Project to Collect Medical Near-miss/ Adverse Event Information 2023 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: https://www.med-safe.jp/
English page: https://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 Project to Collect Dental Near-Miss Event Information, the Medical Information 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. I would like to express my deepest gratitude to the medical institutions that cooperate with our project by reporting medical near-miss and adverse event information, and also to all other stakeholders.

We are now publishing the 2023 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 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 received considerable feedback on the quarterly and annual reports we have published to date, including media coverage and inquiries about medical adverse event information 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 2023 Annual Report, which summarizes the medical near-miss/adverse event information reported between January and December 2023.

This Annual Report provides the collated results for the year and an outline of the themes highlighted in the quarterly reports. 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 1,772 medical institutions were participating in this project as of the end of 2023. By engaging with this project and reporting events that can serve as a useful reference for other medical institutions, participating medical institutions provide us with information crucial to promoting medical safety nationwide, which we can share with a wider audience. While the number of medical institutions participating in the reporting of medical adverse event information has gradually increased, we would be grateful to secure the participation of even more medical institutions.

The JQ received 6,070 reports of medical adverse event information in 2023. 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

2023 Annual Report

I 2023 Annual Report

1. Number of Registered Medical Institutions and Current Reporting Status

A total of 1,772 medical institutions were participating in this project as of the end of 2023. 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 6,070 reports of medical adverse event information were submitted between January and December 2023, the period covered by this Annual Report. Medical institutions subject to reporting requirements reported 5,183 of these, while voluntarily participating medical institutions reported 887. Fig. I-1 shows the number of reported events in past 10 years. 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

Year		2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Number of reports	Mandatory	2,911	3,374	3,428	3,598	4,030	4,049	4,321	4,674	4,631	5,183
	Voluntary	283	280	454	497	535	483	481	569	682	887
	Total	3,194	3,654	3,882	4,095	4,565	4,532	4,802	5,243	5,313	6,070
Number of medical institutions	Mandatory	275	275	276	276	274	274	273	273	275	275
	Voluntary	718	743	755	773	797	812	834	857	883	1,022
	Total	993	1,018	1,031	1,049	1,071	1,086	1,107	1,130	1,158	1,297

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 2023, we made 90 written inquiries to medical institutions and received 87 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. Section "III-2 [2] Collection of Follow-Up Information via On-site Visits" in this Annual Report provides an overview of one of those on-site visits. Fig. I-3 provides details of on-site visits carried out in 2023.

Fig. I-3 List of On-site Visits

Visit	Type of event	Summary of event
1	Drugs	Event in which the order for a drug that had been stopped due to being contraindicated was left on the system without being deleted, and the same drug was administered to the patient after being borrowed from another patient
2		Event in which Patient X's drug was administered to Patient Y, who had the same family name
3		Event in which the physician did not realize that a hemostatic could not be prescribed due to shipping restrictions, and prescribed an antineoplastic drug that was the only drug displayed when searching by three Japanese syllables of the drug name

*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; 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 2023, the themes selected for the first category were "Events Related to Double-Checks," "Events Related to Overdoses of Insulin Vial Preparations," and "Events Related to Prescription Errors Around the Time of Discharge." Details of relevant medical near-miss event information were collected and the results of analysis were published in the 73rd to 76th Quarterly Reports. In the second category, three 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	
[1] Events Related to Double-Checks (2)	73rd
[2] Events Related to Overdoses of Insulin Vial Preparations (1)	74th
[3] Events Related to Overdoses of Insulin Vial Preparations (2)	75th
[4] Events Related to Prescription Errors Around the Time of Discharge (1)	76th
【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 Products for Practicing Self-Injection Technique	74th
[2] Events Related to Closed-System Connectors	75th
[3] Events Involving Ineffective Assisted Ventilation of a Patient with a Permanent Tracheostomy	76th

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.
Extravascular Leakage in Pediatric Patients (Medical Safety Information No.7)	73rd
Inadequate Checks of Oxygen Remaining (Medical Safety Information No.48: Failure to check oxygen remaining; 1st Follow-up Report No.146)	
Burns caused by a high-frequency electric current loop during MRI examination (Medical Safety Information No.56)	74th
Events Related to Drug Mix-up Due to Similar Appearance (45th Quarterly Report)	75th
Administration of a Sustained-Release Preparation in Ground-Up Form (Medical Safety Information No.158)	76th

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 2023, we compiled and published Medical Safety Information No. 194–205 (Fig. I-6). Fig. I-7 shows the recurrent and similar events most commonly reported in 2023 in relation to matters previously highlighted in Medical Safety Information No.1 to No.205.

Fig. I-6 Medical Safety Information released in 2023

Month of information supply	No.	Title
January	No.194	Forgetting to Reconnect Ventilator Circuit Tubing Due to Use of a Test Lung
February	No.195	Examination/Procedure Conducted on Wrong Patient Due to Failure to Carry out Checks
March	No.196	Medical Safety Information released in 2022
April	No.197	Forgetting to Switch on the Bed Leaving Sensor
May	No.198	Magnetic Material (e.g. Metal Products) Taken in the MRI Room (2nd Follow-up Report)
June	No.199	Medical Safety Information Highlighted in Quarterly Reports in 2022
July	No.200	Burn Caused by Hot Water Used to Prevent Laparoscopic Lens Fogging
August	No.201	Wrong Unit Selected on Syringe Pump
September	No.202	Failure to Open the Central Seal of a Dual Chamber Infusion Bag
October	No.203	Extravascular Leakage in Pediatric Patients (1st Follow-up Report)
November	No.204	Misconnection of Inspiratory and Expiratory Sides of a Ventilator Circuit
December	No.205	Implantation of Another Patient’s Intraocular Lens

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—	21
No.153	Gauze Remaining After Surgery (2) —Checking the X-ray Image—	19
No.54	Accidental removal of the endotracheal/tracheostomy tube when changing positions	16
No.80 No.142	Urethral Damage Caused by an Indwelling Bladder Catheter Urethral Damage Caused by an Indwelling Bladder Catheter (1st Follow-up Report)	15
No.47	Mix-up of the tooth extraction site	13
No.7 No.203	Extravascular leakage in pediatric patients Extravascular leakage in pediatric patients (1st Follow-up Report)	12
No.48 No.146	Failure to check oxygen remaining Inadequate checks of Oxygen Remaining (1st Follow-up Report)	12
No.192	Pressure Ulcers Caused by Medical Devices	12
No.137	Burns When Using a Heat Pack	9
No.144	Failure to Submit a Pathology Specimen	9
No.10 No.94 No.198	Magnetic material (e.g. metal products) taken in the MRI room Magnetic Material (e.g. Metal Products) Taken in the MRI Room (1st Follow-up Report) Magnetic Material (e.g. Metal Products) Taken in the MRI Room (2nd Follow-up Report)	8
No.63 No.138	Inadequate Checks Concerning Diagnostic Imaging Reports Inadequate Checks Concerning Diagnostic Imaging Reports (1st Follow-up Report)	8
No.105	Forgetting to Open/Close a T-shaped Stopcock	8
No.168	Failure to Check Oxygen Tank Valve Was Open	8
No.176	Disconnection of Ventilator Circuit Tubing	8
No.197	Forgetting to Switch on the Bed Leaving Sensor	8
No.30	Administration of allergic drug to patient with previous known allergy history	7
No.58	Rupture of the subcutaneous port and catheter	7
No.59	Burns Due to Incorrect Handling of an Electrosurgical Pencil	7
No.149	Operation/Examination Postponed Due to Delays in Stopping Drugs	7

5. Current Status of the Project

The chapter "V Current Status of the Project" provides various information, including details of the dissemination of information about this project, changes to the design of Medical Safety Information, initiatives for World Patient Safety Day, responses by pharmaceutical companies using output from this project, 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, 2023 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	620	84	370	69	307	275	1,297
	Voluntary	Participating	498		286		238		1,022	
		Not participating	160		315		—		475	
Total			780		685		307		1,772	
			1,465							

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, 2023 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.	45	1
	National Hospital Organization	140	0
	National Research and Development Agencies	9	0
	National Hansen's Disease Sanatorium	13	0
	Japan Organization of Occupational Health and Safety	0	29
	Japan Community Health care Organization	0	40
	Other national organizations	0	0
Municipality	Prefecture	3	24
	City/village	0	104
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	9	5
	Local independent administrative institutions	1	27
Parent organization of public medical institution other than municipality	Japan Red Cross	0	55
	Saiseikai Imperial Gift Foundation	0	23
	Hokkaido Social Welfare Association	0	2
	National Welfare Federation of Agricultural Cooperatives	0	22
	National Health Insurance Association Federation	0	1
	Health Insurance Union and their associations	0	2
	Mutual Aid Associations and their associations	0	13
	National Health Insurance Society	0	0
Corporation	School juridical organization	54	19
	Healthcare corporation	0	430
	Charitable organization	1	52
	Company	0	11
	Other corporation	0	37
Individual practitioner		0	125
Total		275	1,022

(Note 1) As of the end of December 2023, details of the medical institutions subject to reporting requirements (275 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) 88 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, 2023 is shown below. There were 6,070 reports in 2023.

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

	2023												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of reports made by medical institutions subject to reporting requirements	382	405	547	340	354	376	372	527	436	505	416	523	5,183
Number of reports made by voluntarily participating medical institutions	81	46	28	69	50	71	89	116	87	113	57	80	887
Number of medical institutions subject to reporting requirements	275	275	275	275	275	275	275	275	275	275	275	275	—
Number of voluntarily participating medical institutions	886	892	894	899	902	905	913	916	924	966	1,002	1,022	—

(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, 2023 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, 2023, the number of medical institutions subject to reporting requirements was 275, and the total number of beds at those institutions was 137,800.

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, 2023)	Number of reporting medical institutions	Number of reports
			January to December, 2023	January to December, 2023
Government	National University Corporation, etc.	45	43	1,497
	National Hospital Organization	140	133	1,586
	National Research and Development Agencies	9	9	151
	National Hansen's Disease Sanatorium	13	12	88
Municipality	Prefecture	13	12	530
	City/village			
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities			
	Local independent administrative institutions			
Corporation	School juridical organization	54	41	1,206
	Charitable organization	1	1	125
Total		275	251	5,183

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 2023
Government	National University Corporation, etc.	14,488
	National Hospital Organization	21,632
	National Research and Development Agencies	2,085
	National Hansen's Disease Sanatorium	678
Municipality	Prefecture	4,478
	City/village	
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	
	Local independent administrative institutions	
Corporation	School juridical organization	13,364
	Charitable organization	616
Total		57,341

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, 2023)	Number of reporting medical institutions	Number of reports
		January to December, 2023	January to December, 2023
0-19 beds	0	0	0
20-49 beds	13	8	17
50-99 beds	5	2	3
100-149 beds	7	3	9
150-199 beds	10	8	40
200-249 beds	14	13	71
250-299 beds	18	17	146
300-349 beds	34	30	269
350-399 beds	13	13	139
400-449 beds	30	29	334
450-499 beds	13	13	218
500-549 beds	9	8	112
550-599 beds	10	8	202
600-649 beds	26	26	788
650-699 beds	8	8	307
700-749 beds	11	11	441
750-799 beds	3	3	75
800-849 beds	12	12	513
850-899 beds	4	4	150
900-999 beds	16	16	658
1,000 beds or more	19	19	691
Total	275	251	5,183

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, 2023)	Number of reporting medical institutions	Number of reports
		January to December, 2023	January to December, 2023
Hokkaido	9	9	82
Tohoku	25	23	302
Kanto/Koshinetsu	86	77	1,888
Tokai/Hokuriku	38	34	635
Kinki	36	33	630
Chugoku/Shikoku	35	35	920
Kyushu/Okinawa	46	40	726
Total	275	251	5,183

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, 2023)
0	24
1	19
2	11
3	11
4	17
5	14
6	5
7	9
8	12
9	12
10	14
11-20	56
21-30	20
31-40	16
41-50	9
51-100	19
101-150	7
151-200	0
200 or above	0
Total	275

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, 2023 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, 2023)	Number of reporting medical institutions	Number of reports
		January to December, 2023	January to December, 2023
Government	70	14	39
Municipality	160	41	379
Public medical institution	118	26	102
Corporation	549	88	364
Individual practitioner	125	3	3
Total	1,022	172	887

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 2023
Government	468
Municipality	2,282
Public medical institution	1,269
Corporation	3,434
Individual practitioner	16
Total	7,469

[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, 2023. 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	3,944
Dentist	92
Nurse	3,549
Assistant nurse	16
Pharmacist	76
Clinical engineer	69
Midwife	45
Nursing assistant	26
Radiological technologist	74
Clinical technologist	35
Registered dietitian	3
Dietitian	3
Cook/kitchen staff	3
Physical therapist (PT)	54
Occupational therapist (OT)	13
Speech -language –hearing therapist (ST)	2
Medical technologist	1
Dental hygienist	5
Dental technologist	0
Others	60
Total	8,070

* 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	492	8.1
Blood transfusion	10	0.2
Treatment/procedure	1,937	31.9
Medical device, etc.	195	3.2
Drainage tubes or other tubes	492	8.1
Examination	284	4.7
Nursing care	1,890	31.1
Others	770	12.7
Total	6,070	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	449	7.4
High potential of residual disability	682	11.2
Low potential of residual disability	1,717	28.3
No potential of residual disability	1,601	26.4
No disability	1,410	23.2
Unknown	211	3.5
Total	6,070	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	10	0.2
Death or disability due to nosocomial infection	0	0
Suicide or suicide attempt of patient	68	1.1
Disappearance of inpatient	16	0.3
Burn of patient	70	1.2
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	5,904	97.3
Total	6,070	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	511	6.8
Anesthesiology	298	3.9
Cardiovascular medicine	508	6.7
Neurology	167	2.2
Respiratory medicine	338	4.5
Gastrointestinal medicine	458	6.1
Hematology	123	1.6
Circulatory surgery	45	0.6
Allergy	8	0.1
Rheumatism	40	0.5
Pediatrics	281	3.7
General surgery	543	7.2
Orthopedics	857	11.3
Plastic surgery	83	1.1
Cosmetic surgery	0	0
Neurosurgery	370	4.9
Respiratory surgery	121	1.6
Cardiovascular surgery	285	3.8
Pediatric surgery	40	0.5
Pain clinic	5	0.1
Dermatology	92	1.2
Urology	318	4.2
Venereology	1	0
Proctology	1	0
Gynecology/Obstetrics	141	1.9
Obstetrics	47	0.6
Gynecology	83	1.1
Ophthalmology	95	1.3
Otolaryngology	188	2.5
Psychosomatic medicine	0	0
Psychiatry	266	3.5
Rehabilitation	44	0.6
Radiology	132	1.7
Dentistry	40	0.5
Orthodontics	0	0
Pediatric dentistry	2	0
Dental/oral surgery	85	1.1
Unknown	48	0.6
Others	893	11.8
Total	7,557	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, 2023 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.	28	17
	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	25
	Other national organizations	0	0
Municipality	Prefecture	31	16
	City/village	151	82
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	13	8
	Local independent administrative institutions	34	15
Parent organization of public medical institution other than municipality	Japan Red Cross	81	48
	Saiseikai Imperial Gift Foundation	24	11
	Hokkaido Social Welfare Association	2	1
	National Welfare Federation of Agricultural Cooperatives	22	8
	National Health Insurance Association Federation	2	0
	Health Insurance Union and their associations	1	0
	Mutual Aid Associations and their associations	22	11
	National Health Insurance Society	1	1
Corporation	School juridical organization	47	32
	Healthcare corporation	555	265
	Charitable organization	58	27
	Company	9	2
	Other corporation	47	19
Individual practitioner		129	93
Total		1,465	780

[2] Information on the Number of Occurrences

The reports of the information on the number of occurrences between January 1 and December 31, 2023 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	2,831	9,880	124,493	218,277	355,481
(2) Blood transfusion	116	292	2,641	7,059	10,108
(3) Treatment/procedure	680	3,627	19,665	48,451	72,423
(4) Medical device, etc.	415	1,443	15,793	24,351	42,002
(5) Drainage tubes or other tubes	361	3,289	32,403	121,965	158,018
(6) Examination	575	3,505	39,142	64,671	107,893
(7) Nursing care	787	6,196	71,690	164,539	243,212
(8) Others	926	3,202	65,926	70,849	140,903
Total	6,691	31,434	371,753	720,162	1,130,040
Re-posted					
[1] Events involving name or dosage form of drug	360	1,784	6,209	17,222	25,575
[2] Events caused by drug	931	5,036	45,147	83,522	134,636
[3] Events caused by medical device, etc.	294	1,001	7,376	14,396	23,067
[4] Current theme	113	301	3,124	5,223	8,761

Number of reporting medical institutions	718
Total number of beds	265,049

[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, 2023 is shown below.

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

	2023												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of medical near-miss event information	5,474	875	987	4,051	859	810	3,164	611	2,058	8,106	551	1,329	28,875
Number of participating medical institutions for medical near-miss event information reporting	693	692	692	695	697	697	700	702	708	737	764	780	—

(2) Summary of Event

Fig. II-3-4 Summary of Event

Summary of event	Number of events	%
Drugs	10,481	36.3
Blood transfusion	119	0.4
Treatment/procedure	1,147	4.0
Medical device, etc.	1,157	4.0
Drainage tubes or other tubes	3,810	13.2
Examination	2,369	8.2
Nursing care	6,124	21.2
Others	3,668	12.7
Total	28,875	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.

(1) FY2023 Workshop on Medical Safety Initiatives Based on Collaboration between Medical Institutions and Health Insurance Pharmacies: Information Sharing at the Time of Hospitalization and Discharge

(Jointly organized by the Project to Collect Medical Near-miss/Adverse Event Information and the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information)

1) **Date:** Sunday December 17, 2023
2) **Format:** Hybrid in-person and live-streamed workshop (archived stream also available)
3) **Target participants:** Staff of registered medical institutions participating in this project
   Staff of pharmacies participating in the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information
4) **Program**
   i) Current Status of the Project to Collect Medical Near-miss/Adverse Event Information and the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information
   ii) Information Sharing Initiatives at Medical Institutions at the Time of Hospitalization and Discharge
   iii) Information Sharing Initiatives at the Time of Hospitalization and Discharge Involving Pharmacists at Medical Institutions
   iv) Information Sharing Initiatives at the Time of Hospitalization and Discharge Involving Pharmacists at Health Insurance Pharmacies
5) **Number of participants**
   553 people took part.

(2) FY2023 Workshop on Process Flows

1) **Date:** Saturday February 17, 2024
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) A 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 to checking for magnetic material (metal items) before the examination and entering the examination room, participation by medical staff involved in those duties, including physicians, nurses, and radiological technologists, and also 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: Participants completed process flows drawn up beforehand for their medical institution and used model cases to consider such matters as vulnerabilities in the processes.
5) **Number of participants**
   A total of 45 people from 15 medical institutions 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 2023, we made 90 written inquiries concerning medical adverse event information and received 87 responses. Fig. III-2-1 shows an overview of the events concerning which inquiries were made.

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

Type of Event	Number of events
Drugs	49
Blood transfusions	1
Treatment/procedure	11
Medical device, etc.	11
Drainage tubes or other tubes	8
Examination	0
Nursing care	6
Others	4
Total	**90**

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

Due to the COVID-19 pandemic, we were unable to carry out any on-site visits in 2021 and 2022, but resumed them in 2023. In 2023, we asked two medical institutions for permission to conduct on-site visits regarding three events and both granted their cooperation.

A list of on-site visits conducted in 2023 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	Type of Event	Summary of Event
1	**Drugs**	Event in which the order for a drug that had been stopped due to being contraindicated was left on the system without being deleted, and the same drug was administered to the patient after being borrowed from another patient
2		Event in which Patient X's drug was administered to Patient Y, who had the same family name
3		Event in which the physician did not realize that a hemostatic could not be prescribed due to shipping restrictions, and prescribed an antineoplastic drug that was the only drug displayed when searching by three Japanese syllables of the drug name

*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 2 **Event in which Patient X's drug was administered to Patient Y, who had the same family name**

Event as reported

Summary of event	Background and causal factors	Improvement measures
Nurse A and Nurse B prepared one Narusus Tablet (6 mg) for Patient X, placing it into a case for handing over to the patient. At 20:20, Nurse C received Patient X's drug case from Nurse A and checked it using the prescription order screen. As it was time to replace Patient Y's infusion, Nurse C went to Patient Y's room, had them give their full name, checked the family name on the drug case, and had Patient Y take the Narusus Tablet. At 20:52, Nurse A noticed that Nurse C was searching for Patient X's night time drug after being unable to find it at Patient Y's bedside. It emerged that Nurse C had given the Narusus Tablet for Patient X to Patient Y, who had the same family name (but a different given name).	• When handing over the drug to the patient, the nurse had the patient give their full name, but only checked the family name on the drug case. • The nurse did not show the patient the name on the drug case to check it together. • The nurse was not aware that they were looking after two patients with the same family name.	• When handing over drugs to patients, nurses will use point-and-call to check the name on the drug case against the full name given by the patient. • When handing over drugs to patients, nurses will show the name on the case to the patient to check it together. • If any patients have the same family name as each other, nurses will share this information at the beginning of the shift.

Details of the On-site Visit

Attendees from the Medical Institution

Medical Safety Management Department: Deputy Director (GRM), Deputy Nursing Director (GRM), head nurse (GRM), senior pharmacist (GRM); Nursing Department: Deputy Nursing Director (in charge of safety management and quality assurance), 2 ward head nurses; Pharmaceutical Department: pharmacist

Findings

1. Lead-up to the event

- At 19:38, Nurse A checked the Narusus Tablet to be given to Patient X at 20:00 with Nurse B.
- Nurse A placed the Narusus Tablet in one of the drug cases used on the ward and placed the drug case in the safe. Affixed to the drug case was a red printed label bearing the word "narcotic" and a white printed label bearing the time "20:00" to indicate the time it should be administered. In addition, Patient X's name had been written by hand in Chinese characters on a piece of white tape affixed to the front of the case.
- At 19:55, Nurse A asked Nurse C to give the narcotic drug to Patient X.
- At 20:20, Nurse C went to Patient Y's room, assuming that Patient Y was the only person with the family name actually shared by Patients X and Y, and checked the order for Narusus Tablet on Patient X's prescription order screen.
- When Nurse C removed the Narusus Tablet from its PTP sheet and placed it on the palm of Patient Y's hand, Patient Y asked what the drug was. When Nurse C said it was a painkiller, Patient Y replied, "But I'm not in pain." However, Nurse C had the patient take the drug nonetheless.
- Nurse C knew that Patient X had a drug to be taken before going to sleep, but assumed that Patient Y was Patient X and therefore went to Patient Y's room to check whether Patient Y had taken the drug. However, the drug case was not on the table.
- When Nurse C returned to the staff station and checked with partner Nurse A where the drug case was that contained the drug to be taken by Patient Y before going to sleep, Nurse A said that Patient X had the same family name and suggested that Nurse C might have the two patients mixed up.
- Becoming aware for the first time that there were two patients with the same family name, Nurse C also realized that they had administered the Narusus Tablet to the wrong patient.
- Nurse C reported the mix-up to the duty physician, who explained the situation to Patient Y and kept them under observation.

2. Background and causal factors

○ Patients
- There were two patients (both male) with the same family name, which is a common one in the area where the medical institution is located. Both patients' given names contained the same Chinese character with the same phonetic reading ("*kazu*"), so their given names also bore some resemblance to each other when written down or spoken.
- Patient X was taking a narcotic.
- Patient Y had been hospitalized for their first chemotherapy session.

○ Measures devised for distinguishing patients with the same family and given names from each other, etc.
- The standard practice was to display the message "!Caution! Same Family Name!" on the panel at the entrance to the room and on the board at the patient's bedside. This message was displayed for both Patient X and Patient Y.
- The standard practice was also to display patients names in red characters on the nurse call board screen if patients shared the same family or given name, or if they were written with different Chinese characters but pronounced the same way.
- On both the day and night shifts, patients were usually allocated to nurses in a way that ensured no nurse was looking after two patients with the same family name, but on this particular day, Nurse C ended up looking after two patients with the same name because, when allocating duties, consideration was given to the fact that there were postsurgical patients and chemotherapy patients, and that Nurse A had relatively few years of professional experience.

○ Staffing and working conditions on the ward
- The ward had 53 beds, 48 of which were occupied by patients on the day in question.
- The ward had introduced a partnership nursing system (PNS), under which Nurses A and C were partnered.
- Nurse B was working the later day shift and had been assigned to general tasks such as treatment procedures, rather than looking after specific patients.
- When handing over to Nurses A and C on the night shift, the day shift lead nurse stated that two of the patients they would be looking after had the same family name.

○ Nurse A
- After the handover from the day shift team, Nurse A told Nurse C to take care, because there were two patients with the same family name, and underlined the family names of the relevant patients with a marker pen on the time schedule.
- Nurse A had intended to give the Narusus Tablet to Patient X themself, but asked Nurse C to do so because Nurse C had returned from their break at 19:55 and Nurse A needed to go on their own break straight afterwards.

○ Nurse C
- Unaware of having been told by the day shift lead nurse and Nurse A to take care about the fact that there were two patients with the same family name, Nurse C conflated the names of Patients X and Y, and thought that Patient Y was the only patient with the family name of Patients X and Y.
- Nurse C identified the patients by family name alone and the screen that was open on the electronic medical record when they went to Patient Y's bedside was the screen for Patient X.
- Although there were signs with the message "!Caution! Same Family Name!" at Patient Y's bedside and elsewhere, Nurse C did not notice them.
- When Nurse C went to Patient Y's room at 20:20 to replace their infusion and give them the Narusus Tablet scheduled for 20:00, Nurse C was rushing, as they were late in administering the narcotic drug.
- After opening Patient X's screen on the electronic medical record to check the Narusus Tablet, Nurse C looked at the name on the prescription order screen for Patient X and on Patient X's drug case to compare them.
- Nurse C then carried out the procedure of having Patient Y give their name and checking the name against that written on the drug case, but only looked at the family name.
- Although Patient Y asked what the drug was and said that he was not in pain, Nurse C did not think anything was amiss and had him take it nonetheless.

3. Main improvement measures introduced after reporting the event
- The medical institution carried out root cause analysis concerning this event and formulated the following measures.
  1) Ensuring that nurses fully understand the significance of the 6R's as the fundamentals of drug administration.
  2) Ensuring that nurses are aware of the possibility that they might themselves cause errors.
  3) Ensuring that nurses equip themselves with the perceptiveness to realize something might be wrong when a patient questions them, and that they stop what they are doing in order to check or seek advice, without fail.
  4) Ensuring that nurses equip themselves with the perceptiveness to realize something might be wrong when a patient questions them, and that they stop what they are doing in order to check or seek advice, without fail.
  5) Ensuring that nurses properly share information even when working in pairs, and use the check back process to prevent errors.
- The medical institution will devise ways to allocate patients between nurses in such a way as to ensure that no nurse is looking after patients with the same family name.

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

○ One feels that there was little awareness of the fact that Narusus Tablet is a narcotic drug. At the medical institution to which the On-site Visitor belongs, narcotic drugs are prepared before the set time for distributing drugs to patients, and the nurse responsible hands the drug over to the patient immediately after the double-check, in order to avoid a time lag.

○ At the medical institution to which the On-site Visitor belongs, nurses do not carry out any other tasks at the set time for distributing narcotic drugs to patients. While there may well be staffing issues and the like, one wonders whether this kind of measure might not also be effective, if possible.

● At our institution, too, the nurse responsible distributed the drugs to the patients under their care, but in this case, the task happened to overlap with the nurse's break time, so they ended up asking the other nurse to do it. As barcode authentication is not possible in the case of oral medication, the nurse should have been more conscious of the need to check the drugs against the patient.

○ Using a drug case alone means there is no correct information to serve as the basis for checks. At the medical institution to which the On-site Visitor belongs, nurses take the prescription bearing the patient name and drug name with them when distributing narcotic drugs to patients.

○ While the drug case indicates only the patient's name, one wonders whether the patient's room number could be added, so that there are two pieces of information.

○ The drug case bears the patient's name in Chinese characters, but it can be difficult to notice errors if patients have the same family names or their names look similar, as in this case, so one wonders whether it would be possible to add the phonetic reading of the name to the label.

● As patients are sometimes moved to different beds, noting the room number actually has the potential to cause errors, so we do not do this, but we intend to consider adding the phonetic readings of names to labels, with a view to introducing this practice.

○ At the medical institution to which the On-site Visitor belongs, the narcotics manager and the medical safety manager together carry out a narcotics round twice a year to check such matters as the status of narcotics storage in the safe. Carrying out rounds in this way also enables them to identify any ambiguities in the medical institution's set procedures regarding narcotic drugs.

○ At the medical institution to which the On-site Visitor belongs, if there are patients with the same family name or with identical family and given names, each of the patients in question is informed of this fact and told about the checks that will be carried out to prevent a mix-up. One feels that it might be advisable for patients themselves to be aware of such situations.

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; 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 73rd to 76th Quarterly Reports, which covered the period under analysis for events reported in 2023.

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	
[1] Events Related to Double-Checks (2)	73rd
[2] Events Related to Overdoses of Insulin Vial Preparations (1)	74th
[3] Events Related to Overdoses of Insulin Vial Preparations (2)	75th
[4] Events Related to Prescription Errors Around the Time of Discharge (1)	76th
[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 Products for Practicing Self-Injection Technique	74th
[2] Events Related to Closed-System Connectors	75th
[3] Events Involving Ineffective Assisted Ventilation of a Patient with a Permanent Tracheostomy	76th

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 73rd to 76th Quarterly Reports, which analyzed events reported in 2023, 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 types of events analyzed in the quarterly reports.

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

Title	Quarterly Report No.
Extravascular leakage in pediatric patients (Medical Safety Information No.7)	73rd
Inadequate Checks of Oxygen Remaining (Medical Safety Information No.48: Failure to check oxygen remaining; 1st Follow-up Report No.146)	
Burns caused by a high-frequency electric current loop during MRI examination (Medical Safety Information No.56)	74th
Events Related to Drug Mix-up Due to Similar Appearance (45th Quarterly Report)	75th
Administration of a Sustained-Release Preparation in Ground-Up Form (Medical Safety Information No.158)	76th

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 2023

Medical Safety Information bulletins No.194 to No.205 were issued between January and December 2023.

Fig. IV-2-1 Medical Safety Information released in 2023

Month of information supply	No.	Title
January	No.194	Forgetting to Reconnect Ventilator Circuit Tubing Due to Use of a Test Lung
February	No.195	Examination/Procedure Conducted on Wrong Patient Due to Failure to Carry out Checks
March	No.196	Medical Safety Information Released in 2022
April	No.197	Forgetting to Switch on the Bed Leaving Sensor
May	No.198	Magnetic Material (e.g. Metal Products) Taken in the MRI Room (2nd Follow-up Report)
June	No.199	Medical Safety Information Highlighted in Quarterly Reports in 2022
July	No.200	Burn Caused by Hot Water Used to Prevent Laparoscopic Lens Fogging
August	No.201	Wrong Unit Selected on Syringe Pump
September	No.202	Failure to Open the Central Seal of a Dual Chamber Infusion Bag
October	No.203	Extravascular Leakage in Pediatric Patients (1st Follow-up Report)
November	No.204	Misconnection of Inspiratory and Expiratory Sides of a Ventilator Circuit
December	No.205	Implantation of Another Patient's Intraocular Lens

V

Current Status of the Project

V Current Status of the Project

This chapter describes the project's achievements in 2023, 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 73rd to 76th 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).

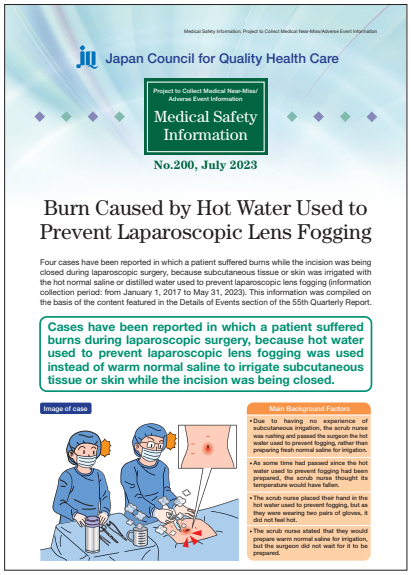
2. Changes to the Design of Medical Safety Information

This project began providing Medical Safety Information in December 2006. Since then, the project has highlighted a variety of themes in providing Medical Safety Information via the project website once a month (https://www.med-safe.jp/contents/info/index.html). We also send Medical Safety Information by fax to around 6,000 medical institutions, including participating medical institutions and hospitals that have requested the provision of information by fax.

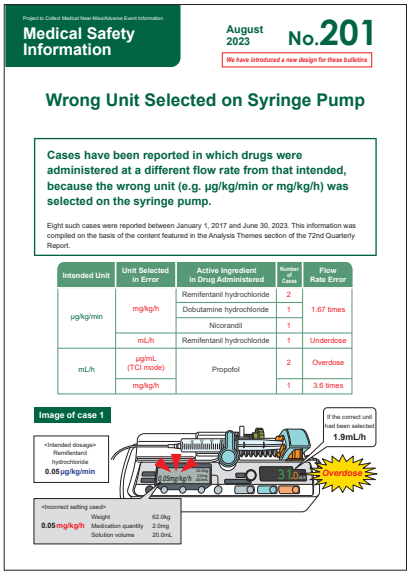
September 2023 marked a milestone with the issue of Medical Safety Information No.200. Due in part to the increasing volume of information provided in recent years, we decided to revamp the design to improve visibility, starting from No.201 (provided in August 2023) (Fig. V-1). In addition to using green as the main color, to match the project's website, the new design adopts a flat design without any shading, in order to ensure that information is conveyed clearly even when faxed versions are photocopied within medical institutions. We hope that this information will continue to be of use in promoting medical safety.

Fig. V-1　Changes to the Design of Medical Safety Information

No.200 (issued in July 2023)



No.201 (issued in August 2023)

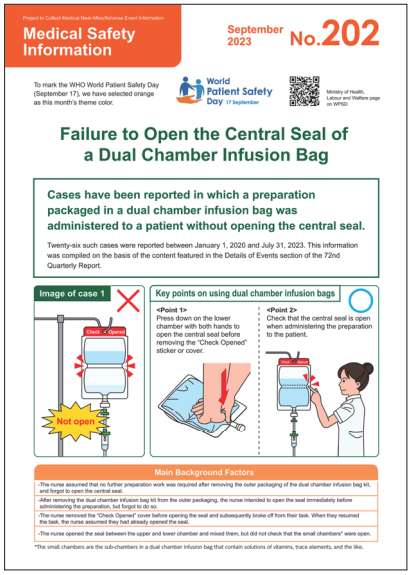


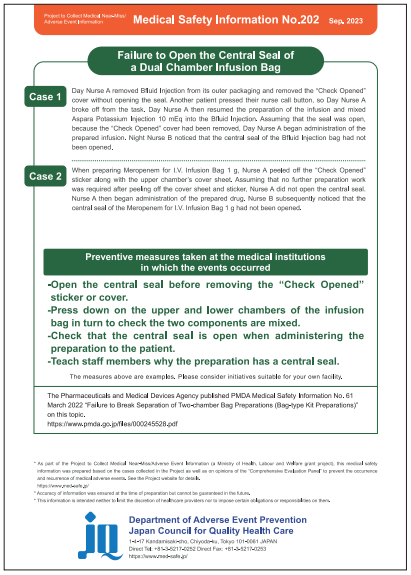
3. Initiatives for World Patient Safety Day

September 17 each year has been designated World Patient Safety Day by the World Health Organization (WHO). The purpose of World Patient Safety Day is to promote global solidarity and concerted action by WHO member countries to improve patient safety. The theme in FY2023 was engaging patients for patient safety, and the slogan was "Elevate the voice of patients!" Public awareness campaigns and the like are promoted both within Japan and overseas for World Patient Safety Day, including the illumination of buildings, landmarks, and monuments in orange, the color symbolizing the campaign. Since 2022, this project has marked the event by changing the background color of the September Medical Safety Information bulletin to orange. In 2023, Medical Safety Information No.202 was colored orange.

Fig. V-2　Medical Safety Information Using Orange as the Background Color

No.202 (issued in September 2023)





4. Use of Output from the Project to Collect Medical Near-miss/ Adverse Event Information: Responses by Pharmaceutical Companies

1) Preventing Drug Mix-Up

This project issued warnings about events involving drug mix-up due to similar drug names in Medical Safety Information No.4 "Drug mix-up" (March 2007) and Medical Safety Information No.68 "Drug mix-up (1st Follow-up Report)." Since then, such events have repeatedly been highlighted in the Analysis of Recurrent and Similar Events section of the Quarterly Reports. Pharmaceutical companies have themselves also issued warnings about similarities in brand names based on events published as part of this project or the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information.

2) Proper Use of Drugs

In Medical Safety Information No.158 "Administration of a Sustained-Release Preparation in Ground-Up Form" (January 2020), this project provided a warning about cases 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. Pharmaceutical companies have themselves also issued warnings about sustained-release preparations in ground-up form based on events published as part of this project or the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information.

3) Other

Pharmaceutical companies have used events published as part of this project or the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information to issue specific warnings about errors in selecting drug specifications, in order to prevent medical adverse events.

Fig. V-3 provides a summary of warnings issued by pharmaceutical companies that were published in Quarterly Reports in 2023. Please refer to the relevant Quarterly Report for details.

Fig. V-3 Warnings from Pharmaceutical Companies Highlighted in the Project's Quarterly Reports

Quarterly Report No.	Warning	Date of Issue	Company Name
73rd	Caution Regarding Mix-ups Due to the Similarity in Brand Names Between Tegretol® and Theodur®	December 2022	Sun Pharma Japan Limited Mitsubishi Tanabe Pharma Corporation
74th	ReQuip CR Tablets 2 mg/8 mg are a sustained-release preparation *Do not prescribe/administer/take them in cut-up, ground-up, or chewed form*	March 2023	GlaxoSmithKline K.K.
75th	Caution Regarding Errors in Selecting Between the 0.5 mg and 5 mg Specifications of Warfarin Tablets	September 2023	Eisai Co., Ltd.
76th	Caution Regarding Mix-ups Between Graceptor® and Ordinary Tacrolimus Preparations (Including Generic Drugs)	November 2023	Astellas Pharma Inc.

5. Publication of the English-language Editions of the 2022 Annual Report and Medical Safety Information No.192-203

An English-language edition of the Annual Report has been compiled and published on the website every year since the 2005 Annual Report. In March 2024, we published the English translation of this project's 2022 Annual Report, entitled "Project to Collect Medical Near-miss/Adverse Event Information 2022 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.192 to No.203 were published in March 2024 (Fig. V-4) and can be found on the website's English page. We hope that you will make use of them.

Fig. V-4 English Editions of Medical Safety Information Published in March 2024

No.	Title in English
No.192	Pressure Ulcers Caused by Medical Devices
No.193	Wrong Drug Administration Route (1st Follow-up Report)
No.194	Forgetting to Reconnect Ventilator Circuit Tubing Due to Use of a Test Lung
No.195	Examination/Procedure Conducted on Wrong Patient Due to Failure to Carry out Checks
No.196	Medical Safety Information Released in 2022
No.197	Forgetting to Switch on the Bed Leaving Sensor
No.198	Magnetic Material (e.g. Metal Products) Taken in the MRI Room (2nd Follow-up Report)
No.199	Medical Safety Information Highlighted in Quarterly Reports in 2022
No.200	Burn Caused by Hot Water Used to Prevent Laparoscopic Lens Fogging
No.201	Wrong Unit Selected on Syringe Pump
No.202	Failure to Open the Central Seal of a Dual Chamber Infusion Bag
No.203	Extravascular Leakage in Pediatric Patients (1st Follow-up Report)

6. Workshops

The project holds workshops for registered medical institutions to inform them about the current status of the project and encourage high-quality reporting. In FY2023, we held two workshops: the Workshop on Medical Safety Initiatives Based on Collaboration between Medical Institutions and Health Insurance Pharmacies: Information Sharing at the Time of Hospitalization and Discharge was held on Sunday, December 17, 2023 as a workshop jointly organized by the Project to Collect Medical Near-miss/Adverse Event Information and the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information, while the Workshop on Process Flows took place on Saturday, February 17, 2024.

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. Fig. V-5 shows the international conferences covered in quarterly reports Published in 2023. Details of the specific topics covered at each conference can be found in the Quarterly Report in which it was covered.

Fig. V-5 International Conferences Covered in Quarterly Reports Published in 2023

Quarterly Report No.	Conference	Schedule	Location
73rd	Training on patient safety incident reporting and learning systems, organized by the Maldives Ministry of Health and WHO SEARO, etc.	March 28-30, 2022	Republic of Maldives (online)
	Training on patient safety incident report analysis, jointly organized by the Maldives Ministry of Health, WHO, and the Department of Health of the Tuscany Region, Italy	April 19 and 28, 2022	Republic of Maldives (online)
74th	WHO Expert consultation meeting	March 30, 2022	Swiss Confederation (online)
	ISQua Virtual Event "Patient flow management"	March 31, 2022	Ireland (online)
	Indonesia Brawijaya hospital lecture	June 2, 2022	Republic of Indonesia (online)
	6th International Congress on Patient Safety	June 9-10, 2022	Republic of Chile (online)
	32nd EPSO conference	June 22, 2022	Republic of Singapore (online)
	1st G20 Global Patient Safety Leaders Group	July 4, 2022	Kingdom of Saudi Arabia (online)
	2022 WHO World Patient Safety Day Steering Committee	July 20, 2022	Swiss Confederation (online)
	Regional Consortium for Patient Safety	August 15, 2022	Islamic Republic of Pakistan (online)
	2022 HIRA Symposium, HIRA International Seminar	August 30-31, 2022	Republic of Korea
	WHO World Patient Safety Day Event	September 15, 2022	Swiss Confederation (online)
	Tabba Heart Institute	September 2022	Islamic Republic of Pakistan (recorded video provided)
	ASQua WPSD Event -Medication safety in transitions of care	September 19, 2022	Malaysia (online)
	HSIB (Healthcare Safety Investigation Branch) conference	September 21, 2022	United Kingdom of Great Britain and Northern Ireland (online)
	Makati Medical Center: WHO World Patient Safety Day Event	September 30, 2022	Republic of the Philippines (online)

Quarterly Report No.	Conference	Schedule	Location
75th	38th ISQua Conference	October 17-20, 2022	Commonwealth of Australia
	Global Action for Leaders & Learning Organizations on Patient Safety (GALLOPS)	November 2022	Republic of Singapore (online)
	Lecture for a delegation from Zimbabwe participating in JICA's "Project for Quality Improvement of Health Service Through 5S-Kaizen-TQM Approach" technical cooperation project	December 5, 2022	Japan
	WHO Experts' Consultation: Implementing the Global Patient Safety Action Plan 2021-2030: Pandemic and Beyond	December 5-8, 2022	Swiss Confederation (online)
	5th Global Ministerial Summit on Patient Safety, Montreux Switzerland	February 23-24, 2023	Swiss Confederation
	Lecture at the Kungpeng Project organized by Peking Union Medical College	February 2023	People's Republic of China (recorded video provided)
	23rd HA National Forum Thailand, International Hybrid Conference	March 15, 2023	Kingdom of Thailand (online)
	CAHOCON2023	April 14-15, 2023	Republic of India
	34th EPSO Conference	April 19-20, 2023	Republic of Malta (online)
	UMC HCM Conference, Vietnam	May 26, 2023	Socialist Republic of Vietnam
76th	Inaugural Asia-Pacific Patient Safety (APPS) Network Webinar organized by the WPRO	June 20, 2023	Republic of the Philippines (online)
	Meeting with senior officials from the UK's HSIB	June 26, 2023	United Kingdom of Great Britain and Northern Ireland (online)
	Meeting with the Maternity Investigation Unit of the UK's HSIB	August 4, 2023	United Kingdom of Great Britain and Northern Ireland (online)

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Project to Collect Medical Near-miss/Adverse Event Information

2023 Annual Report

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