile distilled water into the water seal chamber of the drainage bag, so Resident A thought that the nurse had done it in this case, as well.
- While Resident A had inserted a thoracostomy tube many times before, they had only previously placed a drainage bag in an electric low-pressure suction unit themselves once or twice.
- Resident A knew that the drainage bag should be placed in the electric low-pressure suction unit, because thoracostomy tubes were inserted in all department of respiratory surgery patients after surgery.
- When asked by Nurse C, "Should I check whether there's a bubbling sound?", Resident A did not think that it was a question about the water seal chamber.

○ Supervising Physician B
- Supervising Physician B thought that the post-insertion management would be fine, because some of the nurses on Ward X had experience of managing patients with indwelling thoracostomy tubes.

○ Nurse C
- Nurse C had three years of professional experience and had been assigned to the department for three years.
- Nurse C had managed a patient with an indwelling thoracostomy tube due to pneumothorax once before, but had never assisted during the insertion.
- Nurse C did not look at the procedure manual for thoracostomy tube insertion.
- As the ward was busy, Nurse C was unable to tell the other nurses that it was their first time assisting with the procedure.
- Nurse C did tell Resident A that it was their first time assisting.

○ Situation on Ward X
- While there were nurses on Ward X who had experience of managing patients with indwelling thoracostomy tubes, the ward was busy that day, so those nurses were unable to assist with this patient.
- There were no set rules about what observations should be carried out after the insertion of a thoracostomy tube, so the nurse who assisted with the insertion chose the observations listed on the electronic medical record.

○ Procedure manual for the insertion of a thoracostomy tube and management while indwelling
- The online tool for nursing techniques is used as the procedure manual for the nursing department and can be viewed from a laptop computer.
- The Medical Safety Management Division has prepared safety management manuals for each department. These manuals describe characteristics of the department (names of treatments and examinations distinctive of the clinical department), the names of examinations, errors envisaged when conducting examinations, items to be checked, and measures for dealing with issues.
- The operating theater had a photograph showing a drainage bag placed in an electric low-pressure suction unit and theater nurses referred to this photograph when preparing these items.
- While the nursing department has an online tool for nursing techniques, each department has a departmental safety management manual, and the operating theater has a photograph to which nurses can refer when preparing the items required, these things had not been shared interdepartmentally.

○ Standards for procedures and prescriptions that residents are permitted to handle unsupervised
- The standards drawn up by the postgraduate clinical training center state that residents must not carry out thoracentesis without supervision.

3. Main improvement measures introduced after reporting the event

- The directions for using electric low-pressure suction units and the purpose of the water seal were reviewed in a staff conference.
- Nurses will use the online tool for nursing techniques for prior study before carrying out any procedures for the first time or procedures of which they have little experience.
- The hospital held a medical safety training session on the principles and handling of thoracostomy tubes.
- The event was featured in the institution's risk management bulletin to ensure that staff were fully aware of the issue.

Discussion during the visit, etc. (○: Visitor, ●: Attendees from the Medical Institution)
○ While residents learn techniques in the department of respiratory surgery, one wonders whether they learn about the principles of thoracostomy tubes. ● Resident A had inserted a thoracostomy tube many times before, so they assumed that they understood the principles. While Resident A understood that suction pressure should not be applied immediately, due to the risk of a tension pneumothorax, it appears that they lacked an understanding of the electric low-pressure suction unit's mechanism and the water seal. ○ It would appear necessary to have a checklist to ensure that the proper placement of the drainage bag in the electric low-pressure suction unit can be checked without fail when a thoracostomy tube insertion takes place, just as the settings are checked when a ventilator is restarted. ○ One wonders what happens when a patient is admitted to a department that is unused to mixed wards or shared wards. ● If there is advance warning of their admission, the clinical engineer is asked about the instruments to be used or a contractor is asked to come and explain. A nurse from a ward familiar with the department comes to provide discharge guidance. ○ The nursing department uses an online tool for nursing techniques as its procedure manual, each department has a departmental safety management manual put together by the Medical Safety Management Division, and the operating theater has a photograph to which nurses can refer when preparing the items required. However, it would seem necessary to compile all of these into a hospital-wide procedure manual.

3. Themes Analyzed

[1] Selection of Themes for Information to be Analyzed

This project endeavors to use the data reported to provide information that will help to prevent medical adverse events and ensure that they do not recur. Accordingly, themes are selected for information to be analyzed and events associated with that theme are analyzed and examined. The themes have been selected based on expert opinions and in light of 1) generality/universality, 2) event frequency, 3) effect on patients, 4) preventability, and 5) ability to serve as an object lesson.

This project's Quarterly Reports analyze two types of theme: (1) themes selected for comprehensive analysis of both medical adverse event information and medical near-miss event information relevant to the theme collected over a six-month period; and (2) themes selected from medical adverse event information reported during the period under analysis in the quarterly report, which are then used in analyzing past events.

[2] Overview of Themes Analyzed

Fig. III-3-1 lists the themes analyzed in the 53rd to 56th Quarterly Reports, which covered the period under analysis for events reported in 2018.

Fig. III-3-1 Themes Analyzed

Themes Analyzed	Quarterly Report No.
【1】 Themes selected for comprehensive analysis of both medical adverse event information and medical near-miss event information relevant to the theme collected over a six-month period	
[1] Events Related to Intensive Care Unit Computer Systems (2)	53rd
[2] Events Related to Drugs Administered to Pediatric Patients (1)	54th
[3] Events Related to Drugs Administered to Pediatric Patients (2)	55th
[4] Events Related to Medical Devices Used at Another Institution or at Home and Brought in at Admission (1)	56th
【2】 Themes selected from medical adverse event information reported during the period under analysis in the quarterly report and used in analyzing past events	
[1] Events Related to the Grinding of Drugs	53rd
[2] Events Related to Drug Holidays for Biguanide Oral Hypoglycemic Agents When Using Iodinated Contrast Media	
[3] Events Related to Damaged Guide Wires	54th
[4] Events Related to Injuries from a Wheelchair Footrest	
[5] Events Related to the Management of Drugs Prepared within the Institution	55th
[6] Events Related to Wrong-Site Procedures Due to Mix-ups between Left and Right During Examinations, Treatment and Other Procedures	
[7] Events Related to the Erroneous Administration of G-CSF Preparations	56th
[8] Events Related to Patient Mix-up When Using Electronic Medical Records	

4. Analysis of Recurrent and Similar Events

The 3rd to 17th Quarterly Reports featured a section entitled Medical Adverse Event Information to Be Shared, which provided a summary of events that the Expert Analysis Groups thought should be shared with a wider audience after consideration of individual medical adverse event information reports. In addition, a section entitled Individual Theme Review appeared in the 1st to 49th Quarterly Reports and was renamed Themes Analyzed from the 50th Quarterly Report. Highlighting a specific theme, this section analyzes and examines events related to that theme. Based on previously profiled themes and the like, the project also publishes Medical Safety Information, which provides information that should be common knowledge.

[1] Overview of the Analysis of Recurrent and Similar Events

The Analysis of Recurrent and Similar Events section of the 53rd to 56th Quarterly Reports, which covered the period under analysis for events reported in 2018, highlighted major events about which reports had been received again, looking at trends in the number of recurrent or similar events that occurred between the provision of information and the period under analysis in the quarterly report in question, and also detailing specific improvement measures reported by the medical institutions concerned. Fig. III-4-1 lists the contents of each quarterly report.

Fig. III-4-1 List of Analysis of Recurrent and Similar Events

Title	Quarterly Report No.
Accidental Removal of a Drain/Tube during Transfer (Medical Safety Information No.85)	53rd
Delays in Urgent Contact Regarding Panic Values (Medical Safety Information No.111)	
Wrong Weight When Prescribing an Antineoplastic Agent (Medical Safety Information No.104)	54th
Event Involving Gauze Left Within the Body (14th Quarterly Report)	
Forgetting to Check the Pathologic Diagnosis Report (Medical Safety Information No.71)	55th
Misinterpretation of a Verbal Order (Medical Safety Information No.102)	
Wrong Quantity Prescribed When Switching from Medicines Brought in at Hospitalization to Internal Prescriptions (Medical Safety Information No.78)	56th
Events Related to the Transfer of a Patient from One Bed to Another (13th Quarterly Report) —Events in Which the Patient Fell during Transfer—	

IV

Medical Safety Information

IV Medical Safety Information

In December 2006, this Project began to prepare Medical Safety Information bulletins for both medical institutions participating in the project and the wider public, to provide information about which knowledge should be particularly widespread. This Medical Safety Information is provided by fax and also via the project website.

1. Summary

[1] Objective

The objective of this service is to provide participating medical institutions with information that ought to be made common knowledge, based on the information reported to the Project to Collect Medical Near-Miss/ Adverse Event Information, to assist in preventing the occurrence/recurrence of medical adverse events.

[2] Medical Institutions Receiving Information by Fax

Medical Safety Information is provided to about 6,000 medical institutions:

1) Medical institutions subject to reporting requirements as well as voluntarily participating medical institutions in the Project to Collect, Analyze, and Provide Medical Adverse Event Information

2) Participating medical institutions in the Project to Collect, Analyze, and Provide Medical Near-miss Event Information

3) Hospitals that have requested that information be provided by fax

2. Medical Safety Information Released in 2018

Medical Safety Information bulletins No.134 to No.145 were issued between January and December 2018.

Fig. IV-2-1 Medical Safety Information released in 2018

Month of information supply	No.	Title
January	No.134	Erroneous Administration of Disinfectant in the Sterilized Area
February	No.135	Failure to Release Standby Mode When Resuming Ventilation (1st Follow-up Report)
March	No.136	Medical Safety Information released in 2017
April	No.137	Burns When Using a Heat Pack
May	No.138	Inadequate Checks Concerning Diagnostic Imaging Reports (1st Follow-up Report)
June	No.139	Medical Safety Information released from 2014 to 2016
July	No.140	Administration of an Antineoplastic Agent in Excess of the Total Dosage Limit
August	No.141	Falls from an Examination Table
September	No.142	Urethral Damage Caused by an Indwelling Bladder Catheter (1st Follow-up Report)
October	No.143	Error When Refilling a Prescription Due to Failure to Revise Prescription Details
November	No.144	Failure to Submit a Pathology Specimen
December	No.145	Administration of the Usual Dosage of Drugs for Patients with Impaired Renal Function

V

Current Status of the Project

V Current Status of the Project

This chapter describes the project's achievements in 2018, along with activities and outcomes associated with the project. It mainly provides a summary of information already published in the "IV Current Status of the Project" section of the 53rd-56th Quarterly Reports.

1. Dissemination of Information about the Project

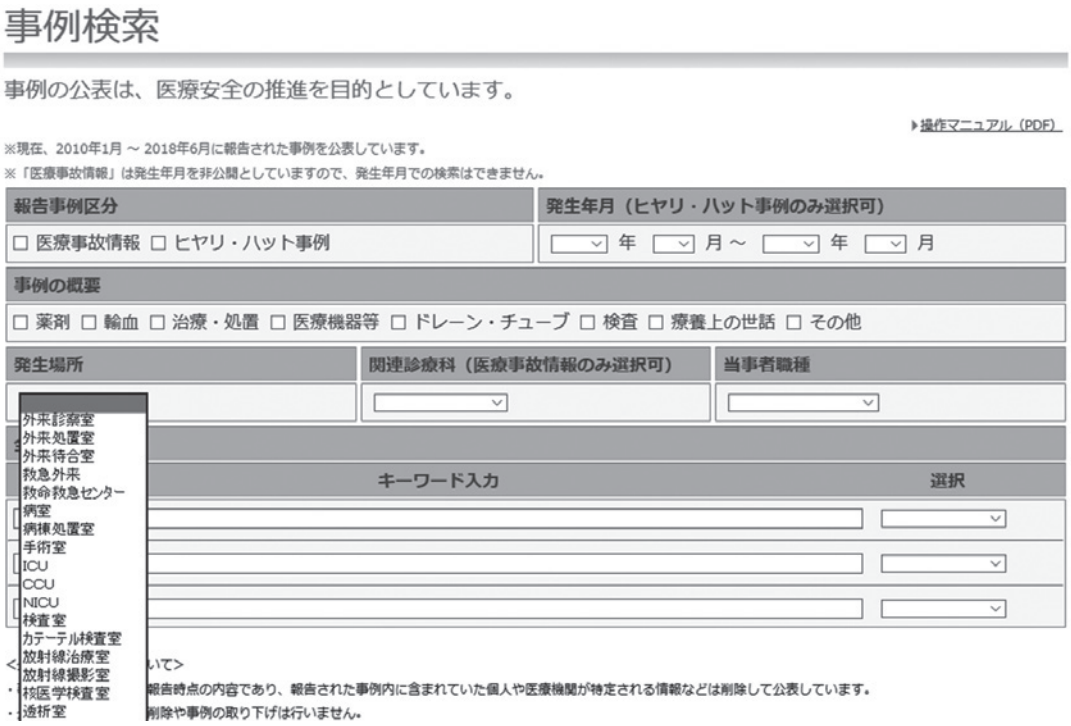
The project prepares and publishes Quarterly Reports, the Annual Report, and monthly Medical Safety Information bulletins, as well as providing a database of events and holding workshops. The pamphlet "Project Activities and How to Participate" (http://www.med-safe.jp/pdf/business_pamphlet.pdf) provides a user-friendly introduction to the project and the information provided on the website (available in Japanese only).

2. Project Website

1) Revamp of the Website

The project's website provides a variety of information, including a list of registered medical institutions, quarterly and annual reports, analyses of themes, analyses of recurrent and similar events, and Medical Safety Information, as well as a searchable database of events. In March 2018, the website was revamped to enable the user to select the location of the occurrence as entered in the reports of individual events from a pull-down menu when performing a search on the website's Event Search page.

Fig. V-1 Addition of the "Location of Occurrence" Pull-down Menu to the Website's Event Search Page



2) Website Access Frequency by Year

The project compiles figures for the number of times each part of the website is accessed each year and refers to these when considering how the outcomes of the project are used. Accordingly, we have compiled figures for the number of times that visitors clicked on the Homepage, Event Search, Medical Safety Information, and Quarterly and Annual Reports buttons on the website between January and December 2018. The homepage was accessed 470,584 times in 2018 (Fig. V-2). Event Search was accessed 69,341 times, Medical Safety Information 187,749 times, and Quarterly and Annual Reports 36,641 times (Fig. V-3). The number of times the website was accessed has been growing year by year, with 2018 no exception to this. In particular, following the March 2017 revamp of the website, we noticed a surge in the number of times that it was accessed, which we believe was due to such factors as increased convenience due to users being able to reach the information they were looking for with just one click, changes in screen design, and making the site compatible with smartphone screens.

Fig. V-2 Homepage Access Frequency

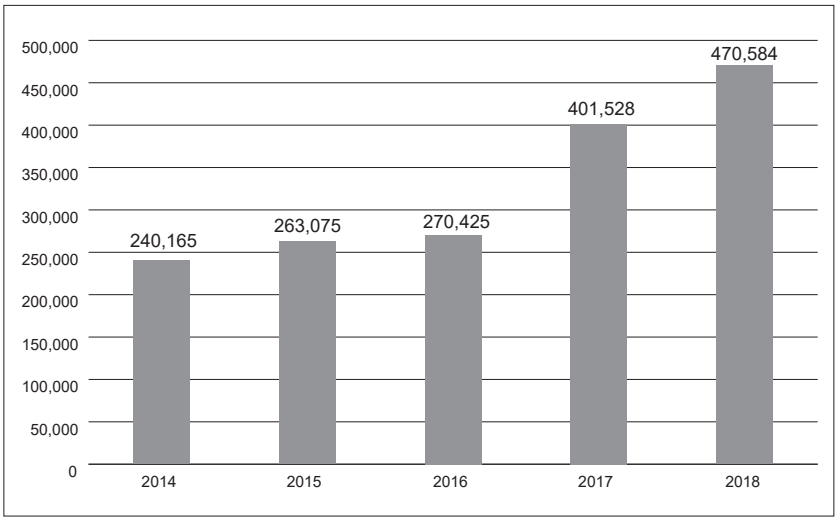
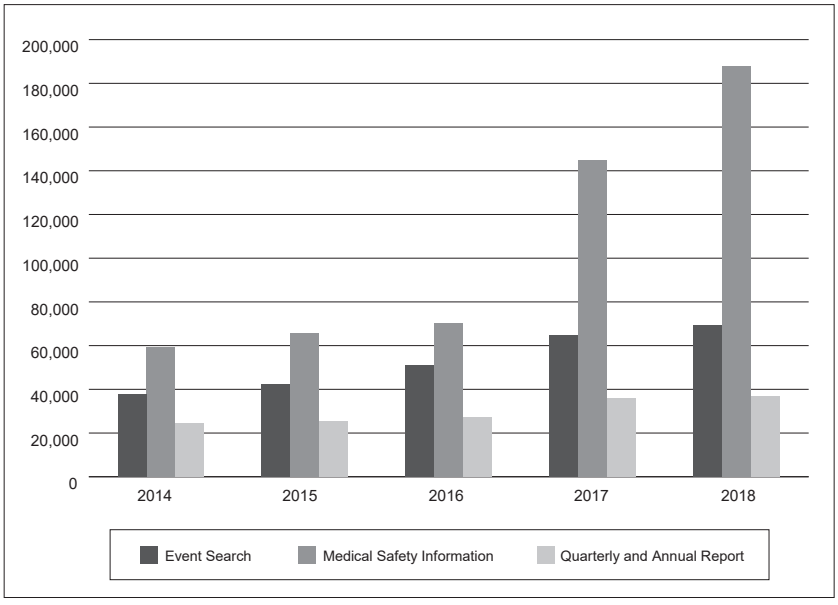


Fig. V-3 Event Search, Medical Safety Information, and Quarterly and Annual Report Page Access Frequency

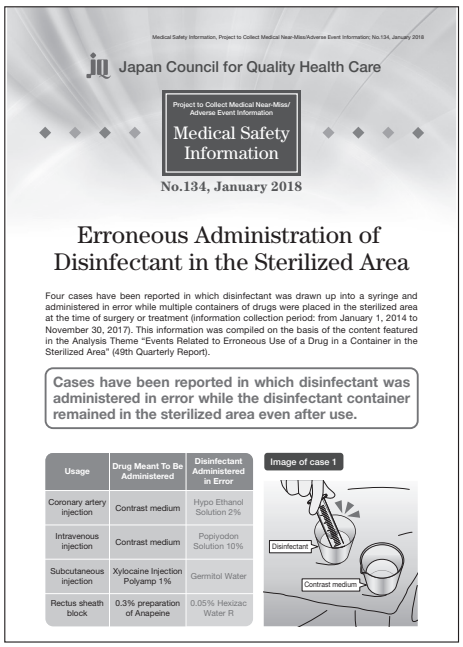


We also investigated how many times each Medical Safety Information issued between January and December 2018 was accessed. Fig. V-4 shows which of those issues had the highest access figures. The number of times an issue is accessed often increases over the course of the month of publication and the following month, and then gradually declines from the third month after publication. Accordingly, readers should bear in mind that the figures for the Medical Safety Information bulletins issued in November and December 2018 are lower. The issue with the highest access figure in 2018 was No.134 “Erroneous Administration of Disinfectant in the Sterilized Area” (Fig. V-5).

Fig. V-4 Medical Safety Information Accessed the Most in 2018

Month of information supply	No.	Title	Access Frequency
January 2018	No.134	Erroneous Administration of Disinfectant in the Sterilized Area	22,201
April 2018	No.137	Burns When Using a Heat Pack	19,761
May 2018	No.138	Inadequate Checks Concerning Diagnostic Imaging Reports (1st Follow-up Report)	19,624
February 2018	No.135	Failure to Release Standby Mode When Resuming Ventilation (1st Follow-up Report)	18,539
March 2018	No.136	Medical Safety Information released in 2017	17,091
July 2018	No.140	Administration of an Antineoplastic Agent in Excess of the Total Dosage Limit	15,895
August 2018	No.141	Falls from an Examination Table	15,473
October 2018	No.143	Error When Refilling a Prescription Due to Failure to Revise Prescription Details	13,115
June 2018	No.139	Medical Safety Information released from 2014 to 2016	12,785
September 2018	No.142	Urethral Damage Caused by an Indwelling Bladder Catheter (1st Follow-up Report)	12,130

Fig. V-5 Medical Safety Information Accessed the Most in 2018: Medical Safety Information No. 134 “Erroneous Administration of Disinfectant in the Sterilized Area”


Medical Safety Information, Project to Collect Medical Near-Miss/Adverse Event Information; No.134, January 2018

Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.134, January 2018

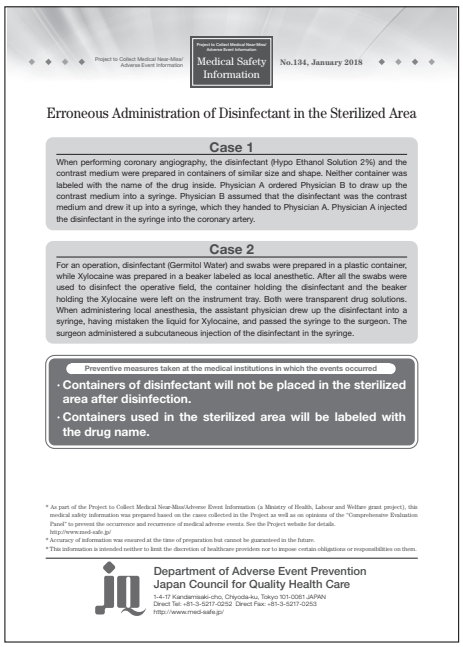
Erroneous Administration of Disinfectant in the Sterilized Area

Four cases have been reported in which disinfectant was drawn up into a syringe and administered in error while multiple containers of drugs were placed in the sterilized area at the time of surgery or treatment (information collection period: from January 1, 2014 to November 30, 2017). This information was compiled on the basis of the content featured in the Analysis Theme “Events Related to Erroneous Use of a Drug in a Container in the Sterilized Area” (49th Quarterly Report).

Cases have been reported in which disinfectant was administered in error while the disinfectant container remained in the sterilized area even after use.

Usage	Drug Meant To Be Administered	Disinfectant Administered in Error
Coronary artery injection	Contrast medium	Hypo Ethanol Solution 2%
Intravenous injection	Contrast medium	Popiyodon Solution 10%
Subcutaneous injection	Xylocaine Injection Polyamp 1%	Germitol Water
Rectus sheath block	0.3% preparation of Anapeine	0.05% Hexizac Water R

Image of case 1


Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.134, January 2018

Erroneous Administration of Disinfectant in the Sterilized Area

Case 1

When performing coronary angiography, the disinfectant (Hypo Ethanol Solution 2%) and the contrast medium were prepared in containers of similar size and shape. Neither container was labeled with the name of the drug inside. Physician A ordered Physician B to draw up the contrast medium into a syringe. Physician B assumed that the disinfectant was the contrast medium and drew it up into a syringe, which they handed to Physician A. Physician A injected the disinfectant in the syringe into the coronary artery.

Case 2

For an operation, disinfectant (Germitol Water) and swabs were prepared in a plastic container, while Xylocaine was prepared in a beaker labeled as local anesthetic. After all the swabs were used to disinfect the operative field, the container holding the disinfectant and the beaker holding the Xylocaine were left on the instrument tray. Both were transparent drug solutions. When administering local anesthesia, the assistant physician drew up the disinfectant into a syringe, having mistaken the liquid for Xylocaine, and passed the syringe to the surgeon. The surgeon administered a subcutaneous injection of the disinfectant in the syringe.

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

- Containers of disinfectant will not be placed in the sterilized area after disinfection.
- Containers used in the sterilized area will be labeled with the drug name.

* As part of the Project to Collect Medical Near-Miss/Adverse Event Information (a Ministry of Health, Labour and Welfare grant project), this medical safety information was prepared based on the cases collected in the Project as well as on opinions of the “Comprehensive Evaluation Panel” to prevent the occurrence and recurrence of medical adverse events. See the Project website for details. http://www.med-safe.jp/
* Accuracy of information was ensured at the time of preparation but cannot be guaranteed in the future.
* This information is intended neither to limit the discretion of healthcare providers nor to impose certain obligations or responsibilities on them.

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3) Use of Information: Use of Events in Pharmaceutical Company Initiatives

Previous Quarterly and Annual Reports have highlighted the fact that pharmaceutical companies have used the Event Search functions of this project and the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information when issuing warnings about mix-ups between drugs with similar names, such as Norvasc and Nolvadex. Thus, reports of events to this project continue to be a catalyst for companies and relevant groups other than the JQ to provide specific warnings aimed at preventing medical adverse events. We highlight initiatives by such companies in the lectures that we give about this project overseas and these voluntary safety measures by Japanese companies are consequently attracting attention. Fig. V-6 provides a summary of warnings issued by pharmaceutical companies that were published in Quarterly Reports in 2018. Please refer to the relevant Quarterly Report for details.

Fig. V-6 Warnings from Pharmaceutical Companies Highlighted in the Project's Quarterly Reports

Quarterly Report No.	Warning	Date of Issue	Company Name
53rd	Brand name change notice Old: Prink Inj. Syringe New: Alprostadil Inj.	February 2018	Kaken Pharmaceutical Co., Ltd.
55th	Caution Regarding Mix-ups Due to the Similarity in Brand Names Between Nolvadex and Norvasc	July 2018	AstraZeneca K.K. Pfizer Japan Inc.

3. Publication of the English-language Editions of the 2017 Annual Report and Medical Safety Information No.132-143

An English-language edition of the Annual Report has been compiled and published on the website every year since the 2005 Annual Report. At the end of March 2019, we published the English translation of this project's 2017 Annual Report, entitled "Project to Collect Medical Near-miss/Adverse Event Information 2017 Annual Report." It can be viewed and downloaded from our website. We also publish English-language versions of the Medical Safety Information for readers overseas. They are made available worldwide via the Canadian Patient Safety Institute's Global Patient Safety Alerts project. The English editions of Medical Safety Information No.132 to No.143 were published at the end of March 2019 (Fig. V-7) and can be found on the project website's English page. We hope that you will make use of them.

Fig. V-7 English Editions of Medical Safety Information Published in March 2019

No.	Title in English
No. 132	Patient Falls While Using the Overbed Table for Support
No. 133	Chest Drain Left Open to Air
No. 134	Erroneous Administration of Disinfectant in the Sterilized Area
No. 135	Failure to Release Standby Mode When Resuming Ventilation (1st Follow-up Report)
No. 136	Medical Safety Information released in 2017
No. 137	Burns When Using a Heat Pack
No. 138	Inadequate Checks Concerning Diagnostic Imaging Reports (1st Follow-up Report)
No. 139	Medical Safety Information released from 2014 to 2016
No. 140	Administration of an Antineoplastic Agent in Excess of the Total Dosage Limit
No. 141	Falls from an Examination Table
No. 142	Urethral Damage Caused by an Indwelling Bladder Catheter (1st Follow-up Report)
No. 143	Error When Refilling a Prescription Due to Failure to Revise Prescription Details

4. Workshops

The project held the 10th Workshop on Process Flows and the Project to Collect Medical Near-miss/Adverse Event Information in December 2018. Every year, this project holds workshops on the analysis of medical adverse events, to promote high-quality reporting. The workshops held to date have focused on the use of root cause analysis (RCA) and the preparation of process flows. The FY2018 workshop focused on the preparation of process flows. Preparing process flows helps to visualize the processes carried out at medical institutions, thereby facilitating consideration of how to minimize the risk of medical adverse events without waste or excessive effort. The workshop program and participants' responses to the questionnaire are shown in Appendix 1.

5. The Third Global Ministerial Summit on Patient Safety

The Summit on Patient Safety is an international ministerial conference founded at the initiative of the UK and Germany. The Summit aims to create an internationally harmonized movement to promote patient safety by reducing the distance between policymakers, experts in clinical practice working in the field of medical safety, researchers, and patients. The first Summit was held in London in March 2016 and the second in Bonn in March 2017. The third Summit took place in Tokyo on Friday, April 13 and Saturday, April 14, 2018, hosted by the Government of Japan. Its objective was to ensure that the importance of patient safety becomes widespread among the leaders of international organizations. The 2018 Summit was rather larger than previous Summits, attracting approximately 500 participants with 44 countries represented, including ministers and vice-ministers from 18 countries, as well as representatives of international organizations and various experts (https://www.mhlw.go.jp/psgms2018/).

The event principally consisted of five panel discussions, with lectures and question and answer sessions at which experts and patient representatives spoke. The themes of each panel were as follows.

Panel Discussion 1: Patient Safety Culture

Panel Discussion 2: Patient Safety in Ageing Society

Panel Discussion 3: Patient Safety Needs for Achieving Universal Health Coverage (UHC) in Low- and Middle-Income Countries (LMICs)

Panel Discussion 4: Information and Communication Technology (ICT) in Patient Safety

Panel Discussion 5: Economics of Patient Safety

Details of the Third Global Ministerial Summit on Patient Safety can be found in the 53rd Quarterly Report (pp. 73-79), 54th Quarterly Report (pp. 97-99), and 56th Quarterly Report (pp. 78-81).

The evening session was devoted to patient safety initiatives originating in Japan and featured lectures from Summit co-organizers the Japan Council for Quality Health Care and the Japan Medical Safety Research Organization, which gave lectures about the JQ's initiatives, with a primary focus on the Project to Collect Medical Near-miss/Adverse Event Information and the Japan Obstetric Compensation System for Cerebral Palsy, and the medical adverse event investigation system, respectively. The section of the lecture dealing with the Project covered the following points.

- The Project is a reporting and learning system covering all realms of health care and all levels of severity, from medical adverse events to medical near-miss events.
- Patient representatives are involved in the Project Management Committee and contribute to the running of the Project.
- As well as quantitative analysis, the Project conducts qualitative analysis in the form of Theme Analysis.
- Events arising from CT imaging reports being overlooked triggered particular concern during the previous fiscal year. In one initiative launched to deal with this issue, representatives of university hospitals belonging to the National University Hospital Medical Safety Council made reciprocal visits to check each other's diagnostic imaging reports.
- Medical Safety Information bulletins make effective use of illustrations to convey important messages.
- An overview was provided concerning real-life examples in which use of the Project's event database resulted in the withdrawal of brand names to ensure medical safety, due to the existence of drugs with similar names.

The end of the meeting saw the announcement of the Tokyo Declaration on Patient Safety, which aims to promote initiatives that encourage patient involvement in policy development. The key section of the Tokyo Declaration (https://www.mhlw.go.jp/psgms2018/pdf/document/10-1_Document.pdf) is reproduced below.

As we are concerned that progress towards ensuring patient safety is too slow, despite the efforts made in each country, we call for greater commitment to accelerate progress towards improving patient safety globally. We

declare that we will:

- Affirm our strong commitment to maintain a high level of political momentum on "Global Action on Patient Safety" worldwide, and to work closely with countries across the world, including low- and middle income countries, in order to strengthen capability through collaboration and learning; and to prioritize patient safety in health sector policies and programmes while advancing efforts towards UHC;
- Pledge to support and enable health care institutions, both public and private, from primary care level through to referral level care, to implement changes in systems and practices to improve patient safety, while contributing to achieving UHC and the SDGs;
- Commit to building capacity in leadership and management to support patient-centered care, implement and strengthen patient safety systems and processes, create a culture of safety and transparency, align incentives, educate and train the health workforce in patient safety, engage patients and families, increase efficiency and minimize harm by sharing knowledge on risks, best practices and successful models;
- Work collaboratively with patients and families who have been affected by harm, international organizations and other key stakeholders to increase visibility and work towards global action on patient safety, including the establishment of an annual World Patient Safety Day, to be celebrated on 17 September each year.

6. Partnership with ISQua (International Society for Quality in Health Care)

1) ISQua's Projects

ISQua (International Society for Quality in Health Care) (http://www.isqua.org/) is an international society dedicated to improving the quality of healthcare, which was established in 1985 and currently has its headquarters in Dublin (Ireland). It is funded by the membership fees of individual and institutional members in around 70 countries, as well as by contributions from the Irish government. In addition to the JQ's institutional membership of ISQua, a number of JQ executives and staff hold individual membership of the society. ISQua's main activities are as follows:

- The International Accreditation Programme (IAP)
  *To be run by an affiliated organization, ISQua External Evaluation Association (IEEA), from 2019

- Publication of the International Journal for Quality in Health Care

- Education programs aimed at improving the quality of health care (ISQua Education)

- Holding the International Conference

The JQ was awarded accreditation under ISQua's International Accreditation Programme (IAP) in 2013, both for its Hospital Standards, which were recognized as Accredited Standards, and as an Accredited Organization. In July 2017, the JQ underwent an examination for the purpose of renewing its accreditation. The JQ is therefore itself internationally accredited as a third-party organization operating a third-party hospital evaluation program.

2) 35th ISQua Conference

This conference took place in the Malaysian capital, at Kuala Lumpur Convention Center between Sunday, September 23 and Wednesday, September 26, 2018. It was co-hosted by ISQua and the Malaysian Society for Quality in Health (MSQH) and focused on the theme "Heads, Hearts and Hands: Weaving the Fabric of Quality and Safety." Forecast to be attended by approximately 1,500 people from various countries, with 180 speakers and around 400 poster presentations, it was one of the largest ISQua conferences yet. The following topics were discussed at this conference.

- Third-party evaluation (hospital functions, clinical training programs)
- Quality and safety of medical care in low- and middle-income countries (LMICs)
- Medical safety for the vulnerable (disaster victims; patients with cardiac disease, cerebrovascular disease, or other critical illnesses; end-of-life patients, etc.)
- Patient safety (culture), patient-centered/human-centered medical care, shared decision-making with patients, and policies for achieving these
- Medical care that uses the patient's voice and reports by patients
- The patient's experience (movie)
- Data for improving quality and safety
- Governance, leadership and health policy
- Education and training
- The future of quality and safety (design, preventing burnout, etc.)
- Traditional and Western medicine

Among other matters, the presentations about the Project mentioned that two Medical Safety Information bulletins have focused on inadequate checks concerning diagnostic imaging reports, following reports of such events.

Fig. V-8 Presentations at the 35th ISQua Conference

Title	Speaker	Presentation Format
Prevention of Diagnostic Error on Cancer Imaging Through On-Site Survey Programme of National University Hospital Group	Shin Ushiro	Oral presentation
Wrong administration of solutions in sterile field: occurrences and alert	Misa Sakaguchi	Poster presentation

7. Presentations at the 13th Annual Congress of the Japanese Society for Quality and Safety in Healthcare

The 13th Annual Congress of the Japanese Society for Quality and Safety in Healthcare took place in Nagoya on Saturday, November 24 and Sunday, November 25, 2018. The Congress included a special program to commemorate the Third Global Ministerial Summit on Patient Safety in Tokyo, on the theme "Global Patient Safety Targets and the Role That Japan Should Play." This featured a speech concerning the Project, which covered the matters outlined in "5. The Third Global Ministerial Summit on Patient Safety."

Representatives of the Project also gave the following presentations.

Fig. V-9 Presentations by the Project to Collect Medical Near-miss/Adverse Event Information

Title	Speaker	Presentation Format
Adverse Events Related to Insulin Preparations in Japan	Misa Sakaguchi	Symposium
Analysis of Events Related to Glucose-Insulin (GI) Therapy —Based on Events Reported to the Project to Collect Medical Near-miss/Adverse Event Information—	Mai Onishi	Poster

8. Dissemination of Information Overseas

Due to growing attention from overseas, the JQ and this project have many opportunities to give lectures. We will continue to participate in shaping international trends in medical safety and strive to exert a positive influence through the JQ's projects focused on the quality and safety of medical care and Japanese achievements in the field of medical safety activities.

Fig. V-10 lists the overseas conferences relating to medical safety attended by us in 2018. Details of the specific matters covered at each meeting can be found in the relevant Quarterly Report.

Fig. V-10 International Conferences Attended in 2018

Quarterly Report No.	Conference	Schedule	City
53rd	Third Global Ministerial Summit on Patient Safety	April 13-14	Tokyo, Japan
54th	The National Joint Action for Patient Safety –0X2020 Rally	April 21	Taichung, Taiwan
	2018 BO'AO CN-HEALTHCARE SUMMIT	April 25-28	Boao, China
55th	The 4th WHO Working Group Meeting on Quality Assurance and Improvement of Acupuncture Service	August 7-8	Shenzhen, China
	20th Congress of International Ergonomics Association - Patient Safety for New Medical Generation-Promoting human factors culture in young medical doctors	August 26-30	Florence, Italy
	Lecture at the Obstetrics and Gynecology, Maternal-Infancy Department, Careggi Hospital, University of Florence; conference speech at "ASFISSIA INTRAPARTUM E PARALISI CEREBRALE INFANTILE: INTRAPARTUM ASPHYXIA AND CEREBRAL PALSY," Clinica Mangiagalli -IRCCS Fondaziona Ca'Granda Policlinico di Milano	September 3-4	Florence and Milan, Italy
56th	35th ISQua Conference	September 23-26	Kuala Lumpur, Malaysia

9. Requests for Lectures

In response to requests from medical institutions, pharmacies, and related groups, we give lectures explaining the current status of the project and the content of its output, such as the Quarterly Reports, Annual Reports and Medical Safety Information. Each year, we give around 50 lectures, both within Japan and overseas. We aim to accept as many requests as possible, so if any representatives of medical institutions or related groups would like us to give a lecture, please do contact us.

10. Role as a Support Organization in the Medical Adverse Event Investigation System and Involvement in the System

The medical adverse event investigation system based on the Medical Care Act began operating in 2015. Like this project, this is a publicly funded system operated pursuant to laws and regulations with the objective of preventing the recurrence of medical adverse events. The JQ has been officially announced to be a "medical accident investigation support organization" as part of the medical adverse event investigation system under the Act. Specifically, the JQ has responded to requests for support from medical institutions by giving speeches about the system's achievements and its relationship to this project. The June 2016 revision of the system provided for in the Act saw the introduction of central- and local-level support organization liaison committees. The JQ participates as a member of the central-level Support Organization Liaison Committee. The JQ compiled and published four Recommendations for Preventing Recurrence under this system in 2018, three of which stated that details of events used in preparing the recommendations had been obtained from the Event Search section of the project website.

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