Project to Collect Medical Near-miss/ Adverse Event Information 2020 Annual Report

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

Division of Adverse Event Prevention

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

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*This Annual Report has been prepared as part of the Project to Collect Medical Near-miss/Adverse Event Information (project subsidized by the Ministry of Health, Labour and Welfare), based on information about medical adverse events gathered by the project and informed by the opinions of members of the Comprehensive Evaluation Panel, for the purpose of preventing the occurrence and recurrence of medical adverse events. Please refer to the project website for details about the purpose of the project. https://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 2020, we have issued 169 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 2020 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 public 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 2020 Annual Report, which summarizes the medical near-miss/adverse event information reported between January and December 2020. We would like to express our sincere gratitude to all those who reported events to this project at a time when medical institutions have been severely impacted by COVID-19.

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 be able to put those parts of this report relevant to the circumstances of their particular medical institution to good use. The JQ also hopes that by reading this Annual Report, the general public—as recipients of medical care—will gain an understanding of the current state of medical adverse events and medical near-misses, as well as efforts by medical institutions and the medical community to prevent their recurrence.

A total of 1,549 medical institutions were participating in this project as of the end of 2020. 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.

The JQ received 4,802 reports of medical adverse event information in 2020. As the number of reports received from medical institutions subject to reporting requirements is increasing year on year, we believe that the practice of reporting such events is becoming firmly established. On the other hand, the number of reports from voluntarily participating medical institutions remains lower than the number from medical institutions subject to reporting requirements. We would like to encourage voluntarily participating medical institutions to take the next step in participating in this project by beginning to report medical adverse event information. 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

2020 Annual Report

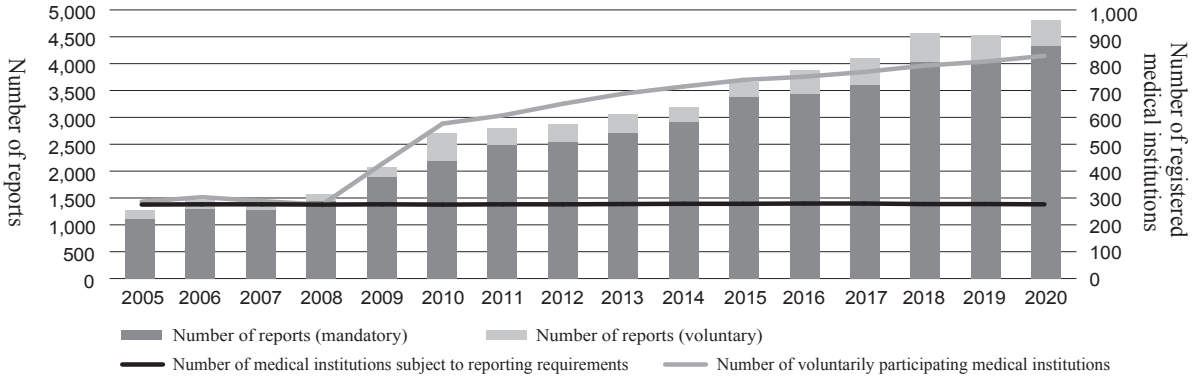
I 2020 Annual Report

1. Number of Registered Medical Institutions and Current Reporting Status

A total of 1,549 medical institutions were participating in this project as of the end of 2020. 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 4,802 reports of medical adverse event information were submitted between January and December 2020, the period covered by this Annual Report. Medical institutions subject to reporting requirements reported 4,321 of these, while voluntarily participating medical institutions reported 481. Fig. I-1 shows the number of reported events between 2005 and 2020. 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 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 2020, we made 86 written inquiries to medical institutions and received 84 responses. We asked two medical institutions for permission to carry out on-site visits regarding three 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. Due to the COVID-19 pandemic, we were unable to carry out on-site visits from March 2020 onward. Section "III-2 [2] Collection of Follow-Up Information via On-site Visits" in this Annual Report provides an overview of on-site visits conducted in January and February 2020. Fig. I-3 provides details of on-site visits carried out in 2020.

Fig. I-3 List of On-site Visits

Visit	The type of event	Summary of event
1	Drugs	Event in which Fycompa tablets were started and the dosage increased in a way that deviated from the usage and dosage on the package insert
2		Event in which a preparation intended for practicing injection technique was subcutaneously injected into a patient
3		Event in which administration of the Opsumit tablets brought in at hospitalization was not continued after admission

*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 2020, the themes selected for the first category were "Events Related to Errors in the Prescription/Ordering of Medicines Brought in at Hospitalization," "Events Related to Patients Undergoing Rehabilitation," and "Events Related to Residents,"; details of relevant medical near-miss event information were collected and the results of analysis were published in the 61st to 64th Quarterly Reports. In the second category, seven 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 relating to such matters as the drugs or medical devices involved was also provided, as appropriate.

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 Errors in the Prescription/Ordering of Medicines Brought in at Hospitalization (2)	61st
[2] Events Related to Patients Undergoing Rehabilitation (1)	62nd
[3] Events Related to Patients Undergoing Rehabilitation (2)	63rd
[4] Events Related to Residents (1)	64th
【2】 Themes selected from medical adverse event information reported during the period under analysis in the quarterly report and used in analyzing past events	
[1] Events Related to Infusion Pump or Syringe Pump Settings	61st
[2] Events Involving Errors in the Selection of a Catheter or Tube Connector	
[3] Events Involving Heparin Preparation Dosage Errors	62nd
[4] Events Involving Provision of an Unexpected Food Item Despite the Selection of a Meal Type Tailored to the Patient's Chewing/Swallowing Function	
[5] Events Involving a Resected Organ or Tissue Left in the Body after Surgery	63rd
[6] Events Related to Burns from a Warmed Towel	
[7] Events Related to COVID-19	64th

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 List of Analysis of Recurrent and Similar Events

Title	Quarterly Report No.
Bone marrow suppression due to antirheumatic (Methotrexate) overdose (Medical Safety Information No.2, No.45 (1st Follow-up Report))	61st
Events relating to intraocular lenses (15th Quarterly Report)	
Vaccination with an Immunization Vaccine Past its Expiry Date (Medical Safety Information No.60)	62nd
Insufficient Understanding of Drugs to be Halted Pre-operatively —Oral Contraceptives— (Medical Safety Information No.125)	
Tubing (catheter/drain) misconnections (Medical Safety Information No.14)	63rd
Events involving failure to communicate the content of the diagnostic imaging report (26th Quarterly Report) —Events in which the physician overlooked the content of the diagnostic imaging report—	
Accidental ingestion of PTP sheets (Medical Safety Information No.57, No.82 (1st Follow-up Report))	64th
Events Related to Tubing Disconnection of Ventilator Circuit (45th Quarterly Report)	

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 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 2020, we compiled and published Medical Safety Information No. 158–169 (Fig. I-6). Fig. I-7 shows the recurrent and similar events most commonly reported in 2020 in relation to matters previously highlighted in Medical Safety Information No.1 to No.169.

Fig. I-6 Medical Safety Information released in 2020

Month of information supply	No.	Title
January	No.158	Administration of a Sustained-Release Preparation in Ground-Up Form
February	No.159	Misconnection Causing Obstructed Exhalation in Patients with an Endotracheal/Tracheostomy Tube
March	No.160	Medical Safety Information Released in 2019
April	No.161	Burns Caused by a Pulse Oximeter Probe
May	No.162	Falls When Transferring to a Bed
June	No.163	Medical Safety Information Highlighted in Quarterly Reports in 2019
July	No.164	Central Venous Catheter Guide Wire Left Behind
August	No.165	Alert Failure Resulting in Administration of a Drug to a Patient Allergic to It
September	No.166	Surgical Procedure Other Than Patient-Consented Procedure Carried Out
October	No.167	Bone Marrow Suppression Due to Antirheumatic (Methotrexate) Overdose (2nd Follow-up Report)
November	No.168	Failure to Check Oxygen Tank Valve Was Open
December	No.169	Omission from Prescription/Order When Continuing Prescription for Current Medicines Brought in at Hospitalization

Fig. I-7 Most Commonly Reported Recurrent and Similar Events Previously the Subject of Medical Safety Information

No.	Title	Number of Events
No.152	Gauze Remaining After Surgery (1) —Gauze Count—	22
No.153	Gauze Remaining After Surgery (2) —Checking the X-ray Image—	20
No.63 No.138	Inadequate Checks Concerning Diagnostic Imaging Reports Inadequate Checks Concerning Diagnostic Imaging Reports (1st Follow-up Report)	19
No.57 No.82	Accidental ingestion of PTP sheets Accidental ingestion of PTP sheets (1st Follow-up Report)	13
No.149	Operation/Examination Postponed Due to Delays in Stopping Drugs	12
No.47	Mix-up of the tooth extraction site	11
No.144	Failure to Submit a Pathology Specimen	11
No.54	Accidental removal of the endotracheal/tracheostomy tube when changing positions	10
No.59	Burns Due to Incorrect Handling of an Electrosurgical Pencil	8
No.23	Wrong input of units on computerized prescription order entry system	7
No.154	Patient Mix-up When Using Electronic Medical Records	7
No.80 No.142	Urethral Damage Caused by an Indwelling Bladder Catheter Urethral Damage Caused by an Indwelling Bladder Catheter (1st Follow-up Report)	6
No.132	Patient Falls While Using the Overbed Table for Support	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 2020, the number of times the website was accessed, and information about the publication of English-language editions of the Annual Report and Medical Safety Information. It also outlines 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, 2020 are shown below.

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

Registration status			Project to Collect, Analyze, and Provide Medical Near-miss Event Information						Total	
			Participating				Not participating			
			Number of occurrences and medical near-miss event information		Only number of occurrences					
Project to Collect, Analyze, and Provide Medical Adverse Event Information	Required	Participating	122	504	85	329	66	274	273	1,107
	Voluntary	Participating	382		244		208		834	
		Not participating	164		278				442	
Total			668		607		274		1,549	
			1,275							

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 requirements and voluntarily participating medical institutions participating in the Project to Collect, Analyze, and Provide Medical Adverse Event Information as of December 31, 2020 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 Requirements and Voluntarily Participating Medical Institutions

Parent organization		Medical institutions subject to reporting requirements(Note 1)	Voluntarily participating medical institutions(Note 2)
Government	National University Corporation, etc.	46	1
	National Hospital Organization	140	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	25
	City/village	0	93
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	9	2
	Local independent administrative institutions	1	24
Parent organization of public medical institution other than municipality	Japan Red Cross	0	55
	Saiseikai Imperial Gift Foundation	0	21
	Hokkaido Social Welfare Association	0	2
	National Welfare Federation of Agricultural Cooperatives	0	19
	National Health Insurance Association Federation	0	1
	Health Insurance Union and their associations	0	2
	Mutual Aid Associations and their associations	0	10
	National Health Insurance Society	0	0
Corporation	School juridical organization	53	18
	Healthcare corporation	0	343
	Charitable organization	1	51
	Company	0	11
	Other corporation	0	33
Individual practitioner		0	53
Total		273	834

(Note 1) As of the end of December 2020, details of the medical institutions subject to reporting requirements (273 institutions) are as follows:
A. National Research and Development Agencies and National Hansen's Disease Sanatorium 22 institutions
B. National Hospital Organizations 140 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) 87 institutions
(Note 2) Voluntarily participating medical institutions are those participating in the project other than medical institutions subject to reporting requirements.

[2] Number of Reports

(1) Number of Monthly Reports

The number of monthly reports made by medical institutions subject to reporting requirements and voluntarily participating medical institutions between January 1 and December 31, 2020 is shown below. There were 4,802 reports in 2020.

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

	2020												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of reports made by medical institutions subject to reporting requirements	335	264	508	384	264	304	329	417	348	467	285	416	4,321
Number of reports made by voluntarily participating medical institutions	32	22	24	49	30	35	49	47	46	74	33	40	481
Number of medical institutions subject to reporting requirements	274	274	274	274	274	274	274	274	273	273	273	273	—
Number of voluntarily participating medical institutions	815	817	820	822	824	824	826	827	827	833	832	834	—

(2) Medical Adverse Event Reporting Status

A. Reporting status of medical institutions subject to reporting requirements

Among medical institutions subject to reporting requirements, the number of reporting medical institutions subject to reporting requirements and the number of reports made by the parent organization between January 1 and December 31, 2020 are shown in Fig. II-2-3, the number of reports made since the launch of the project by the parent organization is shown in Fig. II-2-4, reports by the number of beds are shown in Fig. II-2-5, and reports by region are shown in Fig. II-2-6. In addition, the number 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, 2020, the number of medical institutions subject to reporting requirements was 273, and the total number of beds at those institutions was 138,061.

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

Parent organization		Number of medical institutions (As of December 31, 2020)	Number of reporting medical institutions	Number of reports
			January to December, 2020	January to December, 2020
Government	National University Corporation, etc.	46	42	1,054
	National Hospital Organization	140	132	1,514
	National Research and Development Agencies	8	8	202
	National Hansen's Disease Sanatorium	13	11	50
Municipality	Prefecture	12	11	339
	City/village			
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities			
	Local independent administrative institutions			
Corporation	School juridical organization	53	36	1,078
	Charitable organization	1	1	84
Total		273	241	4,321

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

Parent organization		Number of reports
		October 2004 to December 2020
Government	National University Corporation, etc.	10,498
	National Hospital Organization	17,090
	National Research and Development Agencies	1,634
	National Hansen's Disease Sanatorium	492
Municipality	Prefecture	3,058
	City/village	
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	
	Local independent administrative institutions	
Corporation	School juridical organization	9,870
	Charitable organization	211
Total		42,853

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

Number of beds	Number of medical institutions (As of December 31, 2020)	Number of reporting medical institutions	Number of reports
		January to December, 2020	January to December, 2020
0-19 beds	0	0	0
20-49 beds	14	5	15
50-99 beds	5	4	6
100-149 beds	7	4	12
150-199 beds	9	8	39
200-249 beds	13	10	76
250-299 beds	16	13	113
300-349 beds	29	27	240
350-399 beds	20	16	162
400-449 beds	28	27	347
450-499 beds	16	16	273
500-549 beds	9	9	56
550-599 beds	8	8	99
600-649 beds	26	24	599
650-699 beds	8	7	285
700-749 beds	10	10	249
750-799 beds	5	5	116
800-849 beds	11	11	334
850-899 beds	4	3	74
900-999 beds	13	13	385
1000 beds or more	22	21	841
Total	273	241	4,321

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

Region	Number of medical institutions (As of December 31, 2020)	Number of reporting medical institutions	Number of reports
		January to December, 2020	January to December, 2020
Hokkaido	9	8	64
Tohoku	25	20	277
Kanto/Koshinetsu	85	74	1,557
Tokai/Hokuriku	37	33	545
Kinki	36	32	456
Chugoku/Shikoku	35	33	770
Kyushu/Okinawa	46	41	652
Total	273	241	4,321

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

Number of reports	Number of reporting medical institutions
	As of December 31, 2020
0	33
1	18
2	14
3	12
4	10
5	9
6	11
7	10
8	8
9	10
10	10
11-20	66
21-30	22
31-40	14
41-50	7
51-100	16
101-150	2
151-200	1
200 or above	0
Total	273

B. Reporting status of voluntarily participating medical institutions

The number of voluntarily participating medical institutions and reports made by those institutions between January 1 and December 31, 2020 by the parent organization are shown in Fig. II-2-8 and the number of reports made since the launch of the project by the parent organization is shown in Fig. II-2-9.

Fig. II-2-8 Number of Reporting Voluntarily Participating Medical Institutions and Number of Reports by the Parent Organization

Parent organization	Number of medical institutions (As of December 31, 2020)	Number of reporting medical institutions	Number of reports
		January to December, 2020	January to December, 2020
Government	71	12	31
Municipality	144	31	182
Public medical institution	110	18	44
Corporation	456	63	224
Individual practitioner	53	0	0
Total	834	124	481

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

Parent organization	Number of reports
	October 2004 to December 2020
Government	346
Municipality	1,450
Public medical institution	1,031
Corporation	2,496
Individual practitioner	8
Total	5,331

[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 requirements and voluntarily participating medical institutions) between January 1 and December 31, 2020. 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	2,966
Dentist	73
Nurse	2,713
Assistant nurse	22
Pharmacist	58
Clinical engineer	21
Midwife	27
Nursing assistant	24
Radiological technologist	43
Clinical technologist	13
Registered dietitian	1
Dietitian	2
Cook/kitchen staff	2
Physical therapist (PT)	27
Occupational therapist (OT)	9
Speech -language –hearing therapist (ST)	2
Medical technologist	0
Dental hygienist	2
Dental technologist	0
Others	49
Total	6,054

* 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	387	8.1
Blood transfusion	7	0.1
Treatment/procedure	1,513	31.5
Medical device, etc.	126	2.6
Drainage tubes or other tubes	393	8.2
Examination	261	5.4
Nursing care	1,578	32.9
Others	537	11.2
Total	4,802	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	320	6.7
High potential of residual disability	463	9.6
Low potential of residual disability	1,370	28.5
No potential of residual disability	1,213	25.3
No disability	1,319	27.5
Unknown	117	2.4
Total	4,802	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	9	0.2
Death or disability due to nosocomial infection	3	0.1
Suicide or suicide attempt of patient	61	1.3
Disappearance of inpatient	10	0.2
Burn of patient	53	1.1
Electric shock of patient	0	0
Death or disability of patient due to facility fire	1	0
Handling over of infant to wrong parent	1	0
No applicable option	4,664	97.1
Total	4,802	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	395	6.6
Anesthesiology	204	3.4
Cardiovascular medicine	406	6.8
Neurology	167	2.8
Respiratory medicine	295	4.9
Gastrointestinal medicine	408	6.8
Hematology	94	1.6
Circulatory surgery	33	0.5
Allergy	7	0.1
Rheumatism	26	0.4
Pediatrics	253	4.2
General surgery	449	7.5
Orthopedics	714	11.9
Plastic surgery	51	0.8
Cosmetic surgery	1	0
Neurosurgery	256	4.3
Respiratory surgery	101	1.7
Cardiovascular surgery	262	4.4
Pediatric surgery	47	0.8
Pain clinic	5	0.1
Dermatology	62	1.0
Urology	214	3.6
Venereology	1	0
Proctology	1	0
Gynecology/Obstetrics	91	1.5
Obstetrics	32	0.5
Gynecology	78	1.3
Ophthalmology	62	1.0
Otolaryngology	113	1.9
Psychosomatic medicine	3	0
Psychiatry	241	4.0
Rehabilitation	51	0.8
Radiology	123	2.0
Dentistry	37	0.6
Orthodontics	7	0.1
Pediatric dentistry	2	0
Dental/oral surgery	65	1.1
Unknown	8	0.1
Others	646	10.7
Total	6,011	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, 2020 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.	30	18
	National Hospital Organization	116	67
	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	44	23
	Other national organizations	0	0
Municipality	Prefecture	29	16
	City/village	140	75
	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	82	47
	Saiseikai Imperial Gift Foundation	22	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	51	35
	Healthcare corporation	461	218
	Charitable organization	54	25
	Company	10	3
	Other corporation	46	20
Individual practitioner		61	40
Total		1,275	668

[2] Information on the Number of Occurrences

The reports of the information on the number of occurrences between January 1 and December 31, 2020 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	1,045	7,485	103,117	192,867	304,514
(2) Blood transfusion	119	296	1,964	3,357	5,736
(3) Treatment/procedure	480	2,322	14,415	40,377	57,594
(4) Medical device, etc.	295	1,079	11,904	19,322	32,600
(5) Drainage tubes or other tubes	284	2,661	30,708	106,106	139,759
(6) Examination	371	2,007	30,839	53,821	87,038
(7) Nursing care	511	3,860	59,798	143,186	207,355
(8) Others	557	2,427	53,444	59,042	115,470
Total	3,662	22,137	306,189	618,078	950,066
Re-posted					
[1] Events involving name or dosage form of drug	155	724	6,758	11,963	19,600
[2] Events caused by drug	642	4,214	38,413	79,612	122,881
[3] Events caused by medical device, etc.	196	799	5,960	11,102	18,057
[4] Current theme	186	604	4,061	6,960	11,811

Number of reporting medical institutions	640
Total number of beds	242,104

[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, 2020 is shown below.

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

	2020												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of medical near-miss event information	4,235	580	1,263	3,597	1,318	1,620	3,704	1,120	1,814	4,857	779	812	25,699
Number of participating medical institutions for medical near-miss event information reporting	660	661	661	660	660	659	660	661	659	665	666	668	-

(2) Summary of Event

Fig. II-3-4 Summary of Event

Summary of event	Number of events	%
Drugs	9,107	35.4
Blood transfusion	125	0.5
Treatment/procedure	1,187	4.6
Medical device, etc.	842	3.3
Drainage tubes or other tubes	3,912	15.2
Examination	2,259	8.8
Nursing care	4,909	19.1
Others	3,358	13.1
Total	25,699	100.0

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

III

Current Analysis of Medical Near-miss/Adverse Event Information

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

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

1. Project Overview

[1] Information to be Analyzed

Events with information related to predetermined themes were selected from among the medical adverse event information and medical near-miss event information reported during the period under analysis in each quarterly report and then analyzed. In addition, if additional analysis was deemed necessary, past events outside the period under analysis in the quarterly report were selected and analyzed in the same way, after first determining the period to be examined.

[2] Analysis System

At meetings held once a month or so, Expert Analysis Groups consisting of medical professionals involved in medical safety and experts in safety management review the main medical adverse event information reported through this project and consider the content of themes for analysis. Theme-specific Expert Analysis Groups are established to conduct analysis, based on the field of expertise involved in the events. This department then compiles these analyses and, after review by the Comprehensive Evaluation Panel, publishes information about them.

[3] Workshop

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

FY2020 Project to Collect Medical Near-miss/Adverse Event Information Workshop on RCA and Developing Countermeasures

1) **Date:** Sunday January 24, 2021
2) **Format:** Online
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) Gathering the Information Required to Analyze Events
   iii) RCA in Practice and Key Points
   iv) Key Points to Remember When Developing Countermeasures
5) **Number of participants**
   450 people took part.

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 2020, we made 86 written inquiries concerning medical adverse event information and received 84 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	37
Blood transfusions	3
Treatment/procedure	7
Medical device, etc.	8
Drainage tubes or other tubes	8
Examination	5
Nursing care	9
Others	9
Total	86

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

In 2020, we asked two medical institutions for permission to conduct on-site visits regarding three events and both granted their cooperation. Due to the COVID-19 pandemic, we were unable to carry out on-site visits from March onward. A list of on-site visits conducted in January and February 2020 is provided in Fig. III-2-2, while an overview of one of these visits is 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 Fycompa tablets were started and the dosage increased in a way that deviated from the usage and dosage on the package insert
2		Event in which a preparation intended for practicing injection technique was subcutaneously injected into a patient
3		Event in which administration of the Opsumit tablets brought in at hospitalization was not continued after admission

*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 1 **Event in which Fycompa tablets were started and the dosage increased in a way that deviated from the usage and dosage on the package insert**

Event as reported

Summary of event	Background and causal factors	Improvement measures
After being treated with E Keppra for I.V. Infusion, the patient was switched to E Keppra Tablets, but as partial temporal lobe seizures were observed, the emergency physician consulted the neurologist about combined use of the drug with another attack. The neurologist suggested using Fycompa tablets or Vimpat Tablets as a concomitant drug and the emergency physician chose Fycompa tablets. The emergency physician did not check the dosage when doing so. Fycompa tablets should be started at 2 mg 1 time/day and the dosage increased by 2 mg at a time with an interval of at least a week between changes when used in combination with another drug. However, as the emergency physician wanted the drug to take effect as soon as possible, they began with a dosage of 4 mg 1 time/day, in the knowledge that this deviated from the dosage indicated on the package insert. The ward pharmacist noticed that the dosage deviated from that on the package insert, but assumed the emergency physician had checked the dosage of Fycompa tablets with the neurologist and therefore did not submit an inquiry about the prescription to the emergency physician. As partial seizures were still being observed on the third day of administering Fycompa tablets, the physician increased the dose to 8 mg 1 time/day from the fourth day, whereupon the partial seizures were found to have stopped and the patient was discharged on the fifth day. From the time of discharge, the patient had ongoing symptoms including lightheadedness and difficulty in engaging with conversation. On the eighth day after discharge, the patient was talking incoherently and appeared confused, so a family member took them to the hospital's neurology department for an unscheduled consultation. The neurologist thought that the patient's disorientation and other symptoms were due to an overdose of Fycompa tablets, so the patient was admitted as an emergency.	• The emergency physician wanted the Fycompa tablets to take effect sooner, so they ordered a usage and dosage that deviated from that indicated on the package insert. • The emergency physician did not state on the written records their reasons for deciding to start the drug at a higher dosage than the indicated initial dosage. • The emergency physician did not have any knowledge of Fycompa tablets, which they were unaccustomed to using. • The ward pharmacist noticed that the dosage deviated from that on the package insert, but assumed both clinical departments had considered the dosage and therefore did not submit an inquiry about the prescription. • The nurse was aware that Fycompa tablets are an anticonvulsant. As the nurse had prior experience of using two anticonvulsants as combination therapy, they administered the Fycompa tablets without checking the package insert.	• When physicians in one clinical department consult another clinical department, they will not only select a drug, but also check its usage and dosage, and note the details on the medical records. • Even in cases where the prescribing physician has consulted a specialist clinical department, pharmacists will submit an inquiry about a prescription if the prescription deviates from the package insert. • Medical staff will check the package inserts of drugs that they do not usually use. • The pharmaceutical department will hold workshops for physicians and nurses concerning Fycompa tablets and other new anticonvulsants.

Details of the On-site Visit

Attendees from the Medical Institution

Deputy Hospital Director (in charge of medical safety), Medical Safety Promotion Office: Director (physician), 3 nurses, 1 pharmacist, 2 members of clerical staff, physician from the Emergency and Critical Care Center, Pharmaceutical Department: 2 pharmacists, Nursing Department: 3 nurses

Findings

1. Lead-up to the event

- The patient underwent tracheal intubation due to status epilepticus and was admitted to EICU with the emergency department as the primary clinical department. The patient was extubated the day after admission.
- On the day after admission, Emergency Physician A ordered the dosage of E Keppra for I.V. Infusion to be increased. At that time, the ward pharmacist submitted an inquiry about the prescription, due to the possibility of an overdose, as the patient had reduced renal function. As a result, the physician decided to reduce the dosage of E Keppra for I.V. Infusion.
- On the second day after admission, Emergency Physician A consulted the neurologist to see whether it would be advisable to use another anticonvulsant as well, given that the dosage of E Keppra for I.V. Infusion had been reduced. The neurologist suggested using Vimpat Tablets or Fycompa tablets as a concomitant drug. The physicians from the two clinical departments did not consider usage and dosage at that time and the emergency physician started the patient on Fycompa tablets at 4 mg/day.
- On the fourth day after admission, the emergency physician increased the dosage of Fycompa tablets to 8 mg/day. The convulsions stopped and the physician explained to the patient's family that the patient would be discharged two days later. As that day was a holiday, there was no intervention by the ward pharmacist.
- On the day of discharge, the nurse asked the ward pharmacist to provide discharge guidance. The ward pharmacist provided discharge guidance and handed the drugs over to the patient.

2. Background and causal factors

○ Emergency Physician A: duty physician (4 years and 4 months of professional experience, assigned to the department for 2 years and 4 months)
- They had no experience of providing treatment in the neurology department and joined the emergency department after their two-year residency.
- To check the type of drug to be administered, they consulted the neurologist regarding the concomitant use of anticonvulsants.
- After consulting the neurologist, Emergency Physician A looked at the package insert for Fycompa tablets and, after asking Emergency Physician B's advice, decided to start the patient on Fycompa tablets at 4 mg/day and asked Emergency Physician C to enter the prescription.
- While E Keppra for I.V. Infusion was often used in the emergency department, Fycompa tablets were rarely used. It is unclear how much knowledge Emergency Physician A had regarding Fycompa tablets.
- Physicians in the emergency department sometimes administer antibiotics in excess of the dosage indicated on the package insert, so Emergency Physician A may have thought that anticonvulsants could similarly be administered at doses higher than those indicated on the package insert.

○ Emergency Physician B: attending physician (19 years and 4 months of professional experience, assigned to the department for 9 years and 4 months)
- When approached by Emergency Physician A for advice regarding the choice of anticonvulsant, Emergency Physician B ordered Fycompa tablets at 4 mg/day.
- While they were aware that this deviated from the usage and dosage indicated on the package insert, they wanted to stop the patient's seizures as soon as possible.

○ Emergency Physician C: resident (4 months of professional experience, assigned to the department for 2 months)
- While they were aware that this deviated from the usage and dosage indicated on the package insert, they prescribed the drug in accordance with Emergency Physician A's order.

○ Neurologist
- When consulted by Emergency Physician A, they wrote the following on the medical records: "Patient currently on LEV (E Keppra) 2,000 mg, but has renal dysfunction. I was asked about gradually increasing the dosage or concomitant use with another drug. New anticonvulsants such as LCM (Vimpat) or PER (Fycompa) will be considered to deal with partial seizures. I commented that one of these might be advisable, as Lamictal takes time to have an effect."
- As Emergency Physician A had not asked about the usage and dosage, they did not reply.
- Ward pharmacist
- One ward pharmacist is assigned per ward.
- They looked at the notes on the medical records regarding the consultation with the neurologist and assumed that the neurologist had also issued an order regarding the usage and dosage, so did not submit an inquiry about the prescription.
- On the day of discharge, the nurse asked them to provide discharge guidance. As the patient had been kept waiting, the ward pharmacist was hurrying and provided discharge guidance without noticing that the dosage of Fycompa tablets had been increased to 8 mg/day on the fourth day of administration.

- When recording the discharge guidance afterwards, the ward pharmacist was aware of the dosage increase in Fycompa tablets and that the interval between dosage increases was shorter than indicated. However, they did not check this matter with the physician.

○ Nurse
- They asked the ward pharmacist to provide discharge guidance, because few patients are discharged home from the emergency department and the patient was taking Fycompa tablets.

○ Consultation system
- When physicians in the emergency department consult colleagues in other clinical departments, the consultations often take place verbally. The consultation in this case was carried out by telephone.
- While the medical institution in question has a standardized form for consultations, it was not used.

○ Other
- The patient was not being administered any drugs that would have interacted with Fycompa tablets.

3. Main improvement measures introduced after reporting the event
- When interdepartmental consultations take place, physicians will record the content of both the request and the response. In particular, in the case of anticonvulsants and other high-risk drugs that they are not accustomed to using, physicians will also check the usage and dosage as appropriate.
- In the event of any doubts about the use of a drug, pharmacists will submit an inquiry about the prescription.
- The pharmaceutical department will continue to play a central role in considering the development of a system that will, as far as possible, enable pharmacists to provide discharge guidance regarding high-risk drugs such as anticonvulsants and drugs requiring particular care.
- The Medical Safety Promotion Office and the Pharmaceutical Department prepared materials concerning the proper use of anticonvulsants and ward pharmacists held workshops for physicians in each clinical department and nurses in the emergency ward and EICU.

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

○ One wonders about the extent of discharge guidance provided by ward pharmacists.

● The discharge guidance provided is not adequate, as there are not enough pharmacists. At this hospital, there are two wards on one floor, with one ward pharmacist assigned to each ward. It would be preferable to be able to station three ward pharmacists on a single floor.

○ When recording the discharge guidance afterwards, the ward pharmacist was aware of the dosage increase in Fycompa tablets and that the interval between dosage increases was shorter than indicated. One wonders whether they took any action in response after that. For example, it would have been helpful if they had checked when the patient's next outpatient consultation with the physician was scheduled and whether Fycompa tablets 8 mg/day was the right maintenance dose.

● The ward pharmacist did not check with the physician or take any further action in response.

● Even if the pharmacist had submitted an inquiry about the prescription regarding the fact that the prescribed usage and dosage of the anticonvulsant deviated from that indicated on the package insert, it is not uncommon for prescribing physicians not to alter their prescription in such circumstances.

○ In the event of future inquiries about prescriptions for Fycompa tablets, pharmacists will be able to mention the summary of this event, but it might be more difficult in the case of other anticonvulsants.

● A system enabling multiple physicians and pharmacists to conduct checks regarding high-risk drugs will be created. In addition, the hospital has decided that, in the event that a new anticonvulsant is prescribed, pharmacists will submit an inquiry about the prescription to the physician and will record the details thereof.

○ It would seem important for the hospital as a whole to address such matters as providing explanations to patients, obtaining consent, and the details that should be recorded in writing when it comes to the off-label use of drugs and unapproved drugs.

● Physicians must go through an internal application procedure for off-label use and the pharmaceutical department collates this information.

○ While workshops on anticonvulsants have been held for physicians in each clinical department, one wonders how many physicians actually have the opportunity to prescribe anticonvulsants. Thinking in terms of cost-effectiveness, it might be advisable to adopt such approaches as asking physicians in the relevant specialist field to prescribe them. The emergency department started the patient on anticonvulsants and increased the dosage, but one wonders whether any consideration was given to transferring the patient to the neurology department. At the medical institution to which the On-site Visitor belongs, the emergency department issues the first prescription, but the neurology department issues prescriptions thereafter.

● As the patient had undergone tracheal intubation, the emergency department was the primary clinical department. Consideration will be given to having the emergency department manage the patient's general condition, with the relevant specialist clinical department handling prescriptions for special drugs and the like.

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 61st to 64th Quarterly Reports, which covered the period under analysis for events reported in 2020.

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 Errors in the Prescription/Ordering of Medicines Brought in at Hospitalization (2)	61st
[2] Events Related to Patients Undergoing Rehabilitation (1)	62nd
[3] Events Related to Patients Undergoing Rehabilitation (2)	63rd
[4] Events Related to Residents (1)	64th
【2】 Themes selected from medical adverse event information reported during the period under analysis in the quarterly report and used in analyzing past events	
[1] Events Related to Infusion Pump or Syringe Pump Settings	61st
[2] Events Involving Errors in the Selection of a Catheter or Tube Connector	
[3] Events Involving Heparin Preparation Dosage Errors	62nd
[4] Events Involving Provision of an Unexpected Food Item Despite the Selection of a Meal Type Tailored to the Patient's Chewing/Swallowing Function	
[5] Events Involving a Resected Organ or Tissue Left in the Body after Surgery	63rd
[6] Events Related to Burns from a Warmed Towel	
[7] Events Related to COVID-19	64th

4. Analysis of Recurrent and Similar Events

A section entitled Individual Theme Review appeared in the 1st to 49th Quarterly Reports for this project 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. The Analysis of Recurrent and Similar Events section of the quarterly reports highlights recurrent and similar events to those previously highlighted in Themes Analyzed and Medical Safety Information, providing information once more.

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

The Analysis of Recurrent and Similar Events section of the 61st to 64th Quarterly Reports, which analyzed events reported in 2020, 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. Figure III-4-1 lists the types of events analyzed in the quarterly reports.

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

Title	Quarterly Report No.
Bone marrow suppression due to antirheumatic (Methotrexate) overdose (Medical Safety Information No.2, No.45 (1st Follow-up Report))	61st
Events relating to intraocular lenses (15th Quarterly Report)	
Vaccination with an Immunization Vaccine Past its Expiry Date (Medical Safety Information No.60)	62nd
Insufficient Understanding of Drugs to be Halted Pre-operatively —Oral Contraceptives— (Medical Safety Information No.125)	
Tubing (catheter/drain) misconnections (Medical Safety Information No.14)	63rd
Events involving failure to communicate the content of the diagnostic imaging report (26th Quarterly Report) —Events in which the physician overlooked the content of the diagnostic imaging report—	
Accidental ingestion of PTP sheets (Medical Safety Information No.57, No.82 (1st Follow-up Report))	64th
Events Related to Tubing Disconnection of Ventilator Circuit (45th Quarterly Report)	

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 in the following three categories:

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 other than those in categories 1) and 2) above, which have requested that information be provided by fax

2. Medical Safety Information Released in 2020

Medical Safety Information bulletins No.158 to No.169 were issued between January and December 2020.

Fig. IV-2-1 Medical Safety Information released in 2020

Month of information supply	No.	Title
January	No.158	Administration of a Sustained-Release Preparation in Ground-Up Form
February	No.159	Misconnection Causing Obstructed Exhalation in Patients with an Endotracheal/Tracheostomy Tube
March	No.160	Medical Safety Information Released in 2019
April	No.161	Burns Caused by a Pulse Oximeter Probe
May	No.162	Falls When Transferring to a Bed
June	No.163	Medical Safety Information Highlighted in Quarterly Reports in 2019
July	No.164	Central Venous Catheter Guide Wire Left Behind
August	No.165	Alert Failure Resulting in Administration of a Drug to a Patient Allergic to It
September	No.166	Surgical Procedure Other Than Patient-Consented Procedure Carried Out
October	No.167	Bone Marrow Suppression Due to Antirheumatic (Methotrexate) Overdose (2nd Follow-up Report)
November	No.168	Failure to Check Oxygen Tank Valve Was Open
December	No.169	Omission from Prescription/Order When Continuing Prescription for Current Medicines Brought in at Hospitalization

V

Current Status of the Project

V Current Status of the Project

This chapter describes the project's achievements in 2020, along with activities and outcomes associated with the project. It mainly provides a summary of the "V Current Status of the Project" section of the 61st to 64th Quarterly Reports.

1. Dissemination of Information about the Project

The project 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" (https://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 reports, annual reports, analyses of themes, analyses of recurrent and similar events, and Medical Safety Information, as well as a searchable database of events. In 2020, we added a custom search function to the website's homepage and reviewed the items displayed on the homepage (Fig. V-1). We also redesigned the Quarterly Reports, Annual Reports, Themes Analyzed, Analysis of Recurrent and Similar Events, and Medical Safety Information pages to display the latest publication and past publications in a more user-friendly manner. The Themes Analyzed page is shown below as an example (Fig. V-2). The Event Search page now allows users to search medical near-miss/adverse event information by year reported (Fig. V-3). The Table Search page now allows users to select the name of the table to be searched and also to search and display all the tables of the type selected within a specified period (Fig. V-4).

Fig. V-1　Website Homepage

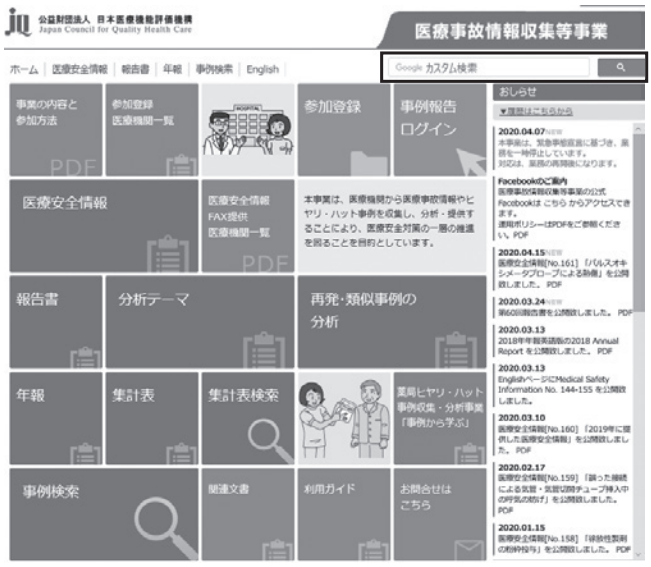


Fig. V-2　Display of Publications (Themes Analyzed)

Fig. V-3　Event Search Page

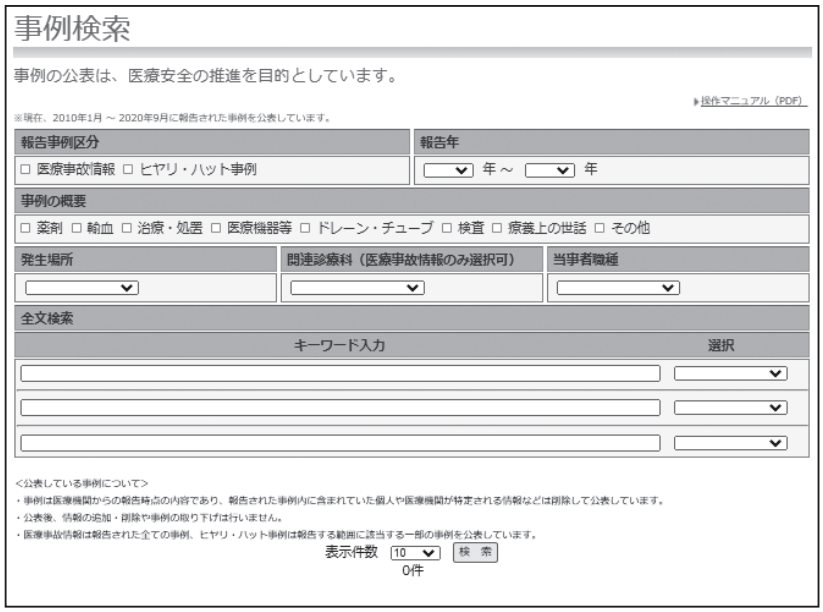


Fig. V-4　Table Search Page

2) Website Access Figures

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 products 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, Quarterly Reports, and Annual Reports buttons on the website between January and December 2020. The homepage was accessed 237,041 times in 2020 (Fig. V-5). Event Search was accessed 76,467 times, Medical Safety Information 130,555 times, Quarterly Reports 39,723 times, and Annual Reports 11,905 times (Fig. V-6). In 2020, we also improved the website by dividing the Quarterly and Annual Reports page into separate Quarterly Reports and Annual Reports pages. These figures show only part of the access data, as there are a variety of different ways to access the Medical Safety Information bulletins and the themes analyzed in the quarterly reports.

Fig. V-5　Homepage Access Frequency

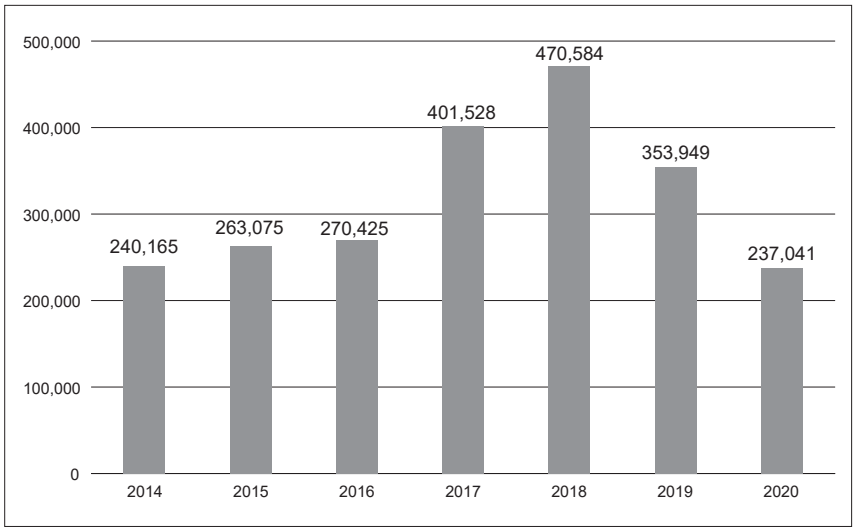


Fig. V-6 Event Search, Medical Safety Information, Quarterly Report, and Annual Report Page Access Frequency

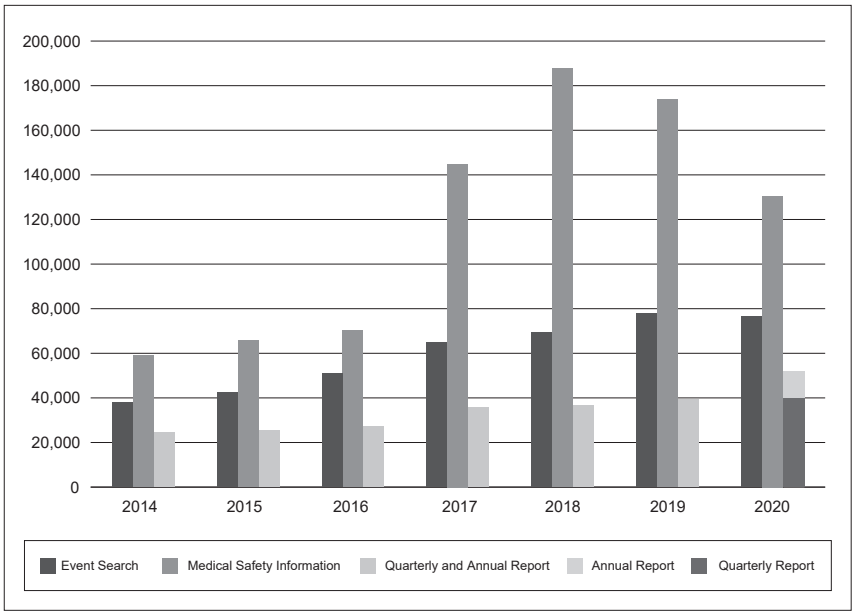
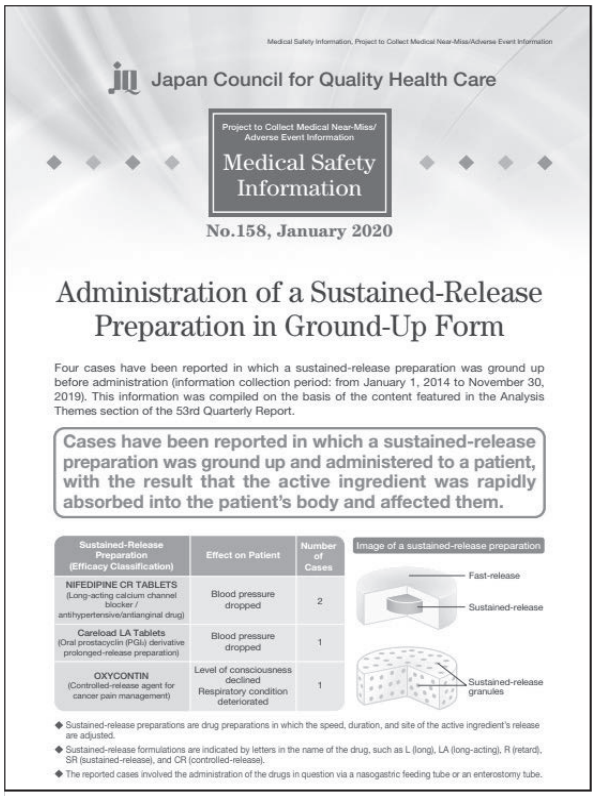


Fig. V-7 shows how many times each Medical Safety Information issued between January and December 2020 (No.158-No.169) was accessed. The number of times an issue is accessed often increases over the course of the month of publication and the following month, and then gradually declines from the third month after publication. Accordingly, those who read the report should bear in mind that the figures for the Medical Safety Information bulletins issued in November and December 2020 are normally lower. The issue with the highest access figure in 2020 was No.158 “Administration of a Sustained-Release Preparation in Ground-Up Form.”

Fig. V-7 Access Frequency of Medical Safety Information Released in 2020

Month of information supply	No.	Title	Access Frequency
January	No.158	Administration of a Sustained-Release Preparation in Ground-Up Form	23,734
May	No.162	Falls When Transferring to a Bed	19,043
February	No.159	Misconnection Causing Obstructed Exhalation in Patients with an Endotracheal/Tracheostomy Tube	16,997
April	No.161	Burns Caused by a Pulse Oximeter Probe	15,218
August	No.165	Alert Failure Resulting in Administration of a Drug to a Patient Allergic to It	14,898
June	No.163	Medical Safety Information Highlighted in Quarterly Reports in 2019	14,769
March	No.160	Medical Safety Information Released in 2019	12,151
July	No.164	Central Venous Catheter Guide Wire Left Behind	9,592
October	No.167	Bone Marrow Suppression Due to Antirheumatic (Methotrexate) Overdose (2nd Follow-up Report)	9,438
September	No.166	Surgical Procedure Other Than Patient-Consented Procedure Carried Out	8,745
November	No.168	Failure to Check Oxygen Tank Valve Was Open	8,105
December	No.169	Omission from Prescription/Order When Continuing Prescription for Current Medicines Brought in at Hospitalization	5,645

Fig. V-8 Medical Safety Information Accessed the Most in 2020: Medical Safety Information No.158 “Administration of a Sustained-Release Preparation in Ground-Up Form”



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

No.158, January 2020

Administration of a Sustained-Release Preparation in Ground-Up Form

Four cases have been reported in which a sustained-release preparation was ground up before administration (information collection period: from January 1, 2014 to November 30, 2019). This information was compiled on the basis of the content featured in the Analysis Themes section of the 53rd Quarterly Report.

Cases have been reported in which a sustained-release preparation was ground up and administered to a patient, with the result that the active ingredient was rapidly absorbed into the patient's body and affected them.

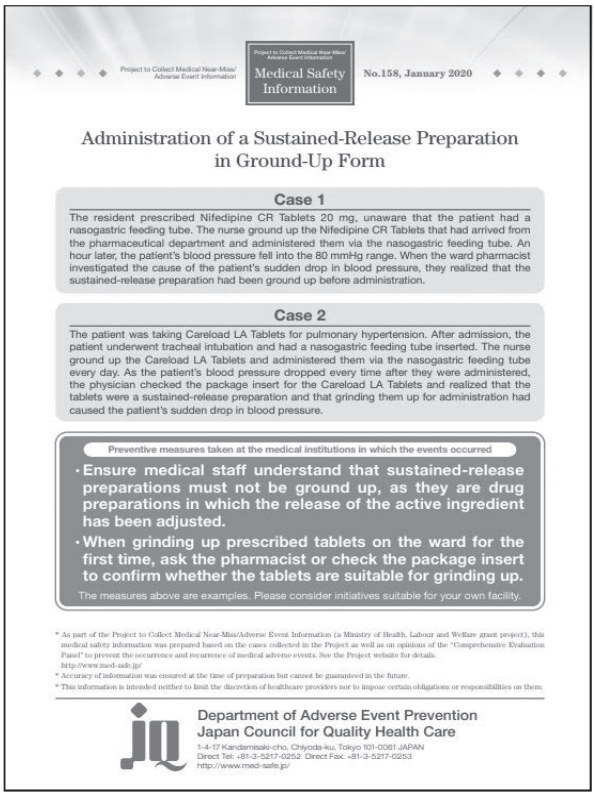
Sustained-Release Preparation (Efficacy Classification)	Effect on Patient	Number of Cases
NIFEDIPINE CR TABLETS (Long-acting calcium channel blocker / antihypertensive/antianginal drug)	Blood pressure dropped	2
Careload LA Tablets (Oral prostacyclin (PGI2) derivative prolonged-release preparation)	Blood pressure dropped	1
OXYCONTIN (Controlled-release agent for cancer pain management)	Level of consciousness declined Respiratory condition deteriorated	1

Image of a sustained-release preparation

◆ Sustained-release preparations are drug preparations in which the speed, duration, and site of the active ingredient's release are adjusted.

◆ Sustained-release formulations are indicated by letters in the name of the drug, such as L (long), LA (long-acting), R (retard), SR (sustained-release), and CR (controlled-release).

◆ The reported cases involved the administration of the drugs in question via a nasogastric feeding tube or an enterostomy tube.



Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.158, January 2020

Administration of a Sustained-Release Preparation in Ground-Up Form

Case 1

The resident prescribed Nifedipine CR Tablets 20 mg, unaware that the patient had a nasogastric feeding tube. The nurse ground up the Nifedipine CR Tablets that had arrived from the pharmaceutical department and administered them via the nasogastric feeding tube. An hour later, the patient's blood pressure fell into the 80 mmHg range. When the ward pharmacist investigated the cause of the patient's sudden drop in blood pressure, they realized that the sustained-release preparation had been ground up before administration.

Case 2

The patient was taking Careload LA Tablets for pulmonary hypertension. After admission, the patient underwent tracheal intubation and had a nasogastric feeding tube inserted. The nurse ground up the Careload LA Tablets and administered them via the nasogastric feeding tube every day. As the patient's blood pressure dropped every time after they were administered, the physician checked the package insert for the Careload LA Tablets and realized that the tablets were a sustained-release preparation and that grinding them up for administration had caused the patient's sudden drop in blood pressure.

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

- **Ensure medical staff understand that sustained-release preparations must not be ground up, as they are drug preparations in which the release of the active ingredient has been adjusted.**
- **When grinding up prescribed tablets on the ward for the first time, ask the pharmacist or check the package insert to confirm whether the tablets are suitable for grinding up.**

The measures above are examples. Please consider initiatives suitable for your own facility.

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

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3. Publication of the English-language Editions of the 2019 Annual Report and Medical Safety Information No.156-167

An English-language edition of the Annual Report has been compiled and published on the website every year since the 2005 Annual Report. In February 2021, we published the English translation of this project's 2019 Annual Report, entitled "Project to Collect Medical Near-miss/Adverse Event Information 2019 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 Healthcare Excellence Canada's Global Patient Safety Alerts project. The English editions of Medical Safety Information No.156 to No.167 were published in February 2021 (Fig. V-9) and can be found on the website's English page. We hope that you will make use of them.

Fig. V-9 English Editions of Medical Safety Information Published in February 2021

No.	Title in English
No.156	Incorrect Administration of Injection Drug Used for Sedation
No.157	Rectal Injury Due to Glycerin Enema Administered in a Standing Position
No.158	Administration of a Sustained-Release Preparation in Ground-Up Form
No.159	Misconnection Causing Obstructed Exhalation in Patients with an Endotracheal/Tracheostomy Tube
No.160	Medical Safety Information Released in 2019
No.161	Burns Caused by a Pulse Oximeter Probe
No.162	Falls When Transferring to a Bed
No.163	Medical Safety Information Highlighted in Quarterly Reports in 2019
No.164	Central Venous Catheter Guide Wire Left Behind
No.165	Alert Failure Resulting in Administration of a Drug to a Patient Allergic to It
No.166	Surgical Procedure Other Than Patient-Consented Procedure Carried Out
No.167	Bone Marrow Suppression Due to Antirheumatic (Methotrexate) Overdose (2nd Follow-up Report)

4. Workshops

The project holds workshops for participating medical institutions to inform them about the current status of the project and encourage high-quality reporting. In January 2021, we held the Workshop on RCA and Developing Preventive Measures.

5. Lecture for Visiting Faculty Members and Students from the University of the Philippines Colleges of Medicine, Nursing, and Public Health

Since 2014, the Japan Science and Technology Agency has been running the Sakura Science Exchange Program, an initiative based on collaboration between industry, academia and government under which young people from Asia and elsewhere are invited to Japan and provided with opportunities to experience Japanese science and technology. As part of this, at the request of Yokohama City University, which was hosting students expected to go on to employment in the medical field, we gave a lecture on January 29, 2020 in the JQ conference room for a lecturer and 12 students from the University of the Philippines. In addition to explaining the JQ's projects, the lecture provided an overview of this project and its achievements.

6. Lecture for a Japanese Government Program on Universal Health Coverage for Invited Republic of Kenya Policymakers

Universal health coverage (UHC) is being promoted as part of an international cooperation program run by the Japan International Cooperation Agency (JICA) in the field of health and medical care. JICA invited policymakers (members of parliament and representatives of central government ministries and agencies) from the Republic of Kenya to Japan, to provide them with information about the features and issues of Japan's health and medical care system, in order to assist them in gaining a deeper understanding of the knowledge required to strengthen their country's health and medical care system with a view to achieving UHC. Nine individuals involved in health and medical care, including representatives of the National Assembly (lower house), Ministry of Health, and National Treasury, visited Japan. As part of the training program during their stay, we gave a lecture on February 20, 2020 concerning the JQ's projects focused on quality and safety in medical care and on this project in particular.

7. 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 patient 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 patient safety activities. Details of these activities are provided in the quarterly reports, as listed in Fig. V-10. Details of the specific topics covered and lectures given at each conference can be found in Chapter V of the Quarterly Report in which it was covered. Due to the impact of the COVID-19 pandemic, conferences and lectures scheduled from late March 2020 onward were postponed or canceled. However, as these resumed online in October, we plan to continue publishing details in the quarterly reports.

Fig. V-10 International Conferences Covered in Quarterly Reports Published in 2020

Quarterly Report No.	Conference	Schedule	Location
61st	CHSI-2019 (Context Sensitive Health Informatics-2019)	August 23-24, 2019	Lille, France
63rd	Moving Measurement into Action: Global Principles for Measuring Patient Safety	September 17, 2019	Salzburg, Austria
64th	36th ISQua Conference	October 20-23, 2019	Cape Town, South Africa

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Project to Collect Medical Near-miss/Adverse Event Information

2020 Annual Report

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