Project to Collect Medical Near-miss/ Adverse Event Information 2019 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

Table of Contents

*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 foundational principles of the Japan Council for Quality Health Care are to carry out projects relating to improving the quality and safety of health care and ensuring reliable medical care from a neutral, scientific perspective, and to contribute to improving the health and welfare of the populace. We believe that an evaluation body's value lies in, among others, building relationships of trust and working in partnership with patients and their family members, medical providers, and all other stakeholders; maintaining fairness, without bias in any direction; and ensuring transparency and fulfilling the duty of accountability to society. These principles and values form the foundations of all the projects that we operate: Hospital Accreditation, Patient Safety Promotion, the Project to Collect Medical Near-miss/Adverse Event Information, the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information, the Medical Information Network Distribution Service (MINDS), and the Japan Obstetric Compensation System for Cerebral Palsy.

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 2019, we have issued 157 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 2019 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 2019 Annual Report, which summarizes the medical near-miss/adverse event information reported between January and December 2019. 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.

In September 2019, we marked the 15th anniversary of the start of this project by renewing our registration as a registered analysis center for a fourth term, in accordance with the Ordinance for Enforcement of the Medical Care Act. We would like to express our deepest gratitude to all the registered medical institutions and other stakeholders. A total of 1,521 medical institutions were participating in this project as of the end of 2019. 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.

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 cooperate with this project while working in busy clinical environments. 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

2019 Annual Report

I

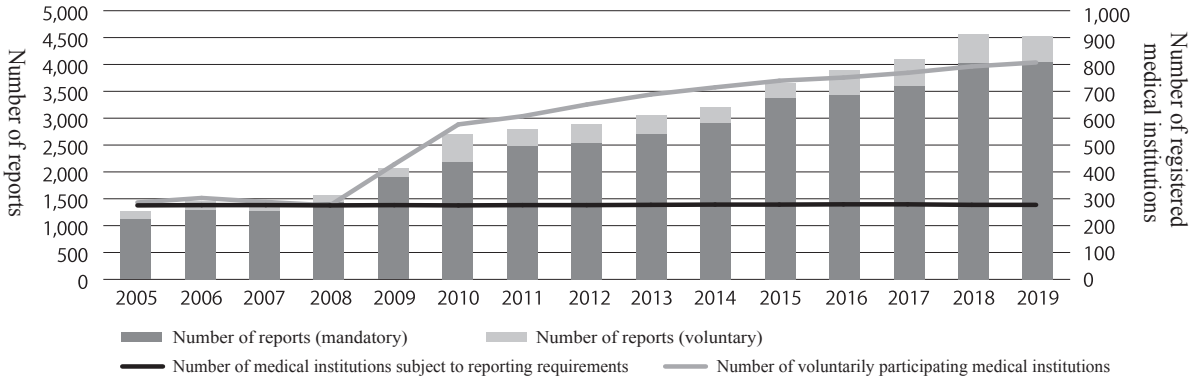
I 2019 Annual Report

1. Number of Registered Medical Institutions and Current Reporting Status

A total of 1,521 medical institutions were participating in this project as of the end of 2019. 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 4,532 reports of medical adverse event information were submitted between January and December 2019, the period covered by this Annual Report. Medical institutions subject to reporting requirements reported 4,049 of these, while voluntarily participating medical institutions reported 483. Fig. I-1 shows the number of reported events between 2005 and 2019. 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 Registered Medical Institutions



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" button on the project website brings up a list of annual and quarterly 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 2019, we made 96 written inquiries to medical institutions and received 95 responses. We asked three medical institutions for permission to carry out on-site visits regarding five events and carried out visits with the cooperation of all the medical institutions concerned. 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 2019.

Fig. I-3 List of On-site Visits

Visit	The type of event	Summary of event
1	Drugs	Event in which three drugs were administered to a patient on a two-drug chemotherapy regimen
2		Event in which the physician forgot to prescribe Predonine Tablets at the time of discharge
3	Blood transfusion	Event in which the patient was administered a blood product without adequate checks
4	Medical device, etc.	Event in which ventilation did not begin because the ventilator was fitted to the patient while in standby mode
5	Examination	Event in which the patient's specimen was mixed in with another patient's when transferring it to a container

*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 2019, the themes selected for the first category were "Events Related to Medical Devices Used at Another Institution or at Home and Brought in at Admission," "Events Related to the Sharing of Drug Allergy Information Using the Electronic Medical Record/Ordering System" and "Events Related to Errors in the Prescription/Ordering of Medicines Brought in at Hospitalization"; details of relevant medical near-miss event information were collected and the results of analysis were published in the 57th to 60th Quarterly Reports. In the second category, eight themes were highlighted. Similar events 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 57th to 60th 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 Medical Devices Used at Another Institution or at Home and Brought in at Admission (2)	57th
[2] Events Related to the Sharing of Drug Allergy Information Using the Electronic Medical Record/Ordering System (1)	58th
[3] Events Related to the Sharing of Drug Allergy Information Using the Electronic Medical Record/Ordering System (2)	59th
[4] Events Related to Errors in the Prescription/Ordering of Medicines Brought in at Hospitalization (1)	60th
【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 Involving Administration at the Wrong Time and Dosage of Drugs Used for Sedation for an Examination or Treatment	57th
[2] Events Related to Mix-ups in Surgical Procedures	
[3] Events Related to External Prescriptions	58th
[4] Events Involving Obstructed Exhalation in Patients with an Endotracheal/Tracheostomy Tube	
[5] Events Involving a Central Venous Catheter Guide Wire Left in the Patient's Body	59th
[6] Events Related to Inadequate Checks of Blood Test Results	
[7] Events Related to Meals/Tube Feeding and Insulin Administration	60th
[8] Events Involving Obstruction of an Internal Shunt Used for Dialysis	

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 2019 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	51
Events Related to Burns (Excluding Burns Sustained During Nursing Care)	32
Event Involving Gauze Left Within the Body	26
Events Involving Administration of Allergic Drug to Patient with Previous Known Allergy History	17
Events Involving the Subcutaneous or Mediastinal Migration of the Patient's Tracheostomy Tube	17
Events Related to Pathology Test Specimens	16
Events Related to Wrong-site Treatment in Dental Consultations	15
Extravascular Leakage in Pediatric Patients	14
Events Related to Beds and Other Objects Used in Patient Care	14
Events Related to Drugs Subject to a Drug Holiday Before an Invasive Procedure	14

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 reported by the medical institutions concerned, so please refer to the 57th to 60th 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.
Drug mix-up due to similar drug names (Medical Safety Information No.4, No.68 (1st Follow-up Report))	57th
Accidental removal of the endotracheal/tracheostomy tube when changing positions (Medical Safety Information No.54)	
Air Embolism after Removal of a Central Venous Catheter (Medical Safety Information No.113)	58th
Events Related to Assisted Reproductive Technology (19th Quarterly Report)	
Surgical Fire Due to Ignition of a Flammable Drug by an Electrosurgical Pencil (Medical Safety Information No.34, No.107 (1st Follow-up Report))	59th
Blood Transfusion to Wrong Patient (Medical Safety Information No.11, No.110 (1st Follow-up Report))	
Burn during assisted bathing (Medical Safety Information No.5) —cases involving neonatal and infant patients—	60th
Catheter or Tube Erroneously Cut with Scissors (Medical Safety Information No.90)	

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 2019, we compiled and published Medical Safety Information No. 146–157 (Fig. I-7). Fig. I-8 shows the recurrent and similar events most commonly reported in 2019 in relation to matters previously highlighted in Medical Safety Information No.1 to No.157.

Fig. I-7 Medical Safety Information released in 2019

Month of information supply	No.	Title
January	No.146	Inadequate checks of Oxygen Remaining (1st Follow-up Report)
February	No.147	Injury from a Wheelchair Footrest
March	No.148	Medical Safety Information released in 2018
April	No.149	Operation/Examination Postponed Due to Delays in Stopping Drugs
May	No.150	Forgetting to Check the Pathologic Diagnosis Report—Upper Gastrointestinal Endoscopy—
June	No.151	Medical Safety Information Highlighted in Quarterly Reports in 2018
July	No.152	Gauze Remaining After Surgery (1)—Gauze Count—
August	No.153	Gauze Remaining After Surgery (2)—Checking the X-ray Image—
September	No.154	Patient Mix-up When Using Electronic Medical Records
October	No.155	Falls from a Pediatric Bed
November	No.156	Incorrect Administration of Injection Drug Used for Sedation
December	No.157	Rectal Injury Due to Glycerin Enema Administered in a Standing Position

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)	22
No.54	Accidental removal of the endotracheal/tracheostomy tube when changing positions	15
No.7	Extravascular leakage in pediatric patients	14
No.132	Patient Falls While Using the Overbed Table for Support	14
No.47	Mix-up of the tooth extraction site	12
No.57 No.82	Accidental ingestion of PTP sheets Accidental ingestion of PTP sheets (1st Follow-up Report)	12
No.147	Injury from a Wheelchair Footrest	11
No. 80 No.142	Urethral Damage Caused by an Indwelling Bladder Catheter Urethral Damage Caused by an Indwelling Bladder Catheter (1st Follow-up Report)	11
No.58	Rupture of the subcutaneous port and catheter	8
No.152	Gauze Remaining After Surgery (1)—Gauze Count—	8
No.15	Wrong pick-up of syringe containing drug	7
No.39	Insufficient confirmation of medicines brought in at hospitalization	7
No.69	Provision of Food to Which the Patient was Allergic	6
No.99	Left-Right Mix-Up When Inserting a Thoracostomy Tube	6
No.144	Failure to Submit a Pathology Specimen	6
No.149	Operation/Examination Postponed Due to Delays in Stopping Drugs	6
No.153	Gauze Remaining After Surgery (2)—Checking the X-ray Image—	6

5. Current Status of the Project

The chapter “V Current Status of the Project” provides various information, including details of the improvements made to the project website in March 2019, 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 offers an overview of the results of questionnaires about this project, as well as outlining academic conference presentations concerning the 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, 2019 are shown below.

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

<table>
<tr><th colspan="3" rowspan="3">Registration status</th><th colspan="4">Project to Collect, Analyze, and Provide Medical Near-miss Event Information</th><th colspan="2" rowspan="3">Total</th></tr>
<tr><th colspan="4">Participating</th><th colspan="2" rowspan="2">Not participating</th></tr>
<tr><th colspan="2">Number of occurrences and medical near-miss event information</th><th colspan="2">Only number of occurrences</th></tr>
<tr><td rowspan="3">Project to Collect, Analyze, and Provide Medical Adverse Event Information</td><td>Required</td><td>Participating</td><td>123</td><td rowspan="2">497</td><td>84</td><td rowspan="2">318</td><td>67</td><td rowspan="2">271</td><td>274</td><td rowspan="2">1,086</td></tr>
<tr><td rowspan="2">Voluntary</td><td>Participating</td><td>374</td><td>234</td><td>204</td><td>812</td></tr>
<tr><td>Not participating</td><td colspan="2">162</td><td colspan="2">273</td><td></td><td colspan="2">435</td></tr>
<tr><td colspan="3" rowspan="2">Total</td><td colspan="2">659</td><td colspan="2">591</td><td colspan="2" rowspan="2">271</td><td colspan="2" rowspan="2">1,521</td></tr>
<tr><td colspan="4">1,250</td></tr>
</table>

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, 2019 is shown below. Reasons for the fluctuation in the number of medical institutions 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	29
	Japan Community Health care Organization	0	41
	Other national organizations	0	0
Municipality	Prefecture	2	21
	City/village	0	89
	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	54
	Saiseikai Imperial Gift Foundation	0	21
	Hokkaido Social Welfare Association	0	2
	National Welfare Federation of Agricultural Cooperatives	0	19
	National Health Insurance Association Federation	0	1
	Health Insurance Union and their associations	0	3
	Mutual Aid Associations and their associations	0	10
	National Health Insurance Society	0	0
Corporation	School juridical organization	53	15
	Healthcare corporation	0	336
	Charitable organization	1	52
	Company	0	11
	Other corporation	0	31
Individual practitioner		0	50
Total		274	812

(Note 1) As of the end of December 2019, 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 22 institutions
B. National Hospital Organizations 141 institutions
C. University hospitals governed by the School Education Act (not including branch hospitals) 110 institutions
D. Special Functioning Hospitals (including those categorized as A, B or C above) 86 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, 2019 is shown below. There were 4,532 reports in 2019.

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

	2019												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of reports made by medical institutions subject to reporting requirement	337	228	468	331	339	334	313	360	273	362	278	426	4,049
Number of reports made by voluntarily participating medical institutions	45	26	20	48	17	45	62	61	32	57	24	46	483
Number of medical institutions subject to reporting requirement	274	274	274	274	274	274	274	274	274	274	274	274	—
Number of voluntarily participating medical institutions	803	804	806	805	804	806	807	807	806	810	811	812	—

(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, 2019 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, 2019, the number of medical institutions subject to reporting requirement was 274, and the total number of beds at those institutions was 139,368.

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, 2019)	Number of reporting medical institutions	Number of reports
			January to December, 2019	January to December, 2019
Government	National University Corporation, etc.	46	42	1,128
	National Hospital Organization	141	126	1,399
	National Research and Development Agencies	8	8	116
	National Hansen's Disease Sanatorium	13	9	45
Municipality	Prefecture	12	11	288
	City/village			
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities			
	Local independent administrative institutions			
Corporation	School juridical organization	53	39	1,035
	Charitable organization	1	1	38
Total		274	236	4,049

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 2019
Government	National University Corporation, etc.	9,444
	National Hospital Organization	15,576
	National Research and Development Agencies	1,432
	National Hansen's Disease Sanatorium	442
Municipality	Prefecture	2,719
	City/village	
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	
	Local independent administrative institutions	
Corporation	School juridical organization	8,792
	Charitable organization	127
Total		38,532

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, 2019)	Number of reporting medical institutions	Number of reports
		January to December, 2019	January to December, 2019
0-19 beds	0	0	0
20-49 beds	14	4	22
50-99 beds	5	2	2
100-149 beds	7	2	6
150-199 beds	9	6	50
200-249 beds	14	10	64
250-299 beds	16	16	127
300-349 beds	29	27	249
350-399 beds	18	16	147
400-449 beds	28	27	321
450-499 beds	17	17	296
500-549 beds	10	6	51
550-599 beds	8	7	83
600-649 beds	25	24	546
650-699 beds	7	7	155
700-749 beds	11	11	256
750-799 beds	5	5	49
800-849 beds	11	11	339
850-899 beds	4	4	150
900-999 beds	13	13	358
1000 beds or more	23	21	778
Total	274	236	4,049

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, 2019)	Number of reporting medical institutions	Number of reports
		January to December, 2019	January to December, 2019
Hokkaido	10	8	64
Tohoku	25	21	199
Kanto/Koshinetsu	85	71	1,408
Tokai/Hokuriku	37	32	523
Kinki	36	29	447
Chugoku/Shikoku	35	34	692
Kyushu/Okinawa	46	41	716
Total	274	236	4,049

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, 2019
0	38
1	14
2	14
3	14
4	6
5	11
6	17
7	8
8	7
9	13
10	11
11-20	63
21-30	27
31-40	8
41-50	9
51-100	12
101-150	1
151-200	0
200 or above	1
Total	274

B. Reporting status of voluntarily participating medical institutions

The number of voluntarily participating medical institutions as of December 31, 2019 and reports made by those institutions between January 1 and December 31, 2019 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, 2019)	Number of reporting medical institutions	Number of reports
		January to December, 2019	January to December, 2019
Government	71	12	54
Municipality	136	32	144
Public medical institution	110	20	54
Corporation	445	66	231
Individual practitioner	50	0	0
Total	812	130	483

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

Parent organization	Number of reports
	October 2004 to December 2019
Government	315
Municipality	1,268
Public medical institution	987
Corporation	2,272
Individual practitioner	8
Total	4,850

[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, 2019. 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 reports
Doctor	2,610
Dentist	70
Nurse	2,677
Assistant nurse	16
Pharmacist	46
Clinical engineer	39
Midwife	20
Nursing assistant	31
Radiological technologist	43
Clinical technologist	21
Registered dietitian	1
Dietitian	4
Cook/kitchen staff	5
Physical therapist (PT)	32
Occupational therapist (OT)	18
Speech -language –hearing therapist (ST)	3
Medical technologist	0
Dental hygienist	1
Dental technologist	1
Others	35
Total	5,673

* 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 events	%
Drugs	346	7.6
Blood transfusion	10	0.2
Treatment/procedure	1,282	28.3
Medical device, etc.	106	2.3
Drainage tubes or other tubes	361	8.0
Examination	260	5.7
Nursing care	1,579	34.8
Others	588	13.0
Total	4,532	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 events	%
Death	315	7.0
High potential of residual disability	463	10.2
Low potential of residual disability	1,353	29.9
No potential of residual disability	1,215	26.8
No disability	1,051	23.2
Unknown	135	3.0
Total	4,532	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 events	%
Accident due to use of contaminated drug/material/ biologic product	6	0.1
Death or disability due to nosocomial infection	1	0
Suicide or suicide attempt of patient	59	1.3
Disappearance of inpatient	7	0.2
Burn of patient	48	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	4,410	97.3
Total	4,532	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 events	%
Internal medicine	340	6.1
Anesthesiology	148	2.6
Cardiovascular medicine	387	6.9
Neurology	138	2.5
Respiratory medicine	247	4.4
Gastrointestinal medicine	361	6.4
Hematology	81	1.4
Circulatory surgery	28	0.5
Allergy	3	0.1
Rheumatism	30	0.5
Pediatrics	281	5.0
General surgery	435	7.8
Orthopedics	696	12.4
Plastic surgery	42	0.7
Cosmetic surgery	1	0
Neurosurgery	267	4.8
Respiratory surgery	94	1.7
Cardiovascular surgery	212	3.8
Pediatric surgery	44	0.8
Pain clinic	2	0
Dermatology	57	1.0
Urology	179	3.2
Venereology	0	0
Proctology	3	0.1
Gynecology/Obstetrics	93	1.7
Obstetrics	15	0.3
Gynecology	47	0.8
Ophthalmology	68	1.2
Otolaryngology	117	2.1
Psychosomatic medicine	3	0.1
Psychiatry	255	4.6
Rehabilitation	41	0.7
Radiology	106	1.9
Dentistry	24	0.4
Orthodontics	2	0
Pediatric dentistry	2	0
Dental/oral surgery	75	1.3
Unknown	6	0.1
Others	672	12.0
Total	5,602	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, 2019 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	29	24
	Japan Community Health care Organization	45	23
	Other national organizations	0	0
Municipality	Prefecture	27	16
	City/village	138	74
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	9	5
	Local independent administrative institutions	26	12
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	22	12
	National Health Insurance Society	1	1
Corporation	School juridical organization	50	34
	Healthcare corporation	445	211
	Charitable organization	54	24
	Company	10	3
	Other corporation	46	21
Individual practitioner		58	39
Total		1,250	659

[2] Information on the Number of Occurrences

The reports of the information on the number of occurrences between January 1 and December 31, 2019 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) Drugs	1,290	8,341	93,621	201,045	304,297
(2) Blood transfusion	102	240	1,862	3,448	5,652
(3) Treatment/procedure	432	2,325	13,560	39,584	55,901
(4) Medical device, etc.	309	1,174	10,755	19,378	31,616
(5) Drainage tubes or other tubes	393	2,198	28,153	109,767	140,511
(6) Examination	407	1,978	29,658	54,314	86,357
(7) Nursing care	569	3,981	57,736	144,192	206,478
(8) Others	757	2,923	49,464	61,312	114,456
Total	4,259	23,160	284,809	633,040	945,268
Re-posted					
[1] Events involving name or dosage form of drug	188	668	6,630	12,736	20,222
[2] Events caused by drug	714	5,096	34,328	81,600	121,738
[3] Events caused by medical device, etc.	212	825	5,384	11,272	17,693
[4] Current theme	155	311	2,021	7,009	9,496

Number of reporting medical institutions	621
Total number of beds	236,278

[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, 2019 is shown below.

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

	2019												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of medical near-miss event information	3,909	1,924	2,076	3,421	1,971	1,184	2,656	1,972	1,608	4,602	1,251	2,033	28,607
Number of participating medical institutions for medical near-miss event information reporting	659	660	660	659	657	660	660	659	657	656	658	659	-

(2) Summary of Event

Fig. II-3-4 Summary of Event

Summary of event	Number of events	%
Drugs	10,339	36.1
Blood transfusion	132	0.5
Treatment/procedure	1,315	4.6
Medical device, etc.	968	3.4
Drainage tubes or other tubes	4,228	14.8
Examination	2,435	8.5
Nursing care	5,100	17.8
Others	4,090	14.3
Total	28,607	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] Lectures and Workshop

We gave lectures and held workshops for participating medical institutions, to inform them about the current status of the project and enhance the quality of reports.

(1) FY2019 Project to Collect Medical Near-miss/Adverse Event Information Lecture Meeting: Sharing and Using Medical Adverse Event Information

1) **Date:** Sunday October 20, 2019
2) **Venue:** Tokyo Medical Association Hall
3) **Target participants:** Staff of registered medical institutions participating in this project
4) **Program**
   i) The Current Status of the Project to Collect Medical Near-miss/Adverse Event Information and Reporting in Practice
   ii) Sharing and Using Medical Adverse Event Information: Enhancing the Quality of Event Reporting—Perspectives of Reporting Medical Institutions—
   iii) Consideration of Medical Adverse Event Information and Individual Events by Expert Analysis Groups
   iv) An Introduction to Kyoto University Hospital's Use of the Medical Safety Information Issued by the Project to Collect Medical Near-miss/Adverse Event Information
   v) Root Cause Analysis (RCA) in Practice
5) **Number of participants**
   A total of 123 people from 84 medical institutions took part.

(2) 11th Workshop on Process Flows and the Project to Collect Medical Near-miss/ Adverse Event Information

1) Date: Saturday February 22, 2020

2) Venue: JQ

3) Target participants: Staff of registered medical institutions participating in this project

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 ordering an MRI examination for an inpatient to checking for metal items before the examination and entering the examination room, participation by medical staff involved in those duties and by staff involved in preparing in-house procedure manuals is preferable.

4) Program

i) Lectures: 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

5) Number of participants

A total of 45 people from 15 medical institutions were scheduled to take part, but a number of medical institutions decided to postpone their attendance, due to the impact of the COVID-19 pandemic, so the workshop was ultimately attended by 24 people from 8 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 2019, we made 96 written inquiries concerning medical adverse event information and received 95 responses. 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	44
Blood transfusions	3
Treatment/procedure	12
Medical device, etc.	6
Drainage tubes or other tubes	6
Examination	6
Nursing care	8
Others	11
Total	96

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

We asked three medical institutions for permission to conduct on-site visits regarding five of the events reported as medical adverse event information and all three granted their cooperation. A list of on-site visits conducted in 2019 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 three drugs were administered to a patient on a two-drug chemotherapy regimen
2		Event in which the physician forgot to prescribe Predonine Tablets at the time of discharge
3	**Blood transfusion**	Event in which the patient was administered a blood product without adequate checks
4	**Medical device, etc.**	Event in which ventilation did not begin because the ventilator was fitted to the patient while in standby mode
5	**Examination**	Event in which the patient's specimen was mixed in with another patient's when transferring it to a container

*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 4 **Event in which ventilation did not begin because the ventilator was fitted to the patient while in standby mode**

Event as reported

Summary of event	Background and causal factors	Improvement measures
The patient, who had been placed on a ventilator due to respiratory failure, was switched to an MRI-compatible paraPAC for an MRI examination, which was then carried out. During the examination, the clinical engineer set the ventilator to standby mode. After the examination, the patient was connected up to the ventilator in standby mode, without adequate checks of its operating condition. The patient's heart rate and SpO_2 subsequently declined and CPR was started. The patient had been connected to the non-functioning ventilator for five minutes. The patient recovered immediately afterwards and, after their condition was confirmed to be stable, they were kept under observation.	• The staff members dealing with the patient were inexperienced (a second-year resident and a first-year nurse) and therefore had deficiencies in their technique/skill. • The nurse had completed a basic ventilator knowledge accreditation course, but there was no education program to enable residents to acquire these techniques/skills. • There were rules about the checks to be carried out before starting the ventilator when reconnecting it, but the staff members did not comply with them. • When ventilators were removed, staff members routinely connected them to a test lung and then reconnected them to patients without carrying out any checks. • There were many items on the checklist and staff often put them off until later. • There was a lack of coordination between staff members, with each thinking the other would probably carry out checks. • Roles were unclear and there was no system of checks conducted aloud.	• The medical institution will put in place a program to ensure that residents take the institution's ventilator accreditation course. • The medical institution will add follow-up training for those who have completed the ventilator accreditation course. • The medical institution will divide the items on the checklist into checks to be carried out when removing the ventilator and checks to be carried out when reconnecting it. It will also create a structure that will enable checks to be divided up into items to be checked when connecting the ventilator and those to be checked afterwards. • The medical institution will determine rules and roles when removing the ventilator and when reconnecting it.

Details of the On-site Visit

Attendees from the Medical Institution

Deputy Hospital Director (Director of the Safety Management Office), Medical Safety Manager (nurse), Pharmaceutical Safety Management Officer (pharmacist), Medical Device Safety Management Officer (clinical engineer), clinical engineer

Findings

1. Lead-up to the event

- The patient was brought in by ambulance after suffering multiple trauma and admitted to a ward in the Emergency and Critical Care Center. The patient had undergone tracheal intubation and been placed on a ventilator (ART-300).
- Due to the patient's prolonged disturbance of consciousness, an MRI examination was carried out on the fifth day of admission.
- At about 11:00, the clinical engineer prepared a paraPAC (MRI-compatible ventilator) for the MRI examination.
- At 11:15, the clinical engineer switched the patient from the ventilator to the paraPAC. They placed the ventilator in standby mode and attached a test lung. They transferred the heart rate and SpO_2 cables to a mobile monitor and the senior physician, resident, and primary nurse took the patient to the MRI room.
- At 12:25, after the MRI had been taken, the resident and the nurse took the patient back to their room. After removing the test lung and handing the ventilator circuit to the resident, the primary nurse left the patient's side to deal with another patient in the adjacent bed. After connecting the ventilator circuit to the endotracheal tube, the resident also left the patient's side.
- At 12:26, when the primary nurse returned to the patient, sputum was emerging from the patient's oral and nasal cavities, so the nurse carried out suction while checking the heart rate and SpO_2 on the mobile monitor.
- At 12:28, the primary nurse continued to carry out suction. The mobile monitor showed that the patient's heart rate had fallen into the 40s and SpO_2 to 60%, with a PEA waveform, and the patient's face was pale, so the nurse started CPR.

• At 12:30, when the lead nurse looked at the ventilator screen, it was in standby mode. The ventilator circuit was removed and ventilation started using a Jackson-Rees circuit.
• At 12:32, the patient's heart rate reached 94 beats per minute, with SpO_2 of 100%.
• At 12:35, the clinical engineer checked the ventilator, confirmed that there were no problems with it, and then fitted it to the patient.

2. Background and causal factors

○ Clinical engineer
• When they switched the patient to the paraPAC, they placed the ventilator in standby mode and attached a test lung, because they thought that the ventilator alarm would keep sounding.
• They did not tell the resident or the primary nurse that they had placed the ventilator in standby mode.

○ Primary Nurse
• Upon returning to the patient's room, they removed the test lung from the ventilator and handed the ventilator circuit to the resident. When doing so, they thought that the resident would check the ventilator screen, so they went to deal with another patient in the adjacent bed without first checking the screen.
• Upon returning to the patient's room, they did not transfer the heart rate and SpO_2 cables from the mobile monitor to the bedside monitor.
• When they returned to the patient after dealing with the other patient in the adjacent bed, sputum was emerging from the patient's oral and nasal cavities, so they carried out suction before checking the ventilator.
• They did not know that the ventilator was in standby mode and thought that it would start operating once the test lung was removed.

○ Resident
• Upon returning to the patient's room, they received the ventilator circuit from the primary nurse and connected it to the endotracheal tube. After connecting it, they left the patient's side without first checking the ventilator screen.
• They were unfamiliar with the screen display in standby mode on the ventilator (ART-300).

○ Ventilators in use on the emergency ward
• At the time of the event, six types of ventilator were deployed on the emergency ward.
[Ventilators with a standby function] ART-300, Servo-s, Savina, V300, PB980
[Ventilator without a standby function] VELA
• The ART-300 and Savina models were added to the ventilators deployed on the ward in order to choose a model to replace the VELA.
• When the ART-300 is in standby mode, the word "standby" is displayed in black katakana characters inside an orange square at the top left of the screen.
• The department held four briefing sessions about the ART-300 and Savina models when they were added to the ventilators deployed on the ward. 10 of the 30 nurses attended those briefing sessions. Physicians did not attend them.

○ Emergency ward
• The ratio of patients to nurses on the emergency ward is 4 to 1.
• There is no clinical engineer deployed to the emergency ward.
• On the emergency ward, staff members' approaches to dealing with switching from a ventilator for an examination, etc. varied, with some staff placing the ventilator in standby mode, while others attached it to a test lung.

○ Other
• The medical institution has a ventilator (IPPV+NPPV) accreditation course for nurses and nurses may not care for patients on ventilators unless they have taken and passed this course. The ventilator accreditation course teaches the basic knowledge and nursing techniques required when caring for patients on ventilators, covering topics that enable nurses to carry out basic checks and handling. There was no systematic training for physicians.
• The $EtCO_2$ monitor is used for about half of all patients. In this event, the $EtCO_2$ value could not be confirmed, because the patient had not been switched over from the mobile monitor.

3. Main improvement measures introduced after reporting the event

• Physicians and the respiratory support team considered the content of a time out to be carried out when fitting a ventilator.
• As it is not possible to standardize such elements as placing the ventilator in standby mode or using a test lung, a decision was taken that the time out should be carried out after fitting the ventilator to the patient.
• The time out to be carried out when fitting a ventilator is described below. The time out was defined as "checking that the ventilator is operating immediately before fitting the ventilator."
1) The time out must be carried out by at least two people (physician + nurse or nurse + nurse), without fail.
2) The following points must be checked aloud.
Immediately before fitting: The standby screen is not displayed
Immediately after fitting: (i) Chest movement (the patient's chest is rising in time with the ventilator's action)
(ii) Tidal volume (read out the actual measurement for tidal volume)
(iii) Check monitor fitted (read out the heart rate and SpO_2 values
3) Timely recording: Enter in the word palette on the electronic medical record.

- The medical institution changed the content of the records of orders and checks during ventilator use from those previously used. It added the following warning: "When fitting the patient with a ventilator again, do so after carrying out the time out and record the following items without delay: 1) ventilation condition settings; 2) alarm settings; 3) checks of monitor values; 4) items on the ventilator circuit and heater-humidifier checklist." The items to be checked under each of the headings 1)-4) above are also described.
- As there is no mechanism for providing residents with education concerning ventilators, the medical institution has decided on a policy of organizing a short course covering the essentials. In addition, the emergency department and clinical training center are taking the lead in considering the curriculum at present and plan to implement the relevant education in due course.

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

○ The content of the time out to be carried out when fitting a ventilator clearly states what is to be done, so it is easy to understand. It would also be advisable to decide who will take the lead in carrying it out. It would be wise, for example, to decide that the lead nurse is to carry it out and to ensure thorough adherence to this practice.
○ One wonders whether there is a rule that a ventilator must not be connected unless the time out is carried out.
● At present, there is no rule that it should not be connected. Rather than connecting the ventilator in standby mode, as in this event, it is safer to ventilate using a paraPAC or Jackson-Rees circuit, so consideration will be given to this matter.
○ One wonders whether an evaluation has been carried out to ensure that the time out is being carried out, without fail.
● At present, there is 100% adherence on the emergency ward, but it is not being implemented in other departments, so no evaluation has been carried out for the medical institution as a whole.
○ Clinical engineers are not among the staff members involved in the time out, but one wonders whether any thought has been given to making use of them in future.
● Consideration is being given to deploying a clinical engineer in the emergency and critical care center's ICU and to having them accompany patients to examinations, etc.
○ Matters concerning the handling of ventilators are hard to cover in undergraduate education, so they end up being dealt with as on-the-job training. It is important to create a mechanism that specifies where and when this education is to be provided.
○ Residents at the medical institution to which the On-site Visitor belongs have expressed the desire to learn about the details of medical adverse events that have actually occurred in clinical practice. As hour-long conferences attended by members of the Safety Management Office are held on each ward once a month at your institution, one wonders whether it might be possible to have residents attend these conferences, to provide opportunities to inform them about events that have occurred at this institution.
● We intend to consider ways to enable residents to attend conferences as part of their education.

Visit 5 **Event in which the patient's specimen was mixed in with another patient's when transferring it to a container**

Event as reported

Summary of event	Background and causal factors	Improvement measures
Surgery for endometrial cancer was performed on Patient A and, as there was a risk of peritoneal dissemination, the physician asked the pathology department to carry out a peritoneal washing cytology examination. At the time of the event, the pathology department's specimen stand held a total of four containers: one containing Patient A's peritoneal washing and three containing pancreatic juice from Patient B. The clinical laboratory technologist (hereinafter, "the technologist") checked with the pathologist whether the three samples of pancreatic juice from Patient B could be combined in a single container and then began to transfer the contents of one of the small containers in the specimen stand into a large container that was also in the stand. While in the midst of this, the technologist noticed that the large container had a printed label bearing the name of Patient A, while the small container had one with Patient B's name, but as the two samples had already become mixed together, it was not possible to use Patient A's sample for a peritoneal washing cytology examination. Patient A was due to undergo about three cycles of chemotherapy, regardless of whether the peritoneal washing tested positive or negative, and there was no impact on the staging of their endometrial cancer, but it was not possible to carry out the test required.	• The patient's name was not properly checked when transferring pancreatic juice from another patient into a different container.	• When preparing specimens, technologists will check the patient's name and say it aloud while processing them. • Technologists will not transfer samples into different containers, but prepare the specified number of specimens individually from the respective containers.

Details of the On-site Visit

Attendees from the Medical Institution

Safety Management Department: Deputy Hospital Director and Departmental Director (physician), nurse GRM, pharmacist GRM, previous nurse GRM; Pathology Department: Departmental Director (physician), pathology department senior technologist (clinical laboratory technologist)

Findings

1. Lead-up to the event

- The samples from Patient A and Patient B were submitted to the pathology department at about the same time.
- There was a specimen stand with room for multiple samples at the reception window and it held the samples from Patient A and Patient B.
- Patient A's peritoneal washing was in a single large container.
- Patient B's pancreatic juice was in three containers, one large and two small.

2. Background and causal factors

○ Situation in the pathology department
- The hospital in question was rebuilt a few years ago, but the pathology department is located in the old hospital building.
- There is little space in the laboratory, with apparatus for processing samples taking up most of the limited room.
- There are many items around the reception window and not enough room to place several specimen stands there.

○ Handling of submitted samples
- Messengers collect specimen containers from around the hospital and submit them to the pathology department.
- Once the samples and request form are delivered together, the technologist checks whether the number of samples matches what is written on the request form. Then the technologist uses the electronic medical record to process the receipt of the samples and places the containers in the specimen stand.
- As both submitted containers and containers whose receipt has been processed are placed in the specimen stand, there were always containers for several patients in the stand.
- Although multiple samples for a single patient are sometimes submitted, there were no rules about how to arrange the samples in the stand, such as dividing them up by patient.

- While it is rare for multiple samples from a single patient to be submitted for the same test, the most common procedure in that situation is to test each of the samples individually or to test only one and discard the other containers. Technologists had not previously consolidated multiple samples into a single container, as was the case in this event.

○ Samples from Patient A and Patient B

- The request form for the test on Patient B's pancreatic juice asked for a test on just one sample, but as the technologist had confirmed with the pathologist that it was fine to combine the three samples into one, they decided to put them all into a single container. The reason why the physician who requested the test had submitted three samples is unknown.
- The big container with Patient A's sample and the two small containers with Patient B's samples were near each other in the specimen stand, while the big container with Patient B's other sample was a little further away. While a label with the relevant patient's name was affixed to all the containers, the writing on the labels on the big containers for Patient A and Patient B was facing away from the technologist processing them.
- The technologist assumed that the three containers near each other were the three containers of Patient B's pancreatic juice and did not check the labels on the containers when removing their lids or transferring their contents to the big container.
- In the process of transferring Patient B's pancreatic juice to the container of Patient A's peritoneal washing, the technologist noticed that the patient names on the labels differed.

3. Main improvement measures introduced after reporting the event

- The pathology department has switched from the specimen stand to grouping each patient's samples in separate paper cups after receiving the specimen containers from the messenger.
- The pathology department has reconfirmed that the technologists will not consolidate samples into a single container if the number of samples on the request form is 1, but multiple containers from the same sample are submitted, and has established this as a procedure.

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

○ While using a paper cup to group samples by patient does make the situation clearer, paper cups are light and could fall over if several samples are placed inside. This also gives rise to concerns that errors could occur when returning fallen specimen containers to the cup. Options for keeping patient samples apart when using a specimen stand include placing a partition between different patients' samples in the stand and establishing clear rules for how they should be lined up.

● They are about the size of a urine sample cup, so a number of other options have also been provided, including larger paper cups and plastic ones. As the samples are sent for processing as they come in, they do not spend a lot of time sitting at the reception window, so the system is working without any problems at the moment.

○ There is no way of clearly identifying where and how errors have been made, because there is no check procedure, so it might be advisable to clarify the operational process.

○ On this occasion, three samples of pancreatic juice were submitted, when the request was for only one to be tested. Rather than having the pathology department process the samples after receiving them, it might be wise to remind the clinical departments submitting the samples of important points to bear in mind when submitting samples and to request their cooperation in terms of ensuring that the number of samples submitted matches the number on which tests have been requested.

● The issue has not been discussed with clinical departments, so consideration will be given to requesting their cooperation going forward.

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 57th to 60th Quarterly Reports, which covered the period under analysis for events reported in 2019.

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 Medical Devices Used at Another Institution or at Home and Brought in at Admission (2)	57th
[2] Events Related to the Sharing of Drug Allergy Information Using the Electronic Medical Record/Ordering System (1)	58th
[3] Events Related to the Sharing of Drug Allergy Information Using the Electronic Medical Record/Ordering System (2)	59th
[4] Events Related to Errors in the Prescription/Ordering of Medicines Brought in at Hospitalization (1)	60th
【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 Involving Administration at the Wrong Time and Dosage of Drugs Used for Sedation for an Examination or Treatment	57th
[2] Events Related to Mix-ups in Surgical Procedures	
[3] Events Related to External Prescriptions	58th
[4] Events Involving Obstructed Exhalation in Patients with an Endotracheal/Tracheostomy Tube	
[5] Events Involving a Central Venous Catheter Guide Wire Left in the Patient's Body	59th
[6] Events Related to Inadequate Checks of Blood Test Results	
[7] Events Related to Meals/Tube Feeding and Insulin Administration	60th
[8] Events Involving Obstruction of an Internal Shunt Used for Dialysis	

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 57th to 60th Quarterly Reports, which covered the period under analysis for events reported in 2019, 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.
Drug mix-up due to similar drug names (Medical Safety Information No.4, No.68 (1st Follow-up Report))	57th
Accidental removal of the endotracheal/tracheostomy tube when changing positions (Medical Safety Information No.54)	
Air Embolism after Removal of a Central Venous Catheter (Medical Safety Information No.113)	58th
Events Related to Assisted Reproductive Technology (19th Quarterly Report)	
Surgical Fire Due to Ignition of a Flammable Drug by an Electrosurgical Pencil (Medical Safety Information No.34, No.107 (1st Follow-up Report))	59th
Blood Transfusion to Wrong Patient (Medical Safety Information No.11, No.110 (1st Follow-up Report))	
Burn during assisted bathing (Medical Safety Information No.5) —cases involving neonatal and infant patients—	60th
Catheter or Tube Erroneously Cut with Scissors (Medical Safety Information No.90)	

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 2019

Medical Safety Information bulletins No.146 to No.157 were issued between January and December 2019.

Fig. IV-2-1 Medical Safety Information released in 2019

Month of information supply	No.	Title
January	No.146	Inadequate checks of Oxygen Remaining (1st Follow-up Report)
February	No.147	Injury from a Wheelchair Footrest
March	No.148	Medical Safety Information released in 2018
April	No.149	Operation/Examination Postponed Due to Delays in Stopping Drugs
May	No.150	Forgetting to Check the Pathologic Diagnosis Report—Upper Gastrointestinal Endoscopy—
June	No.151	Medical Safety Information Highlighted in Quarterly Reports in 2018
July	No.152	Gauze Remaining After Surgery (1)—Gauze Count—
August	No.153	Gauze Remaining After Surgery (2)—Checking the X-ray Image—
September	No.154	Patient Mix-up When Using Electronic Medical Records
October	No.155	Falls from a Pediatric Bed
November	No.156	Incorrect Administration of Injection Drug Used for Sedation
December	No.157	Rectal Injury Due to Glycerin Enema Administered in a Standing Position

V

Current Status of the Project

V Current Status of the Project

This chapter describes the project's achievements in 2019, 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 57th to 60th Quarterly Reports.

1. Dissemination of Information about the Project

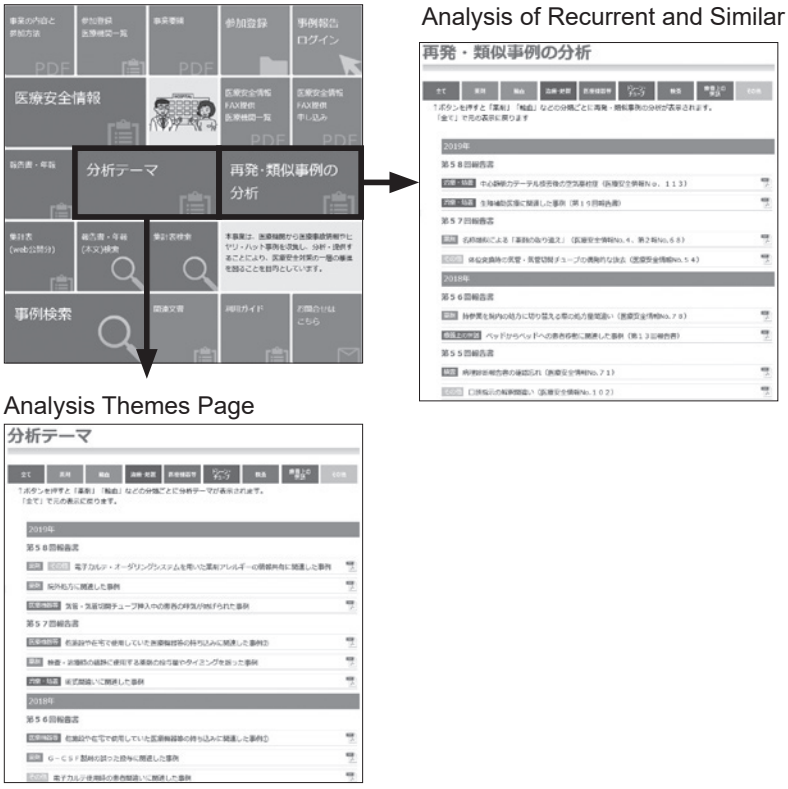
The project prepares and publishes Quarterly Reports, the Annual Report, and monthly Medical Safety Information bulletins, as well as providing a database of events and holding workshops. The pamphlet "Project Activities and How to Participate" (http://www.med-safe.jp/pdf/business_pamphlet.pdf) provides 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 2019, we added color-coded labels indicating the type of event (such as drugs, blood transfusions, etc.) to the website's Analysis Themes and Analysis of Recurrent and Similar Events pages, and also added a function enabling users to display themes by type.

Fig. V-1 Analysis Themes and Analysis of Recurrent and Similar Events Pages on the Website



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 2019. The homepage was accessed 353,949 times in 2019 (Fig. V-2). Event Search was accessed 77,739 times, Medical Safety Information 173,752 times, and Quarterly and Annual Reports 39,173 times (Fig. V-3). These figures show only part of the story, as a variety of different access methods are used to open the Medical Safety Information bulletins and PDFs of the themes analyzed in the quarterly reports.

Fig. V-2 Homepage Access Frequency

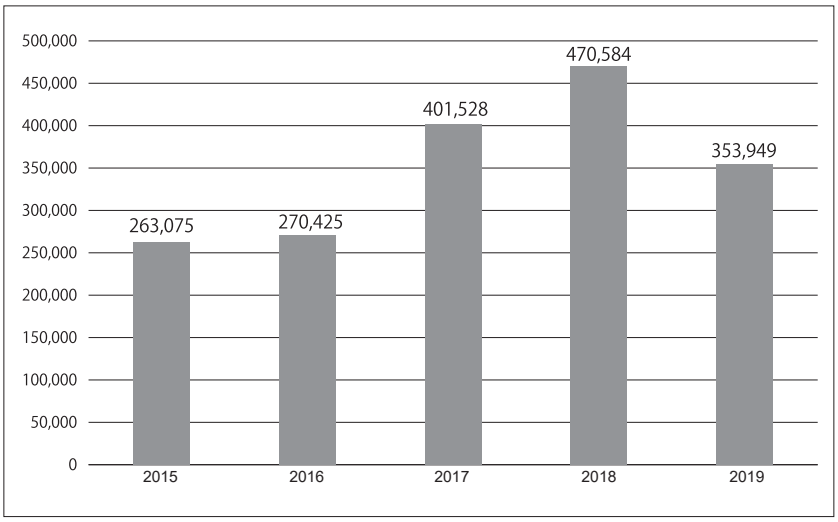
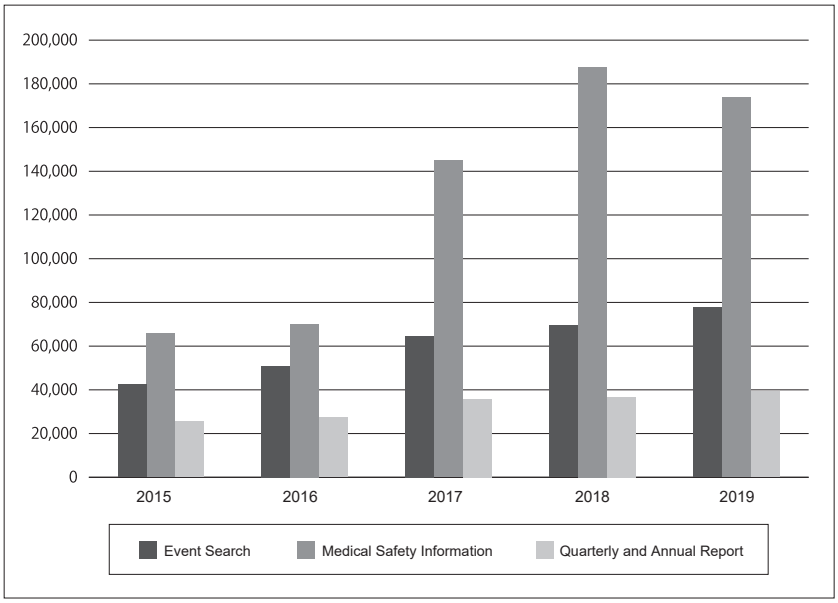


Fig. V-3 Event Search, Medical Safety Information, and Quarterly and Annual Report Page Access Frequency

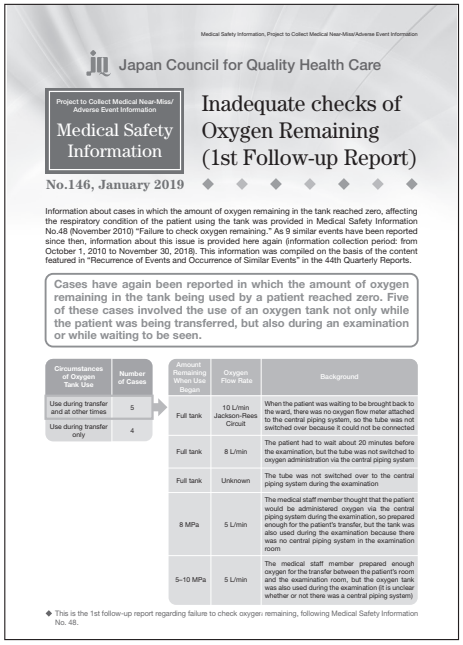


We also investigated how many times each Medical Safety Information issued between January and December 2018 was accessed. Fig. V-4 shows which of those issues had the highest access figures. The number of times an issue is accessed often increases over the course of the month of publication and the 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 Access Frequency of Medical Safety Information Released in 2019

No.	Title	Access Frequency
No.146	Inadequate checks of Oxygen Remaining (1st Follow-up Report)	17,889
No.147	Injury from a Wheelchair Footrest	15,202
No.149	Operation/Examination Postponed Due to Delays in Stopping Drugs	14,793
No.150	Forgetting to Check the Pathologic Diagnosis Report —Upper Gastrointestinal Endoscopy—	11,915
No.148	Medical Safety Information released in 2018	11,607
No.151	Medical Safety Information Highlighted in Quarterly Reports in 2018	11,186
No.154	Patient Mix-up When Using Electronic Medical Records	11,171
No.152	Gauze Remaining After Surgery (1)—Gauze Count—	10,420
No.153	Gauze Remaining After Surgery (2)—Checking the X-ray Image—	10,070
No.156	Incorrect Administration of Injection Drug Used for Sedation	8,793
No.155	Falls from a Pediatric Bed	7,456
No.157	Rectal Injury Due to Glycerin Enema Administered in a Standing Position	4,576

Fig. V-5 Medical Safety Information Accessed the Most in 2019: Medical Safety Information No.146 “Inadequate checks of Oxygen Remaining (1st Follow-up Report)”



Medical Safety Information, Project to Collect Medical Near-Miss/Adverse Event Information

Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

Inadequate checks of Oxygen Remaining (1st Follow-up Report)

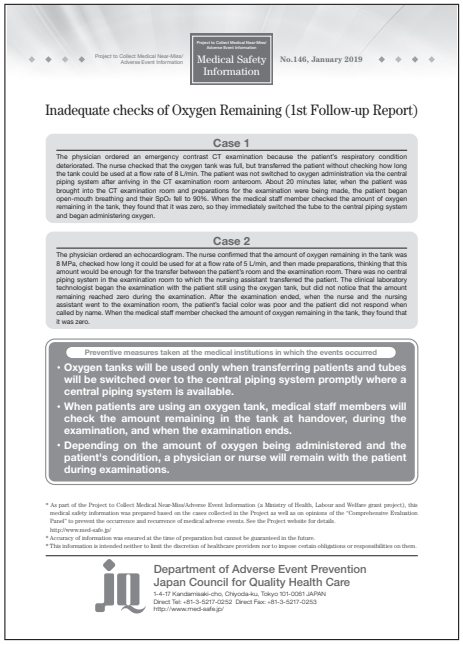
No.146, January 2019

Information about cases in which the amount of oxygen remaining in the tank reached zero, affecting the respiratory condition of the patient using the tank was provided in Medical Safety Information No.48 (November 2010) “Failure to check oxygen remaining.” As 9 similar events have been reported since then, information about this issue is provided here again (information collection period: from October 1, 2010 to November 30, 2018). This information was compiled on the basis of the content featured in “Recurrence of Events and Occurrence of Similar Events” in the 44th Quarterly Reports.

Cases have again been reported in which the amount of oxygen remaining in the tank being used by a patient reached zero. Five of these cases involved the use of an oxygen tank not only while the patient was being transferred, but also during an examination or while waiting to be seen.

Circumstances of Oxygen Tank Use	Number of Cases	Amount Remaining When Use Began	Oxygen Flow Rate	Background
Use during transfer and at other times	5	Full tank	10 L/min Jackson-Rees Circuit	When the patient was waiting to be brought back to the ward, there was no oxygen flow meter attached to the central piping system, so the tube was not switched over because it could not be connected
Use during transfer only	4	Full tank	8 L/min	The patient had to wait about 20 minutes before the examination, but the tube was not switched to oxygen administration via the central piping system
		Full tank	Unknown	The tube was not switched over to the central piping system during the examination
		8 MPa	5 L/min	The medical staff member thought that the patient would be administered oxygen via the central piping system during the examination, so prepared enough for the patient’s transfer, but the tank was also used during the examination because there was no central piping system in the examination room
		5–10 MPa	5 L/min	The medical staff member prepared enough oxygen for the transfer between the patient’s room and the examination room, but the oxygen tank was also used during the examination (it is unclear whether or not there was a central piping system)

◆ This is the 1st follow-up report regarding failure to check oxygen remaining, following Medical Safety Information No. 48.



Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.146, January 2019

Inadequate checks of Oxygen Remaining (1st Follow-up Report)

Case 1

The physician ordered an emergency contrast CT examination because the patient’s respiratory condition deteriorated. The nurse checked that the oxygen tank was full, but transferred the patient without checking how long the tank could be used at a flow rate of 8 L/min. The patient was not switched to oxygen administration via the central piping system after arriving in the CT examination room anteroom. About 20 minutes later, when the patient was brought into the CT examination room and preparations for the examination were being made, the patient began open-mouth breathing and their SpO₂ fell to 90%. When the medical staff member checked the amount of oxygen remaining in the tank, they found that it was zero, so they immediately switched the tube to the central piping system and began administering oxygen.

Case 2

The physician ordered an echocardiogram. The nurse confirmed that the amount of oxygen remaining in the tank was 8 MPa, checked how long it could be used for at a flow rate of 5 L/min, and then made preparations, thinking that this amount would be enough for the transfer between the patient’s room and the examination room. There was no central piping system in the examination room to which the nursing assistant transferred the patient. The clinical laboratory technologist began the examination with the patient still using the oxygen tank, but did not notice that the amount remaining reached zero during the examination. After the examination ended, when the nurse and the nursing assistant went to the examination room, the patient’s facial color was poor and the patient did not respond when called by name. When the medical staff member checked the amount of oxygen remaining in the tank, they found that it was zero.

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

- Oxygen tanks will be used only when transferring patients and tubes will be switched over to the central piping system promptly where a central piping system is available.
- When patients are using an oxygen tank, medical staff members will check the amount remaining in the tank at handover, during the examination, and when the examination ends.
- Depending on the amount of oxygen being administered and the patient’s condition, a physician or nurse will remain with the patient during examinations.

* 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.

Department of Adverse Event Prevention
Japan Council for Quality Health Care
1-4-17 Kandamisaki-cho, Chiyoda-ku, Tokyo 101-0061 JAPAN
Direct Tel: +81-3-5217-0252 Direct Fax: +81-3-5217-0253
http://www.med-safe.jp/

3. Renewing the JQ's Registration as a Registered Analysis Center

The JQ has been operating this project since October 2014 as a registered analysis center that has undergone registration with the Minister of Health, Labour and Welfare, as prescribed by Article 12 of the Ordinance for Enforcement of the Medical Care Act. As the JQ has decided to continue operating this project to contribute to assuring the quality and safety of medical care in Japan, in accordance with our objectives, we renewed our registration as a registered analysis center with the Minister of Health, Labour and Welfare in September 2019. Over the next five-year registration period, we will, with the understanding and cooperation of registered medical institutions, seek to further increase participation and the number of reports by medical institutions, improve the quality of report content, and bring to fruition more examples of improvements through greater use of the information about events that we have gathered.

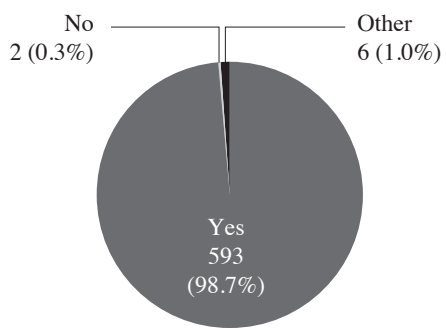
4. Results of a Questionnaire Concerning the Project

As this project marked its 15th anniversary in September 2019, we conducted a questionnaire-based survey among medical institutions participating in the project. Our goal in doing so was to ascertain the extent to which participating medical institutions make use of the information published as part of the project—including Medical Safety Information, quarterly and annual reports, and the event search section of the website—and also to provide data for reference when examining the reporting system. Some of the results concerning the extent to which the published information is used are shown below. The JQ received responses from 601 of the 1,513 registered medical institutions participating in the project at the time of the survey (a response rate of 39.7%). Please note that percentages have been rounded to two decimal places and therefore may not add up to 100.0.

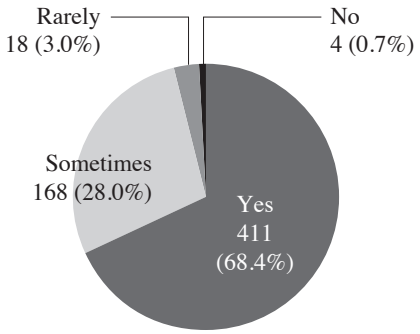
Fig. V-6 Overview of the Results of the Questionnaire Concerning the Project

1) Medical Safety Information

Question 1
Do you find the content of Medical Safety Information useful?



Question 2
Do you use the content of Medical Safety Information in medical safety activities at your institution?



○ If you answered “Yes” or “Sometimes” to Question 2

Question 3 Please specify the issue numbers of Medical Safety Information bulletins that you were able to put to particular use. (Multiple responses permitted)

Rank	No.	Title	Summary of event	Number of responses
1	147	Injury from a Wheelchair Footrest	Nursing care	113
2	146	Inadequate checks of Oxygen Remaining (1st Follow-up Report)	Medical device, etc.	96
2	149	Operation/Examination Postponed Due to Delays in Stopping Drugs	Drugs	96
4	150	Forgetting to Check the Pathologic Diagnosis Report —Upper Gastrointestinal Endoscopy—	Examination	95
5	138	Inadequate Checks Concerning Diagnostic Imaging Reports (1st Follow-up Report)	Examination	92
6	142	Urethral Damage Caused by an Indwelling Bladder Catheter (1st Follow-up Report)	Drainage tubes or other tubes	84
7	152	Gauze Remaining After Surgery (1)—Gauze Count—	Treatment/ procedure	66
8	153	Gauze Remaining After Surgery (2)—Checking the X-ray Image—	Treatment/ procedure	52
9	141	Falls from an Examination Table	Examination	38
10	131	Misunderstanding of Insulin Units (1st Follow-up Report)	Drugs	33

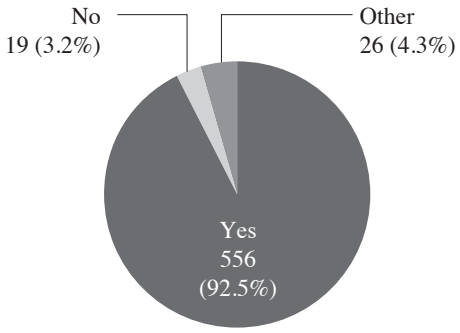
(Top 10)

Question 4 How do you use Medical Safety Information at your institution? (Multiple responses permitted)

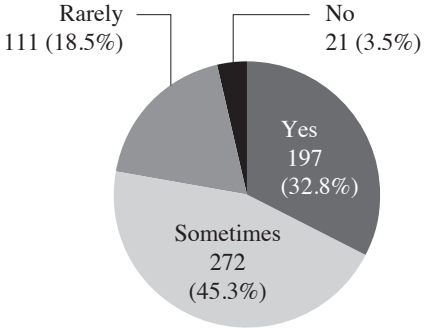
Items selected	Number of responses
Distributed to all staff	408
Distributed to the medical safety committee for use as a resource	356
Distributed to clinical departments or hospital divisions to which the content is relevant	268
Used as reference materials when drawing up or revising manuals	220
Used as reference materials if an adverse event occurs	199
Distributed to staff categories to whom the content is relevant	187
Used as a teaching aid in safety management workshops	182
Printed out and displayed in the medical institution	171
Illustrations/diagrams cut out and/or bulletins otherwise modified for use	109
Used as data when choosing which drugs or medical devices to adopt	29
Used as reference materials for research	12

2) Quarterly and Annual Reports

Question 5
Do you find the content of the Quarterly and Annual Reports useful?



Question 6
Do you use the content of the Quarterly and Annual Reports in medical safety activities at your institution?



○ If you answered “Yes” or “Sometimes” to Question 6

Question 7 How do you use the Quarterly and Annual Reports at your institution? (Multiple responses permitted)

Items selected	Number of responses
Distributed to the medical safety committee for use as a resource	239
Used as reference materials if an adverse event occurs	199
Distributed to clinical departments or hospital divisions to which the content is relevant	182
Used as reference materials when drawing up or revising manuals	177
Used as a teaching aid in safety management workshops	167
Distributed to staff categories to whom the content is relevant	143
Distributed to all staff	99
Used as data when choosing which drugs or medical devices to adopt	28
Quarterly Report notice enclosed with the booklet distributed to staff	21
Used as reference materials for research	17

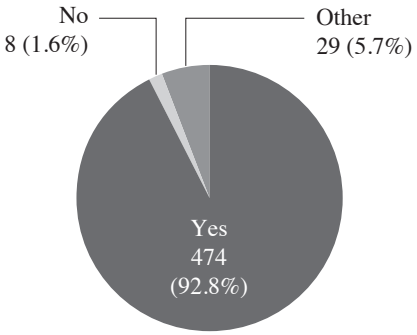
3) Event Search

Question 8 Did you know that the events reported to this project are published on the project website's Event Search page?

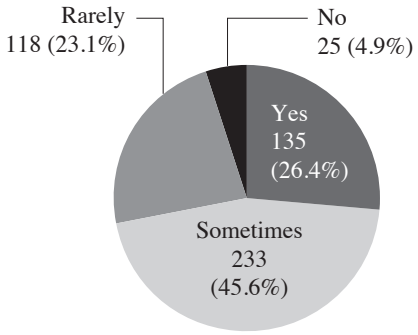
	Number of responses	%
Yes	511	85.0
No	90	15.0
Total	**601**	**100.0**

○ If you answered "Yes" to Question 8

Question 9
Do you find the published event information useful?



Question 10
Do you use the events searchable via the Event Search page in medical safety activities at your institution?



○ If you answered "Yes" or "Sometimes" to Question 10

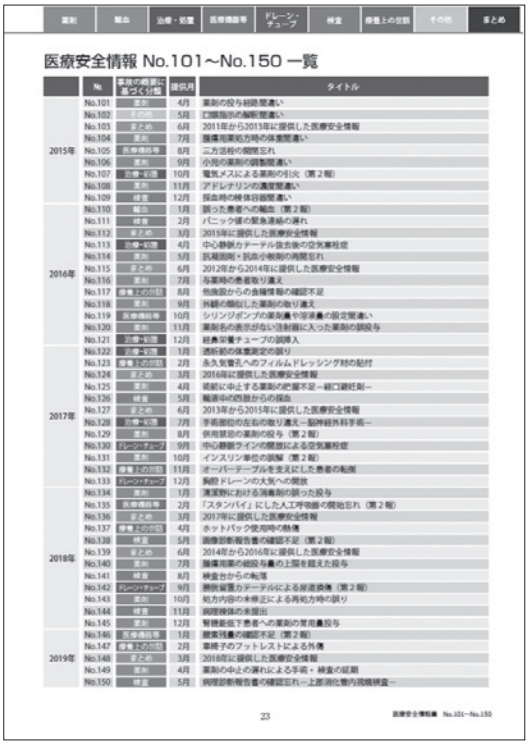
Question 11 How do you use the events searched for via the Event Search page at your institution? (Multiple responses permitted)

Items selected	Number of responses
Used to check the occurrence of similar events if an adverse event occurs	217
Used as a source of information about improvement measures at other institutions if an adverse event occurs	201
Distributed to the medical safety committee as a resource	191
Used as reference materials when compiling information for distribution within the institution	153
Used as a teaching aid in safety management workshops	131
Used as reference materials when drawing up or revising manuals	128
Used as reference materials for research	7

5. Anthology of Medical Safety Information No.101-No.150

The project began issuing Medical Safety Information in December 2006 and, as May 2019 saw the issue of Medical Safety Information No.150, we published the Anthology of Medical Safety Information No.101-No.150 in December 2019.

Fig. V-7 Anthology of Medical Safety Information No.101-No.150



6. Publication of the English-language Editions of the 2018 Annual Report and Medical Safety Information No.144-155

An English-language edition of the Annual Report has been compiled and published on the website every year since the 2005 Annual Report. In mid-March 2020, we published the English translation of this project's 2018 Annual Report, entitled "Project to Collect Medical Near-miss/Adverse Event Information 2018 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.144 to No.155 were published at the middle of March 2020 (Fig. V-8) and can be found on the project website's English page. We hope that you will make use of them.

Fig. V-8 English Editions of Medical Safety Information Published in March 2020

No.	Title in English
No.144	Failure to Submit a Pathology Specimen
No.145	Administration of the Usual Dosage of Drugs for Patients with Impaired Renal Function
No.146	Inadequate checks of Oxygen Remaining (1st Follow-up Report)
No.147	Injury from a Wheelchair Footrest
No.148	Medical Safety Information released in 2018
No.149	Operation/Examination Postponed Due to Delays in Stopping Drugs
No.150	Forgetting to Check the Pathologic Diagnosis Report —Upper Gastrointestinal Endoscopy—
No.151	Medical Safety Information Highlighted in Quarterly Reports in 2018
No.152	Gauze Remaining After Surgery (1)—Gauze Count—
No.153	Gauze Remaining After Surgery (2)—Checking the X-ray Image—
No.154	Patient Mix-up When Using Electronic Medical Records
No.155	Falls from a Pediatric Bed

7. Workshops

The project gives lectures and holds workshops for participating medical institutions to inform them about the current status of the project and encourage high-quality reporting. In October 2019, we gave a lecture on the theme "Sharing and Using Medical Adverse Event Information" and in February 2020, we organized a workshop on preparing process flows.

8. Presentations at the 14th Annual Congress of the Japanese Society for Quality and Safety in Healthcare

The 14th Annual Congress of the Japanese Society for Quality and Safety in Healthcare took place in Kyoto on November 29 and 30, 2019. The Congress included a symposium organized by this department, entitled "Ensuring the Safe Use of Medical Devices: Learning from Past Events."

Fig. V-9 Symposium Details

Ensuring the Safe Use of Medical Devices: Learning from Past Events Chair: Shin Ushiro (Professor, Medical Safety Management Department, Kyushu University Hospital / Director, Department of Adverse Event Prevention, Japan Council for Quality Health Care)	
Topic	**Presenter**
Reporting and Providing Information about Events Involving Medical Devices	Misa Sakaguchi General Manager Department of Adverse Event Prevention Japan Council for Quality Health Care
Ensuring the Safe Use of Medical Devices —Perspectives of Manufacturers and Distributors (Learning from Past Events)—	Tetsuya Sanda Vice Chairperson Safety Information Committee Medical Technology Association of Japan
Why Events Recur: The Use of Past Events Related to Medical Devices and the Status of Education at Medical Institutions—Perspectives of Expert Analysis Group and Comprehensive Evaluation Panel Members—	Junko Ayuzawa Associate Professor Health Care Administration and Management Faculty of Medical Sciences Kyushu University

9. Visit by KOIHA Representatives

On July 23, 2019, staff and other representatives of the Korea Institute of Healthcare Accreditation (KOIHA)—a South Korean third-party evaluation body—visited the JQ to gather information and exchange opinions concerning this project. This was their second visit for this purpose, following one on December 6, 2016. In May 2015, KOIHA representatives visited the JQ to gather information about Hospital Accreditation. Both the JQ and KOIHA have undergone international accreditation by the International Society for Quality in Health Care (ISQua). KOIHA was established in October 2010 as a dedicated healthcare accreditation body, following the 2010 amendment of Article 58 of the Medical Service Act, which prescribed that medical care providers should voluntarily seek accreditation. KOIHA was established as a hub for the healthcare accreditation system and other assessments of medical institutions in order to improve healthcare quality and patient safety, thereby contributing to enhancing and maintaining public health. KOIHA's main duties are (1) tasks required for accreditation, including handling applications for accreditation, evaluating facilities, analyzing the results of evaluation, and deciding on the accreditation rating; (2) providing the support services required to operate accreditation, including dealing with medical facilities' requests for advice; (3) providing support for research, studies, and policymaking relating to the accreditation of medical care providers; (4) conducting accreditation through the integrated evaluation of the services provided by medical care providers as prescribed in other laws; and (5) duties relating to patient safety, including patient safety reporting and the development and operation of learning systems. Thus, like Japan, South Korea's reporting and learning system is an initiative

operated at the national level. According to a speech about KOIHA's patient safety project given by Ms. Hwang In-Sun at the Workshop on Healthcare Accreditation in APEC Region held in Beijing on June 22, 2019, South Korea's Patient Safety Act prescribes the voluntary reporting of patient safety incidents. These reports can be submitted via a website or by post or e-mail. Feedback is provided in the form of alerts to medical institutions from the Minister of Health and Welfare concerning new types of incident and incidents that have the potential to cause severe harm to patients. In addition, KOIHA publishes leaflets about the patient safety system and annual reports providing statistics about patient safety, as well as ensuring thorough awareness of patient safety standards and indicators. Regarding confidentiality, the Patient Safety Act stipulates that information about medical facilities and individuals must be protected and imposes restrictions on the publication of such information. The question and answer session included questions about penalties for failing to report incidents and medical institutions' resistance to the publication of information, suggesting that these are points of contention in the operation of South Korea's adverse event reporting system.

10. 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 2019. Details of the specific matters covered at each meeting can be found in the relevant Quarterly Report.

Fig. V-10 International Conferences Attended in 2019

Quarterly Report No.	Conference	Schedule	Location
58th	Fourth Global Ministerial Summit on Patient Safety	March 2-3	Jeddah, Saudi Arabia
59th	Quality in Healthcare Summit 2019	Match 21	Ireland
	Annual Meeting of the Taiwan Patient Safety Culture Club	April 27	Taiwan
60th	IEA 2nd International Meeting on Patient Safety for New Generation	July 1-2	Lisbon, Portugal

Date of publication: July 3, 2020

Project to Collect Medical Near-miss/Adverse Event Information

2019 Annual Report

Edited and published by: Division of Adverse Event Prevention,
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ISBN978-4-902379-91-4