Project to Collect Medical Near-miss/ Adverse Event Information 2016 Annual Report

August 28, 2017

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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Foreword

Hirobumi Kawakita
President
Japan Council for Quality Health Care

The Japan Council for Quality Health Care undertakes a variety of initiatives, such as the evaluation of hospital functions, with the objective of providing third-party accreditation of medical institutions and supporting the provision of high-quality medical services by medical institutions, in order to improve the quality of medical care and ensure that the public have confidence in it. Today, what is expected of health care is becoming more advanced and diverse, so we are aware that providing the public with accurate information concerning medical care provision and promoting and securing the provision of high-quality medical care is an increasingly important task. Moreover, amidst this situation in Japan, we believe that the JQ should play a major role in this.

Since FY2004 the Department of Adverse Event Prevention has been 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 aim of preventing medical adverse events and promoting safety in medical care; the information gathered about medical adverse events is compiled into quarterly reports, along with the total figures for the events and an analysis thereof, and published as regular quarterly reports and annual reports available to a wide range of individuals and organizations in society, including medical professionals, the public and government bodies, as well as being sent out by fax about once a month as Medical Safety Information. As of December 2016, we have issued 121 Medical Safety Information bulletins. I would like to express my deepest gratitude to the medical institutions and other parties which provide ongoing cooperation with our project, through such endeavors as providing medical near-miss and adverse event information.

We are now publishing the 2016 Annual Report, which was compiled based on the content of previously published quarterly reports. In addition to totals for the year concerning medical near-miss/adverse event information, this report carries a large quantity of information that is useful in promoting safety in medical care, such as an overview of surveys conducted to ascertain the actual situation on the ground, an overview of analyses of individual themes and medical adverse event information to be shared, and an overview of holding workshops; accordingly, we hope that this Annual Report will be of use to those working on the front line of medical care, as well as helping the public to gain a deeper understanding of the current status of medical safety initiatives in Japan.

Hitherto, we have received a great deal of feedback concerning our quarterly reports, in terms of inquiries and media coverage relating to the numbers of medical adverse events and the details thereof; as such, we are aware that public concern about the promotion of medical safety and the prevention of medical adverse events is still high. We would like to strive to further enhance the content of our quarterly reports, in order to continue to provide useful information to everyone, so we would greatly appreciate any guidance that you can provide.

In addition, in order to improve the level of medical care in Japan, we at the JQ would like to do our utmost to improve the quality of medical care and ensure that the public has confidence in it, through such projects as the Hospital Accreditation, so we would be most grateful for your continued understanding and cooperation.

The Current Status of the Project to Collect Medical Near-miss/Adverse Event Information — Focusing on the Content of the 2016 Annual Report —

Shin Ushiro
Director
Japan Council for Quality Health Care

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

1. Foreword

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

Based on the project plan approved by the JQ Board of Directors meeting held in March 2016, the project has been run during FY2016 with a core focus on the collection, analysis and provision of medical near-miss/adverse event information and training relating to medical safety. As of the end of 2016, 1,447 registered medical institutions were participating in the project and we received 3,882 reports over the course of that year. Qualitative improvements in such areas as the content of the reports are also required, so in addition to holding workshops, the project has made written inquiries about events and carried out on-site visits with the cooperation of medical institutions. Going forward, we will continue our efforts to develop a user-friendly reporting environment and feed back project outcomes, to encourage participation and reporting by even more medical institutions. We would like to analyze information on medical adverse events – both those that involve deaths and those that do not – and near-miss events occurring in a variety of hospital departments, and gain an understanding of their fundamental causes, so that we can highlight the issues that are faced by the whole of the medical community. As such, we greatly appreciate your continued understanding and cooperation in this endeavor.

We are hereby pleased to publish our 2016 Annual Report, which summarizes the medical near-miss/adverse event information reported between January and December 2016. 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 safety management, will review this report thoroughly and share the parts which are most useful and relevant to the circumstances of their particular medical institution.

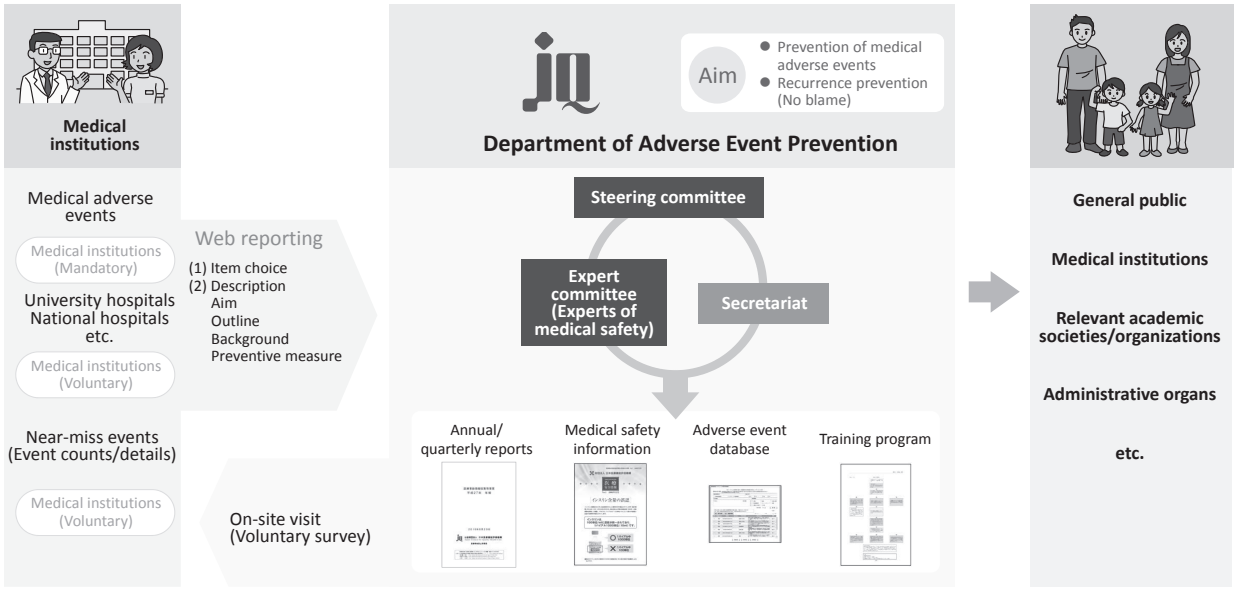
Moreover, the JQ also hopes that, by reading this Annual Report and viewing information published on the project homepage, the general public, as recipients of medical care, will gain an understanding of the various different types of medical adverse events and medical near-misses and the nature thereof, as well as current efforts by medical institutions and the medical community to prevent their recurrence.

Furthermore, we would like to take this opportunity to provide the following introduction to the Project to Collect Medical Near-miss/Adverse Event Information and the current status of related initiatives.

2. 2016 Project Outline

The project plan for FY2016 was approved at a February 2016 meeting of the project's Management Committee. As usual, it focused on such activities as collecting, analyzing and providing medical near-miss/adverse event information and holding workshops.

Figure 1 Content of the Project



3. 2016 Annual Report

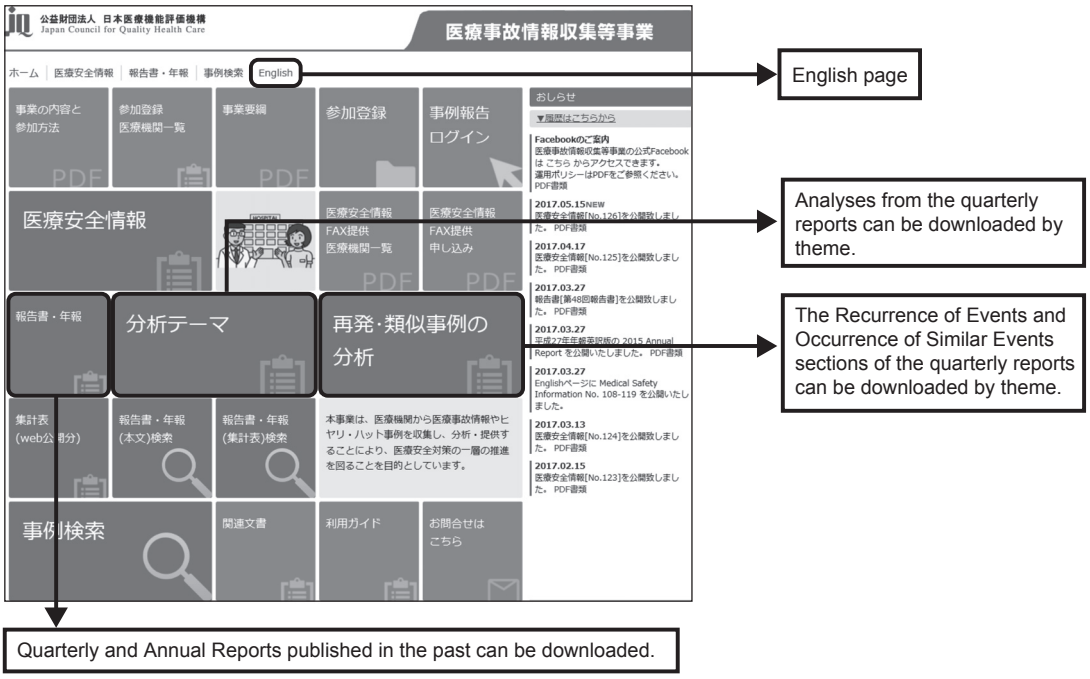
1) Composition of the Annual Report

The project has published an annual report featuring the collated results for the year and a compilation of content from the quarterly reports every year since 2006. The first annual report, the 2005 Annual Report, was around 200 pages in length and contained tabulated data for such matters as the number of reported events during the previous year, as well as providing a summary of analyses of individual themes carried in the previous year's quarterly reports. We have sought to enhance the content of the annual reports by such means as publishing the full text of all analyses carried in the Individual Theme Review by the Expert Division and Recurrence of Events and Occurrence of Similar Events sections of all quarterly reports for that year, as well as a detailed section entitled Collection of Follow-Up Information Concerning Medical Adverse Events (Overview of On-site Visits). Consequently, the 2013 and 2014 Annual Reports were around 600 pages long and while they provided exhaustive details of the results compiled for the previous year and the content of analysis, they contained an extremely large volume of information. As such, we felt that they were no longer easy for people working in busy clinical environments to cast their eye over.

Accordingly, starting with the 2015 Annual Report, we adopted a more compact format, simply providing an outline of the analysis carried in the Individual Theme Review and Recurrence of Events and Occurrence of Similar Events sections of the quarterly reports, to make it easier for readers to browse through. An outline of the themes highlighted in quarterly reports over the course of the year is provided, along with key figures, in "2. Individual Theme Review by the Expert Division" and "3. Recurrence of Events and Occurrence of Similar Events" in the chapter "III Current Analysis of Medical Near-miss/Adverse Event Information" in this Annual Report. We hope that you will refer to the relevant quarterly reports for further details. Please do make use

of the project website (Figure 2), from which PDF files of each quarterly report and theme analyzed can be downloaded.

Figure 2 Project Website



2) Number of Medical Institutions Participating in this Project

As of the end of 2016, the number of medical institutions participating in this project has increased slightly, to 1,447 institutions. A breakdown of the number of medical institutions participating in the project can be found on p.62. These show the number of medical institutions participating in the Project to Collect, Analyze, and Provide Medical Adverse Event Information, the number of medical institutions participating in the Project to Collect, Analyze, and Provide Medical Near-miss Event Information, and the number of medical institutions participating in the project, with any duplications removed.

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 "Medical Institutions Participating in Each Project" link on the List of Participating Medical Institutions page (http://www.med-safe.jp/contents/register/index.html).

3) Number of Event Reports

Between January and December 2016, the project received 3,882 reports of medical adverse event information, 3,428 of which were reported by medical institutions subject to reporting requirements, with the remaining 454 being reported by voluntarily participating medical institutions (Table 1). These figures exceed the number of events reported in 2015 and represent the highest number of reported events since the project began. As mentioned in previous publications, we believe that this is because reporting medical adverse events has gradually become an established practice over the more than 10 years since we began accepting reports in October 2004. We are aware that the medical care environment is becoming increasingly demanding, so we would like to express our sincere gratitude to all cooperating medical institutions. Going forward, the project would encourage them to review the scope of reports described in "I-2-[2]-2 Information Reported as Medical Adverse Events" (p.54-55) and report events appropriately in order to promote medical safety in Japan.

Since January 2010, participating medical institutions have reported on medical near-miss events; information about such events is divided into two categories: information about the number of events occurring and information about events. All participating medical institutions provide information about the number of medical near-miss events that have occurred; in addition, medical institutions may provide information about events if they wish. It was reported that, as of the end of 2016, 856,802 events (p.74) occurred from 237,814 hospital beds, with information being provided about 30,318 events (p.75) from 210,218 hospital beds.

We are aware that it is certainly not always easy for the registered medical institutions that provide these reports to identify the fact that an event that falls within the scope of the reporting guidelines has occurred; to check and organize the facts; and to put together a report on the event. However, medical institutions can expect many positive outcomes from ongoing participation in this project and the submission of high quality reports, including improvements in their ability to identify, analyze, and report on the facts of an event, as well as access to data that can be useful when an integrated organizational body – namely, a medical institution – is making decisions about a management policy with a high regard for medical safety. Since the medical adverse event investigation system began operating in October 2015, medical institutions have an even greater need than ever to be able to identify the facts of cases, analyze the background and causal factors, and formulate improvement measures based on an understanding of the root causes. We believe that participating in this project and actively submitting reports will not only promote medical safety at individual medical institutions, but also contribute to raising the overall level of medical safety in Japan, so we would like to thank you for your continued participation and reporting in this project.

Table 1 Number of Reported Medical Adverse Event Information

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

4) Number of Reported Events at Voluntarily Participating Medical Institutions

Having been quite low for many years since the start of the project, compared with the figures for medical institutions obliged to submit reports, the number of medical adverse event information reported by voluntarily participating medical institutions rose to 521 in 2010, an increase of around threefold on the figures reported hitherto. Thereafter, the number of reported events remained at around the 300 mark from 2011, but reached its highest figure in recent years in 2016, with 454 reported events. On the other hand, we believe that the rise in the number of voluntarily participating medical institutions demonstrates a will to cooperate in this project, for which we are very grateful. In addition, after taking the step of participating, it is important to actually report relevant events. Looking at the number of reported events, it would seem that endeavors at the reporting level – including our own – are still inadequate. Although it is a voluntary endeavor, we believe that the utilization and maintenance of a large number of reports through an adverse event reporting system such as this project is tremendously meaningful not only for the medical community, but also for society as a whole, so we will continue ask medical institutions to participate and submit reports. At the same time, we would like to request the continued cooperation of medical institutions that are participating voluntarily.

The fact that the number of events reported by voluntarily participating medical institutions is considerably lower than the number of events reported by medical institutions subject to the reporting requirement appears to indicate a difference in awareness of reporting, something that has been pointed out at meetings of the project's Management Committee. When asked to give lectures, we always explain this point and ask those in attendance to provide their cooperation in this regard. At the same time, we also explain that once adequate motivation to report medical adverse event information to an external body develops within medical institutions and the medical community as a whole, we will see not only an increase in the number of reported events, but also the reporting of high-quality information about such events. In other words, we do not believe that anything will be achieved by the government unnecessarily expanding the obligation to submit reports or imposing penalties, because of an undue perception that the low number of reported events constitutes a problem.

With the medical adverse event investigation system having begun operating in October 2015, we believe that it is vital for this project to play its own key role. We will strive to promote a more widespread understanding of the significance of this project as a system for reporting and learning from adverse events, in order to enhance medical safety.

The number of reported medical adverse event information is considered to be one indication that the willingness of the medical community to actively promote medical safety is being evaluated. The fact that there is such a large disparity between the number of events reported by medical institutions subject to the reporting requirement and the number reported by voluntarily participating medical institutions would seem to suggest that the reported figures do not necessarily reflect the reality of efforts to promote medical safety in everyday medical care situations. Accordingly, we would like to ask medical institutions that are participating voluntarily for their continued cooperation in providing appropriate reports of events that fall within the scope of reporting guidelines.

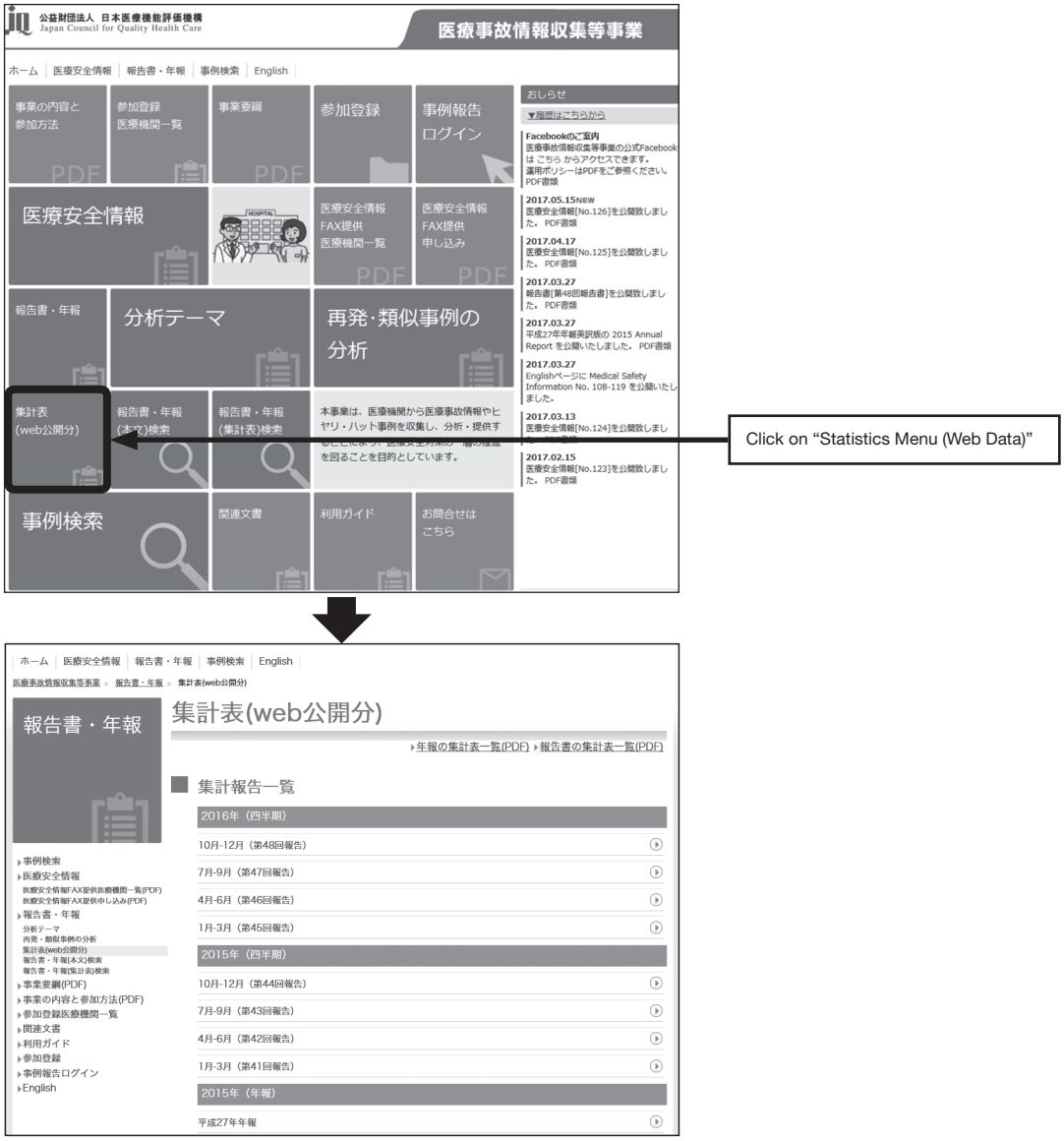
5) Current Reporting Status

"Details of Reports Made by Registered Medical Institutions (by Month of Report)" in the chapter "II Current Reporting Status" in this Annual Report provides figures compiled on the basis of medical adverse event information reports from medical institutions subject to reporting requirements and voluntarily participating medical institutions (p.68-72). As stated above, there are few reports from voluntarily participating medical institutions, so figures for such institutions are published in the Annual Report alone and do not appear in the quarterly reports.

There is a tendency for there to be no major changes in the figures in many of the diagrams published in in the Annual Report from year to year. However, irrespective of whether or not there are any changes, we believe that the role of this project is to present to society the current status of medical adverse events and near-miss events on an ongoing basis, thereby contributing to increasing the transparency of medical care.

As we have sought to make this Annual Report more concise, it does not contain the "Details of Reports from Medical Institutions Subject to Reporting Requirements (by Month of Report)" or "Details of Reports from Medical Institutions Subject to Reporting Requirements (by Month of Occurrence)" sections carried each year until the 2014 Annual Report, but these can be found on the website. Please refer to the "Statistics Menu (Web Data)" (http://www.med-safe.jp/contents/report/html/StatisticsMenu.html) section of the website for figures that do not appear in this Annual Report.

Figure 3 Statistics Menu Page (available in Japanese only)



6) Individual Theme Review

This project analyzes two types of theme: (1) themes subject to comprehensive analysis in conjunction with medical adverse event information, while continuing to collect details of relevant medical near-miss event information; and (2) themes selected from medical adverse event information reported during the period under analysis in the quarterly report and then used to identify and analyze details of similar events in the past. In 2016, the theme selected for the first category was Events Related to Antineoplastic Agents; details of relevant medical near-miss event information were collected over the course of the year and the results of analysis were published in the 45th–48th Quarterly Reports. In the second category, eight themes were highlighted, as shown in Table 2. Similar events in the past were highlighted and the analysis published along with the summary of each event, background and causal factors, and improvement measures reported by the medical institution concerned. Relevant information about medical safety within Japan and overseas was also provided, as appropriate.

In this Annual Report, an outline of the individual themes highlighted for analysis in 2016 is provided in [2] Themes Highlighted in ‘Individual Theme Review’, “2. Individual Theme Review” in the chapter “III Current

Analysis of Medical Near-miss/Adverse Event Information." Each quarterly report provides information about the number of reported events, summary of events, an analysis of the background and causal factors, and a summary of improvement measures taken to prevent recurrence, so please refer to the 45th to 48th Quarterly Reports for details. We hope that you will make use of the project website, which enables users to peruse and download information by theme analyzed.

Table 2 Themes Analyzed

Themes Analyzed		Quarterly Report
(1) Themes subject to comprehensive analysis in conjunction with medical adverse event information, while continuing to collect details of relevant medical near-miss event information over the course of a year		
Events Related to Antineoplastic Agents		45th-48th
(2) Themes selected from medical adverse event information reported during the period under analysis in the quarterly report and then used to identify and analyze details of similar events in the past		
[1]	Events Related to Drug Mix-up Due to Similar Appearance	45th
[2]	Events Related to Tubing Disconnection of Ventilator Circuit	45th
[3]	Events Related to Double Dosing of Medicines Brought in at Hospitalization and Drugs Prescribed in Hospital	46th
[4]	Events in Which a Film Dressing Was Affixed to a Permanent Tracheostomy	46th
[5]	Events in Which a Patient Accidentally Ingested or Aspirated a Foreign Substance During Dental Treatment	47th
[6]	Events Related to Falls From a Pediatric Bed	47th
[7]	Events in Which Nor-Adrenalin Was Administered Instead of Adrenaline During Resuscitation	48th
[8]	Events Related to the Fitting of Elastic Stockings to Patients With Arteriosclerosis Obliterans of the Lower Limbs	48th

7) Recurrence of Events and Occurrence of Similar Events

It is a fact that similar events continue to be reported even after information about medical adverse events has been provided in Quarterly Reports and Medical Safety Information, so follow-up is required. Accordingly, starting with the 18th Quarterly Report, we added a section entitled "Recurrence of Events and Occurrence of Similar Events," which provides an analysis of these events. This analysis highlights a number of events reported after we had provided information about events of a similar nature, looking at trends in the number of recurrent or similar events after the provision of information about each theme and providing details of the summary of event and specific improvement measures reported by the medical institutions concerned.

Tables 3 and 4 show the events most commonly reported in 2016 that were recurrences of or similar to events previously profiled in Medical Adverse Event Information to Be Shared, Individual Theme Review, and Medical Safety Information.

Table 3 Most Commonly Reported Recurrent and Similar Events Previously the Subject of Medical Adverse Event Information to Be Shared or Individual Theme Review

Summary	Information Provided	Number of events
Event Involving Gauze Left Within the Body	14th Quarterly Report [Medical Adverse Event Information to Be Shared]	22
Events Related to Burns (Excluding Burns Sustained During Nursing Care)	9th Quarterly Report [Medical Adverse Event Information to Be Shared]	20
Event Involving Infarction and Hemorrhage Occurred in Patients Treated with Warfarin Potassium for the Management of Blood Coagulability	9th Quarterly Report [Medical Adverse Event Information to Be Shared]	19
Events Related to the Transfer of a Patient from One Bed to Another	13th Quarterly Report [Medical Adverse Event Information to Be Shared]	18
Events Related to Wrongly Inserted Gastric Tube	43rd Quarterly Report [Individual Theme Review]	14
Events involving the wrong site (confusion between right and left)	8th Quarterly Report [Medical Adverse Event Information to Be Shared]	13
Events Involving Suicide or Attempted Suicide in Hospital	41st Quarterly Report [Individual Theme Review]	11
Events involving administration of multiple times the correct dosage to pediatric patients	10th Quarterly Report [Medical Adverse Event Information to Be Shared]	10
Events involving administration of allergic drug to patient with previous known allergy history	12th Quarterly Report [Medical Adverse Event Information to Be Shared]	10
Events Related to Pathology Test Specimens	15th Quarterly Report [Medical Adverse Event Information to Be Shared]	10
Events Involving Failure to Communicate the Content of the Diagnostic Imaging Report	26th Quarterly Report [Individual Theme Review]	10

Table 4 Most Commonly Reported Recurrent and Similar Events Previously the Subject of Medical Safety Information

Title	Issue No.	Month Issued	Number of events
Accidental removal of the endotracheal/tracheostomy tube when changing positions	No.54	May 2011	10
Wrong site surgery (right/left) Wrong site surgery (right/left) (1st Follow-up Report)	No.8 No.50	July 2007 January 2011	8
Accidental ingestion of PTP sheets Accidental ingestion of PTP sheets (1st Follow-up Report)	No.57 No.82	August 2011 September 2013	8
Rupture of the subcutaneous port and catheter	No.58	September 2011	8
Accidental Removal of a Drain/Tube during Transfer	No.85	December 2013	8
Urethral Damage Caused by an Indwelling Bladder Catheter	No.80	July 2013	7
Extravascular leakage in pediatric patients	No.7	June 2007	6
Mix-up of the tooth extraction site	No.47	October 2010	6
Wrong Drug Administration Route	No.101	April 2015	5
Inadequate Checks Concerning Diagnostic Imaging Reports	No.63	February 2012	4

Table 5 shows themes highlighted in the section “Recurrence of Events and Occurrence of Similar Events” in 2016. Each quarterly report provides details of changes in the number of reported events, summary of events, an analysis of background and causal factors, a summary of improvement measures to prevent recurrence, and information about warnings provided by other groups about such events, so please refer to the 45th to 48th Quarterly Reports for details. We hope that you will also make use of the project website, which enables users to peruse and download information about recurrent and similar events by theme.

Table 5 Content Highlighted in “Recurrence of Events and Occurrence of Similar Events”

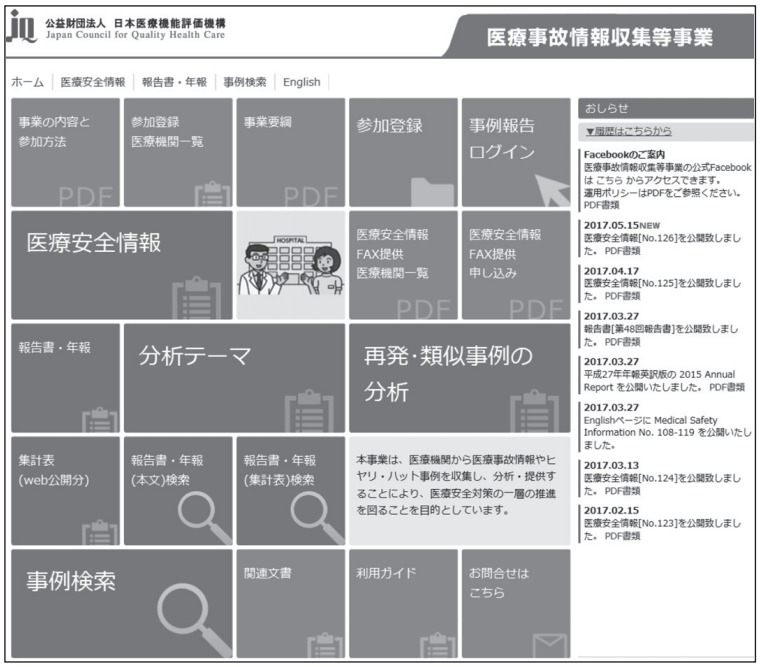
Summary		Quarterly Report
[1] Specimen mix-up at pathological diagnosis	Medical Safety Information No.53	45th
[2] Event related to intraocular lenses	15th Quarterly Report [Medical Adverse Event Information to Be Shared]	45th
[3] Provision of Food to Which the Patient was Allergic	Medical Safety Information No.69	46th
[4] Patient Mix-up during Radiological Examinations	Medical Safety Information No.73	46th
[5] Drug Mix-up	Medical Safety Information No.4 Medical Safety Information No.68	47th
[6] Urethral Damage Caused by an Indwelling Bladder Catheter	Medical Safety Information No.80	47th
[7] Wrong site surgery (right/left) —Wrong site surgery (right/left) in neurosurgical procedures—	Medical Safety Information No.8 Medical Safety Information No.50	48th
[8] Events Related to Reactivation of Hepatitis B Due to Immunosuppression/Chemotherapy	34th Quarterly Report [Individual Theme Review]	48th

4. Website Redesign and Use of Information Provided

Visitors to the project’s website can view and download a variety of information, including a list of registered medical institutions, quarterly and annual reports, analysis themes, analyses of recurrent and similar events, and Medical Safety Information, as well as searching our database of reports. As the project has continued, the volume of its output has grown, with website users forced to click multiple buttons to get to the content that they want from the homepage, which impaired its user-friendliness. Accordingly, at the end of March 2017, we redesigned the website to make it more convenient to use, by such means as enabling one-click access to information that had previously been buried deep within the site.

The revamped website has been designed to be smartphone-compatible, so that people can access information from smartphones and other handheld devices, without needing to go somewhere that has a computer. We hope that, along with our Facebook page, through which we have been publishing information since 2014, this will result in people making more use of the output from this project, due to the greater accessibility of more useful information.

Figure 4 Website Homepage



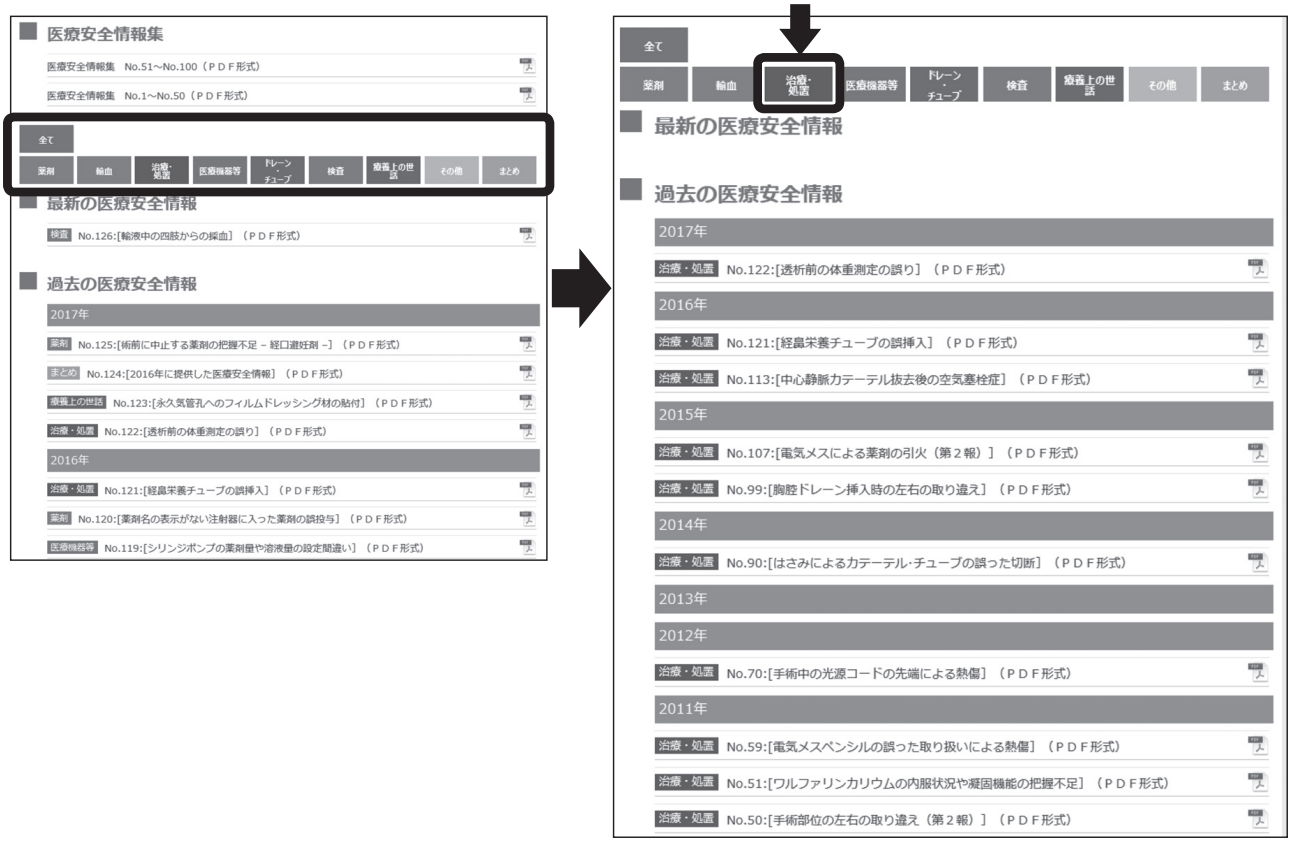
1) Medical Safety Information

The project provides 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 in color for maximum visual impact. We began to provide Medical Safety Information in December 2006 and in 2016 we compiled and published Medical Safety Information No.110–121.

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 Event Information, and is also published on the project website. In addition, to share this information with a wider audience, we also send Medical Safety Information by fax free of charge to non-participating hospitals that wish 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. We have published and distributed two anthologies of Medical Safety Information: the first in December 2011, covering No.1–50, and the second in September 2015, covering No.51–100. These are also available on our website.

On the Medical Safety Information page, we have assigned color-coded labels according to the category of information and are trying to make it more user-friendly through various means, including enabling users to display Medical Safety Information by category. We also took this opportunity to refresh the website's visual design, giving it a look more in keeping with the design language found on most modern websites.

Figure 5 Medical Safety Information Page (Display by Summary of Event: Page Display When “Treatment” is Selected)



Currently, 5,932 medical institutions receive Medical Safety Information by fax, equating to around 70% of all hospitals nationwide. Requests to receive Medical Safety Information by fax may be submitted at any time. In redesigning the website, we added two new buttons to the homepage: “List of Medical Institutions Receiving Medical Safety Information by Fax” and “Application to Receive Medical Safety Information by Fax.” Accordingly, we hope that hospitals not currently receiving Medical Safety Information will consult these sections of our website to see which medical institutions in their area currently receive Medical Safety Information and then apply to receive the information that we already send out to approximately 70% of Japanese hospitals.

2) Report Full Text Search and Table Search Functions

Clicking on the “Quarterly/Annual Report Full Text Search” and “Quarterly/Annual Report Table Search” buttons enables users to search the content of text and tables in the Quarterly and Annual Reports. More specifically, this means that users can search for the cases and events in which they are most interested by narrowing down the range of reports searched or by means of a keyword search. Clicking on the “Statistics Menu (Web Data)” button enables users to browse numerous tables not published in the Quarterly and Annual Reports. This section features approximately 110 tables covering the Quarterly Reports and approximately 180 tables covering the Annual Reports.

Figure 6 Quarterly/Annual Report Full Text Search Page

Figure 7 Statistics Menu (Web Data) Page

3) Event Search

(1) Published Data Search of Events / Search Function
—There are now more than 20,000 medical adverse event information reports in the database—

Clicking on the Event Search button on the project's website enables users to search medical adverse event information and medical near-miss information. There are also buttons that enable the user to download the selected events for use on their computer in any of three file formats: XML, PDF or CSV. With reference to such events, medical and technological research is being conducted in the field of medical safety, as well as the upgrading of manuals concerning safe medical care, nursing and dispensing, and the improvement of pharmaceutical labeling. Furthermore, if a medical adverse event occurs, website users can refer to changes in patient conditions and treatment methods by perusing similar events. In the questionnaire survey concerning the use of this function, many respondents stated that they "used it as reference material if an adverse event occurs," "distributed it to the safety management committee for use as a resource," or "used it as a teaching aid in safety management workshops." In 2014, the Event Search page was equipped with pull-down menus that enable the user to select the clinical department involved and the occupation of the person involved. Leading academic societies in a range of clinical fields have invited representatives of this project to give lectures. We understand that among them are the medical safety committees of academic societies that are considering embarking on projects to gather data about adverse events. However, systematically gathering information about events is not easy, so some academic societies were considering making use of this project's Event Search page. Functions that enable results to be filtered by clinical department involved and job title of the person involved would seem to be useful in aiding such deliberations. We also continue to receive requests from a number of academic societies to give lectures about medical safety, as the model training programs prescribed in the new specialist physician system due to be introduced next year include a requirement to learn about medical safety and cultivate the ability to provide safe medical care. During these lectures, we highlight and examine events closely related to the field of medicine in which the physicians affiliated to the academic society concerned practice. We hope that the "Filter by Clinical Department" and "Filter by Job Title of the Person Involved" functions will help to further encourage the use of the Event Search function in promoting medical safety.

This search function has been developed in response to the numerous requests we have received from the medical institutions participating in this project and researchers, as well as many other people, asking us to develop a web-based system that enables events to be perused and searched, because a large number of events have now been published in the reports and they also contain a great deal of detail. In the recent redesign, we made the screen easier to read. As of the time of writing, this search page enables the user to search details of 23,143 medical adverse events and 51,376 medical near-miss events. Thus, the number of medical adverse event information reports in the database is now in excess of 20,000. Please note that, due to the increasing number of events in the database, no search results will be displayed if the number of hits is greater than 1,000. Instead, the following message requesting that the search conditions be adjusted will be displayed: "○ reported events were found. The maximum number of results that can be displayed is 1,000. Please adjust the search conditions."

We hope that the publication of the reported information in this form and its appropriate use will ensure further improvements in mechanisms and products used in the provision of medical care and that it will assist in dispute resolution. In addition, we hope that it will help reporting to become better established as the fruits of this initiative become more perceptible, thereby creating a virtuous circle of further improvements in medical safety and ensuring that it becomes an important function not only in the medical community, but also in Japanese society as a whole.

Figure 8 Event Search Page (available in Japanese only)

(2) Use of Event Information

① Responses by Pharmaceutical Companies to Assist in Preventing Drug Mix-up —Warning about Mix-ups Due to the Similarity in Brand Names Between Nolvadex and Norvasc, and Between PRINK and Primperan—

Previous Quarterly and Annual Reports have highlighted the fact that pharmaceutical companies have used the project's Event Search function when issuing warnings about mix-ups between drugs with similar names, such as Almarl and Amaryl, and Norvasc and Nolvadex. Thus, reports to this project continue to be a catalyst for companies and relevant groups other than the JQ to provide specific warnings aimed at preventing medical adverse events. In July 2015, the manufacturers of Duphaston® (generic name: dydrogesterone) and Fareston® Tab. (generic name: toremifene citrate), which is used to treat breast cancer, issued a warning about the similarities between the two brand names. They have vastly different efficacies, with Duphaston used to treat threatened miscarriage/premature delivery, recurrent miscarriage/premature delivery, amenorrhea, menstrual cycle abnormalities, and dysmenorrhea, while Fareston is used to treat postmenopausal breast cancer.

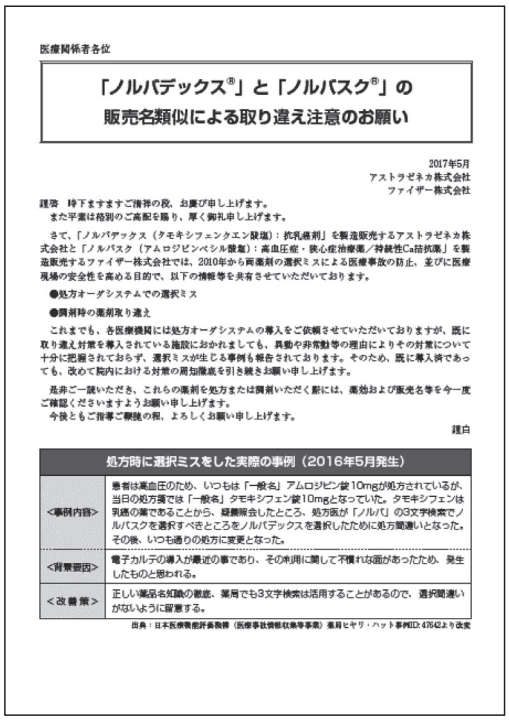
Pharmaceutical companies have also cited the outcomes of this project and the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information in repeated warnings concerning the mix-up of two drugs that are renowned for having similar names: Nolvadex® (generic name: tamoxifen citrate), an anticancer drug used to treat breast cancer, and Norvasc® (generic name: amlodipine besylate), a drug to treat hypertension and angina that is also used as a long-acting calcium channel blocker. Another warning was issued in November 2013 and the information in the warning was updated in July 2014, May 2015, March 2016, and May 2017 (Figure 9).

In September 2016, a warning about similar brand names was jointly prepared and issued by the manufacturers of PRINK® / PRINK® Inj. Syringe 5μg/10μg (alprostadil): prostaglandin E_1 preparation (Teva Pharma Japan Inc.) and Primperan® Injection 10mg (metoclopramide hydrochloride): a drug for treating dysfunction of the digestive organs (Astellas Pharma Inc.) The manufacturer and distributor of PRINK® / PRINK® Inj. Syringe 5μg/10μg, Teva Pharma Japan Inc., explained that it is moving forward with procedures to change the name of the drug to the generic name (Alprostadil Injection) and that it had submitted the application to alter the name to the regulatory authorities in August (Figure 10). In 2012, the name of the drug Almarl® (generic name: arotinolol hydrochloride): a drug for treating hypertension, angina, arrhythmia and essential tremor, was changed for the same reason, due to the similarity of its name to Amaryl® (generic name: glimepiride): an oral hypoglycemic agent. Thus, as far as we at this project are aware, this is the second case of a name change for a similar reason.

Documents published by these companies to warn medical professionals have not only provided details of relevant events reported to this project, but also highlighted specific measures taken to deal with the problem, in the form of improvements to screen displays and search systems, as well as providing photographs showing the drugs concerned. Drug mix-up events may still occur even after steps have been taken to address the issue, as personnel transfers and part-time work among physicians can result in a lack of understanding of the measures concerned. Accordingly, pharmaceutical companies are calling for continued efforts to ensure full awareness of this issue.

We believe that using the output from this project in this way to facilitate the provision of safe medical care to the populace by increasing the safety of clinical practice is entirely appropriate and fully in keeping with the purpose of this project. The role of this project is to issue repeated warnings about similar events, and we would appreciate it if pharmaceutical companies would also continue to undertake activities of this nature going forward.

Figure 9 Caution Regarding Mix-ups Due to the Similarity in Brand Names Between Nolvadex® and Norvasc® (excerpt)



医療関係者各位

「ノルバデックス®」と「ノルバスク®」の販売名類似による取り違え注意のお願い

2017年5月
アストラゼネカ株式会社
ファイザー株式会社

謹啓　時下ますますご清祥の段、お慶び申し上げます。
また平素は格別のご高配を賜り、厚く御礼申し上げます。

さて、「ノルバデックス（タモキシフェンクエン酸塩）：抗乳癌剤」を製造販売するアストラゼネカ株式会社と「ノルバスク（アムロジピンベシル酸塩）：高血圧症・狭心症治療薬／持続性Ca拮抗薬」を製造販売するファイザー株式会社では、2010年から両薬剤の選択ミスによる医療事故の防止、並びに医療現場の安全性を高める目的で、以下の情報等を共有させていただいております。

●処方オーダシステムでの選択ミス
●調剤時の薬剤取り違え

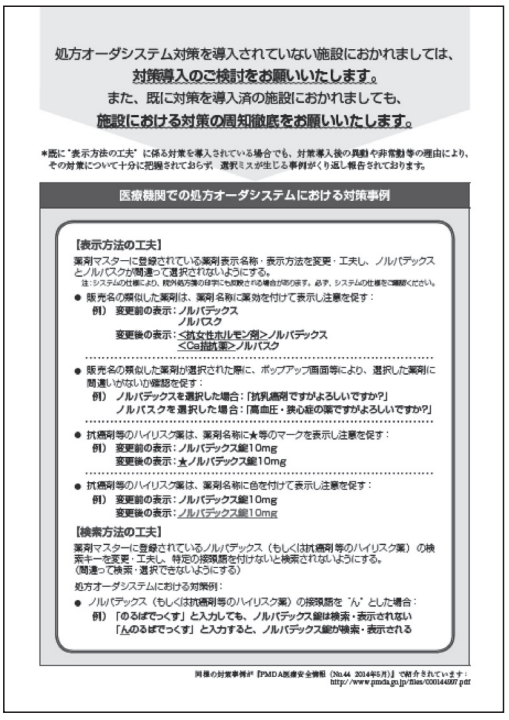
これまでも、各医療機関には処方オーダシステムの導入をご依頼させていただいておりますが、既に取り違え対策を導入されている施設におかれましても、異動や非常勤等の理由によりその対策について十分に把握されておらず、選択ミスが生じる事例も報告されております。そのため、既に導入済であっても、改めて院内における対策の周知徹底を引き続きお願い申し上げます。

是非ご一読いただき、これらの薬剤を処方または調剤いただく際には、薬効および販売名等を今一度ご確認くださいますようお願い申し上げます。
今後ともご指導ご鞭撻の程、よろしくお願い申し上げます。

謹白

処方時に選択ミスをした実際の事例（2016年5月発生）	
<事例内容>	患者は高血圧のため、いつもは「一般名」アムロジピン錠10mgが処方されているが、当日の処方箋では「一般名」タモキシフェン錠10mgとなっていた。タモキシフェンは乳癌の薬であることから、疑義照会したところ、処方医が「ノルバ」の3文字検索でノルバスクを選択すべきところをノルバデックスを選択したために処方間違いとなった。その後、いつも通りの処方に変更となった。
<背景要因>	電子カルテの導入が最近の事であり、その利用に関して不慣れな面があったため、発生したものと思われる。
<改善策>	正しい薬品名処置の徹底、薬局でも3文字検索は活用することがあるので、選択間違いがないように留意する。

出典：日本医療機能評価機構（医療事故情報収集等事業）薬局ヒヤリ・ハット事例ID：47642より改変



処方オーダシステム対策を導入されていない施設におかれましては、
対策導入のご検討をお願いいたします。
また、既に対策を導入済の施設におかれましても、
施設における対策の周知徹底をお願いいたします。

＊既に"表示方法の工夫"に係る対策を導入されている場合でも、対策導入後の異動や非常勤等の理由により、その対策について十分に把握されておらず、選択ミスが生じる事例がくり返し報告されております。

医療機関での処方オーダシステムにおける対策事例

【表示方法の工夫】

薬剤マスターに登録されている薬剤表示名称・表示方法を変更・工夫し、ノルバデックスとノルバスクが間違って選択されないようにする。
注：システムの仕様により、対応内容の様子にた調整が必要な場合が異なります。必ず、システムの仕様をご確認ください。

- 販売名の類似した薬剤は、薬剤名称に薬効を付けて表示し注意を促す：
  例）変更前の表示：ノルバデックス
  ノルバスク
  変更後の表示：<抗女性ホルモン剤>ノルバデックス
  <Ca拮抗薬>ノルバスク
- 販売名の類似した薬剤が選択された際に、ポップアップ画面等により、選択した薬剤に間違いがないか確認を促す：
  例）ノルバデックスを選択した場合：「抗乳癌剤ですがよろしいですか?」
  ノルバスクを選択した場合：「高血圧・狭心症の薬ですがよろしいですか?」
- 抗癌剤等のハイリスク薬は、薬剤名称に★等のマークを表示し注意を促す：
  例）変更前の表示：ノルバデックス錠10mg
  変更後の表示：★ノルバデックス錠10mg
- 抗癌剤等のハイリスク薬は、薬剤名称に色を付けて表示し注意を促す：
  例）変更前の表示：ノルバデックス錠10mg
  変更後の表示：ノルバデックス錠10mg

【検索方法の工夫】

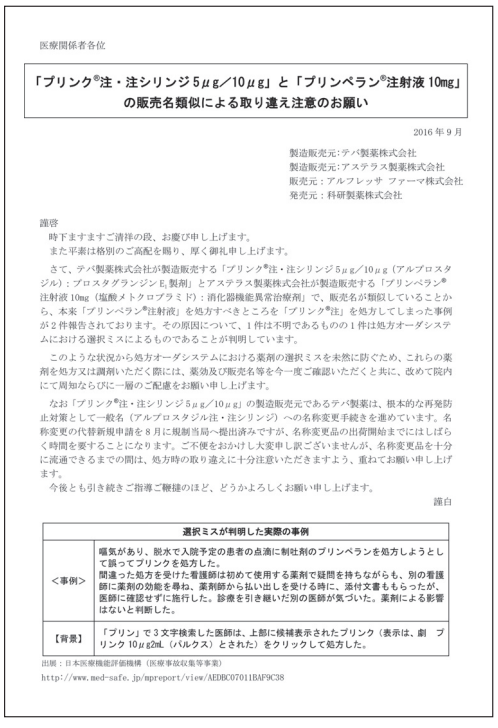
薬剤マスターに登録されているノルバデックス（もしくは抗癌剤等のハイリスク薬）の検索キーを変更・工夫し、特定の接頭語を付けないと検索されないようにする。
（間違って検索・選択できないようにする）

処方オーダシステムにおける対策例：

- ノルバデックス（もしくは抗癌剤等のハイリスク薬）の接頭語を「ん」とした場合：
  例）「のるばでっくす」と入力しても、ノルバデックス錠は検索・表示されない
  「んのるばでっくす」と入力すると、ノルバデックス錠が検索・表示される

同様の対策事例が『PMDA医療安全情報（No.44 2014年5月）』で紹介されています：
http://www.pmda.go.jp/files/000144007.pdf

Figure 10 Caution Regarding Mix-ups Due to the Similarity in Brand Names Between PRINK® and Primperan®



医療関係者各位

「プリンク®注・注シリンジ5μg／10μg」と「プリンペラン®注射液 10mg」の販売名類似による取り違え注意のお願い

2016年9月

製造販売元：テバ製薬株式会社
製造販売元：アステラス製薬株式会社
販売元：アルフレッサ ファーマ株式会社
発売元：科研製薬株式会社

謹啓
時下ますますご清祥の段、お慶び申し上げます。
また平素は格別のご高配を賜り、厚く御礼申し上げます。

さて、テバ製薬株式会社が製造販売する「プリンク®注・注シリンジ5μg／10μg（アルプロスタジル）：プロスタグランジンE1製剤」とアステラス製薬株式会社が製造販売する「プリンペラン®注射液 10mg（塩酸メトクロプラミド）：消化器機能異常治療剤」で、販売名が類似していることから、本来「プリンペラン®注射液」を処方すべきところを「プリンク®注」を処方してしまった事例が2件報告されております。その原因について、1件は不明であるものの1件は処方オーダシステムにおける選択ミスによるものであることが判明しています。

このような状況から処方オーダシステムにおける薬剤の選択ミスを未然に防ぐため、これらの薬剤を処方又は調剤いただく際には、薬効及び販売名等を今一度ご確認いただくと共に、改めて院内にて周知ならびに一層のご配慮をお願い申し上げます。

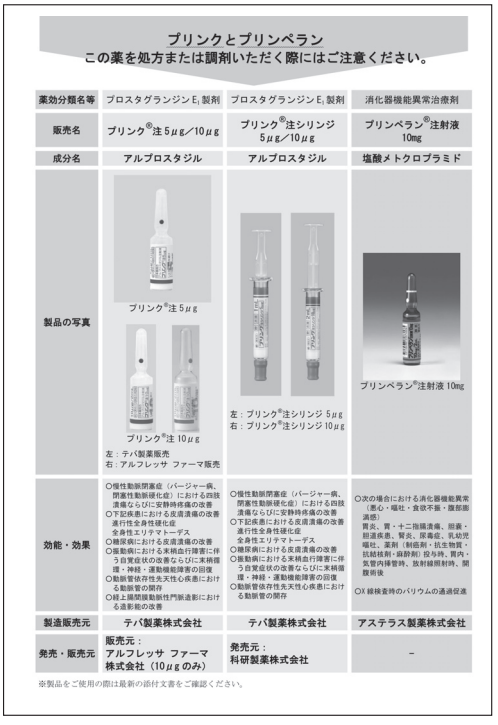
なお「プリンク®注・注シリンジ5μg／10μg」の製造販売元であるテバ製薬は、根本的な再発防止対策として一般名（アルプロスタジル注・注シリンジ）への名称変更手続きを進めています。名称変更の代替新規申請を8月に規制当局へ提出済みですが、名称変更品の出荷開始までにはしばらく時間を要することになります。ご不便をおかけし大変申し訳ございませんが、名称変更品を十分に流通できるまでの間は、処方時の取り違えに十分注意いただきますよう、重ねてお願い申し上げます。

今後とも引き続きご指導ご鞭撻のほど、どうかよろしくお願い申し上げます。

謹白

選択ミスが判明した実際の事例	
<事例>	嘔気があり、脱水で入院予定の患者の点滴に制吐剤のプリンペランを処方しようとして誤ってプリンクを処方した。 間違った処方を受けた看護師は初めて使用する薬剤で疑問を持ちながらも、別の看護師に薬剤の効能を尋ね、薬剤師から払い出しを受ける時に、添付文書ももらったが、医師に確認せずに施行した。診療を引き継いだ別の医師が気づいた。薬剤による影響はないと判断した。
【背景】	「プリン」で3文字検索した医師は、上部に候補表示されたプリンク（表示は、劇　プリンク10μg2mL（バルクス）とされた）をクリックして処方した。

出展：日本医療機能評価機構（医療事故収集等事業）
http://www.med-safe.jp/mpreport/view/AEDBC07011BAF9C38



プリンクとプリンペラン
この薬を処方または調剤いただく際にはご注意ください。

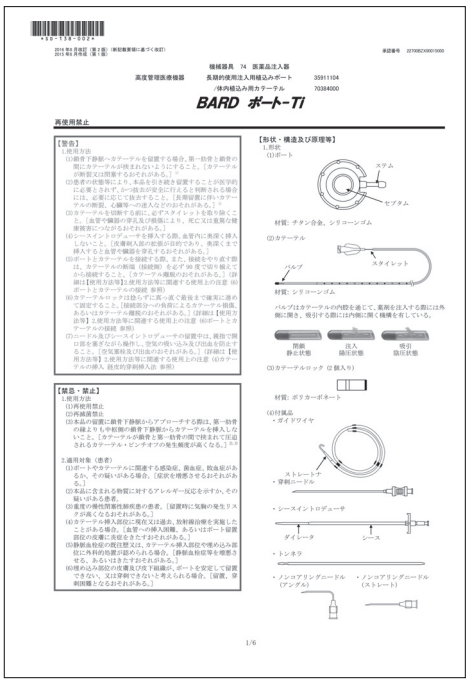
薬効分類名等	プロスタグランジンE1製剤	プロスタグランジンE1製剤	消化器機能異常治療剤
販売名	プリンク®注5μg／10μg	プリンク®注シリンジ5μg／10μg	プリンペラン®注射液10mg
成分名	アルプロスタジル	アルプロスタジル	塩酸メトクロプラミド
製品の写真	 プリンク®注5μg プリンク®注10μg 左：テバ製薬販売 右：アルフレッサ ファーマ販売	 左：プリンク®注シリンジ5μg 右：プリンク®注シリンジ10μg	 プリンペラン®注射液10mg
効能・効果	○慢性動脈閉塞症（バージャー病、閉塞性動脈硬化症）における四肢潰瘍ならびに安静時疼痛の改善 ○下記疾患における皮膚潰瘍の改善 進行性全身性硬化症 全身性エリテマトーデス ○糖尿病における皮膚潰瘍の改善 ○閉鎖病における末梢血行障害に伴う自覚症状の改善ならびに末梢循環・神経・運動機能障害の回復 ○動脈管依存性先天性心疾患における動脈管の開存 ○経上腸間膜動脈性門脈造影における造影能の改善	○慢性動脈閉塞症（バージャー病、閉塞性動脈硬化症）における四肢潰瘍ならびに安静時疼痛の改善 ○下記疾患における皮膚潰瘍の改善 ○糖尿病における皮膚潰瘍の改善 ○閉鎖病における末梢血行障害に伴う自覚症状の改善ならびに末梢循環・神経・運動機能障害の回復 ○動脈管依存性先天性心疾患における動脈管の開存	○次の場合における消化器機能異常（悪心・嘔吐・食欲不振・腹部膨満感） 胃炎、胃・十二指腸潰瘍、胆嚢・胆道疾患、腎炎、尿毒症、乳幼児嘔吐、薬剤（制癌剤・抗生物質・抗結核剤・鎮静剤）投与時、胃内・気管内挿管時、放射線照射時、開腹術後 ○X線検査時のバリウムの通過促進
製造販売元	テバ製薬株式会社	テバ製薬株式会社	アステラス製薬株式会社
発売・販売元	販売元： アルフレッサ ファーマ株式会社（10μgのみ）	発売元： 科研製薬株式会社	－

※製品をご使用の際は最新の添付文書をご確認ください。

② Initiatives by Medical Device Manufacturers and Distributors

In the 43rd Quarterly Report, this project highlighted Events Related to Central Venous Catheter Procedures on Patients in a Sitting Position and analyzed cases of air embolism when handling a central venous catheter (http:// www.med-safe.jp/pdf/report_2015_3_T002.pdf). In addition, Medical Safety Information No.113 Air Embolism after Removal of a Central Venous Catheter (http://www.med-safe.jp/pdf/med-safe_113.pdf) was compiled to offer a warning on the basis of this content. This output has been cited, for example, in the package insert for Bard Port-Ti, which is classed as "Infusion apparatus: Infusion apparatus / implantable catheters." The "[Precautions for Use] 1. Important Basic Precautions" section of the package insert states, "(7) Ensure that the patient is in a supine position when removing this product. [There is a risk of causing an air embolism if it is removed while the patient is in a sitting position.]" In addition, the "[References and Addresses for Requests for Literature] 1. References" section states, "(7) Project to Collect Medical Near-miss/Adverse Event Information, Japan Council for Quality Health Care 43rd Quarterly Report; December 22, 2015."

Figure 11 Use of the Outcomes of This Project in the Package Insert of a Medical Device (Example: Bard Port-Ti)


BARD ポート-Ti

再使用禁止

【警告】

【禁忌・禁止】

【形状・構造及び原理等】

1/6

[Precautions for Use] 1. Important Basic Precautions

(7) Ensure that the patient is in a supine position when removing this product. [There is a risk of causing an air embolism if it is removed while the patient is in a sitting position.]

[References and Addresses for Requests for Literature] 1. References

(7) Project to Collect Medical Near-miss/Adverse Event Information, Japan Council for Quality Health Care
43rd Quarterly Report; December 22, 2015

Thus, increasing the transparency of events reported to this project and details of its analyses by publishing them is helping to promote more widespread use of project output. As described in the explanation of similar initiatives relating to drugs, we believe that using the output from this project in this way is entirely appropriate and fully in keeping with the purpose of this project. We would be grateful if companies that are medical device marketing license holders would also continue to undertake activities of this nature going forward.

(3) Disclosure of Medical Adverse Events by Medical Institutions via This Project
—The Guidelines for the Disclosure of Medical Adverse Events at National University Hospitals—

When a medical adverse event occurs, a medical institution may disclose details of the event to increase the transparency of medical care or prevent the recurrence of similar events by enabling other institutions to learn from it. It may also disclose details of a medical adverse event at the request of the patient involved in the event or a member of their family, who wish other institutions to learn from it in order to prevent the recurrence of such events.

In March 2005, the National University Hospital Council of Japan published the Guidelines for the Disclosure of Medical Adverse Events at National University Hospitals, which set out standards for the disclosure of any medical adverse events that have occurred. These guidelines were subsequently revised in 2012, based on a recognition that a system for the public disclosure of outlines of medical adverse events, measures to prevent recurrence, and other medical safety information had become established and was functioning via this project. Just like the original version, the revised Disclosure Guidelines set out certain standards for the disclosure of information about medical adverse events at national university hospitals, in order to enhance the transparency of medical care, increase trust among the public, and assist in thorough medical safety management and the prevention of recurrence at other medical institutions. Some medical adverse events at national university hospitals must be disclosed via the websites, etc. of the medical institutions concerned, while most others are disclosed through reporting to this project. Amid growing interest in ensuring medical safety at advanced treatment facilities, many of which are university hospitals, we believe that, as one of the outcomes of this project, the Event Search function plays an important role in increasing the transparency of medical safety and improving the disclosure of medical adverse events at medical institutions.

4) Browse Function for “Analysis Themes” and “Analysis of Recurrent and Similar Events”

Clicking on the “Analysis Themes” button on the website enables the user to browse and download PDF files of pages that correspond to the titles of themes highlighted for analysis in the 1st-48th Quarterly Reports. In total, almost 190 themes have been subjected to analysis, highlighting many technical issues that have actually occurred in clinical practice. As such, we have received feedback from many users who say that looking at the list of themes is like looking at a list of events that have occurred at their own institutions. The analysis of themes includes a description of specific events, a summary of background and causal factors, a summary of the improvement measures reported by the medical institutions, and information relevant to the theme. Accordingly, we hope that medical institutions at which similar events have occurred will draw upon these analyses as reference material in conferences focused on considering their own events and that, in doing so, they will find useful pointers in the information about causal factors and improvement measures at other institutions. The themes that have been featured in Quarterly Reports in the last two years are listed below.

Figure 12 Analysis Themes Page

Figure 13 Analysis of Recurrent and Similar Events Page

Table 6 List of Analysis Themes on the Website (Past 2 Years)

Year	Quarterly Report	Cumulative Theme No.	Theme
2016	48th	189	Events Related to Antineoplastic Agents (iv) Events occurring at the administration or checks/observation associated with injection stage
		188	Events in Which Nor-Adrenalin Was Administered Instead of Adrenaline During Resuscitation
		187	Events Related to the Fitting of Elastic Stockings to Patients With Arteriosclerosis Obliterans of the Lower Limbs
	47th	186	Events Related to Antineoplastic Agents (iii) Events occurring at the order, dispensing, preparation, or explanation/guidance to patient stage
		185	Events in Which a Patient Accidentally Ingested a Foreign Substance During Dental Treatment
		184	Events Related to Falls From a Pediatric Bed
	46th	183	Events Related to Antineoplastic Agents (ii) Events occurring at the regimen registration, treatment plan, or prescription stage
		182	Events Related to Double Dosing of Current Medications and Drugs Prescribed in Hospital
		181	Events in Which a Film Dressing Was Affixed to a Permanent Tracheostomy
	45th	180	Events Related to Antineoplastic Agents (i) Overview
		179	Events Related to Drug Mix-up Due to Similar Appearance
		178	Events Related to Tubing Disconnection of Ventilator Circuit
2015	44th	177	Medical Adverse Events Related to Insulin (iv) Events classed as drug not administered, injected when drug had been stopped, wrong time of administration, or other
		176	Events Related to Drugs Subject to a Drug Holiday Before an Invasive Procedure
		175	Events Related to Fires Caused by Use of an Electrosurgical Pencil During a Tracheotomy
	43rd	174	Medical Adverse Events Related to Insulin (iii) Events Classed as Wrong Dosage of the Drug or Wrong Rate of Administration
		173	Events Related to Central Venous Catheter Procedures on Patients in a Sitting Position
		172	Events Related to Wrongly Inserted Gastric Tube
	42nd	171	Medical Adverse Events Related to Insulin (ii) Events Classed as Drug Mix-up or Patient Mix-up
		170	Events Related to Patient or Drug Mix-up at the Time of Administration
		169	Events Related to Urgent Contact Regarding Panic Values
	41st	168	Medical Adverse Events Related to Insulin (i) Overview
		167	Events Related to the Lithotomy Position during Surgery
		166	Events Involving Suicide or Attempted Suicide in a Hospital Room

Users can also browse PDF files of pages that correspond to the titles of themes highlighted in the "Analysis of Recurrent and Similar Events" section of the 18th-48th Quarterly Reports. Where similar events are reported even after information has been provided via the Analysis Themes, we prepare a follow-up, describing the reporting situation since the information was originally provided, as well as the background and causal factors and improvement measures newly reported during that period and any new relevant information. To date, follow-ups on a total of around 90 themes have been published. We hope that, as with the Analysis Themes, medical institutions will make use of this information when considering similar events. The following lists the themes featured over the last two years in the "Analysis of Recurrent and Similar Events" section, which first appeared in the 18th Quarterly Report.

Table 7 List of Themes Featured in Analysis of Recurrent and Similar Events on the Website (Past 2 Years)

Year	Quarterly Report	Cumulative Theme No.	Theme
2016	48th	89	Wrong site surgery (right/left) (Medical Safety Information No.8, 1st Follow-up Report: No.50) —Wrong site surgery (right/left) in neurosurgical procedures—
		88	Events Related to Reactivation of Hepatitis B Due to Immunosuppression/Chemotherapy (34th Quarterly Report)
	47th	87	Drug mix-up (Medical Safety Information No.4, No.68: 1st Follow-up Report)
		86	Urethral damage caused by an indwelling bladder catheter (Medical Safety Information No.80)
	46th	85	Provision of Food to Which the Patient was Allergic (Medical Safety Information No.69)
		84	Patient Mix-up during Radiological Examinations (Medical Safety Information No.73)
	45th	83	Specimen mix-up at pathological diagnosis (Medical Safety Information No.53)
		82	Medical Adverse Event Information to Be Shared: Event relating to intraocular lenses (15th Quarterly Report)
2015	44th	81	Contraindicated Combined Administration of Drugs (Medical Safety Information No.61)
		80	Medical Adverse Event Information to Be Shared: Events related to management of quantity remaining in oxygen tanks (17th Quarterly Report)
	43rd	79	Failure to implement measures to prevent mother-to-child transmission of Hepatitis B (Medical Safety Information No.49)
		78	Medical Adverse Event Information to Be Shared: Gauze left within the body (15th Quarterly Report)
	42nd	77	Tubing misconnection of ventilator circuit (Medical Safety Information No.24)
		76	Insufficient Confirmation Concerning Medical Devices Implanted into the Patient's Body (Medical Safety Information No.62)
	41st	75	Bone marrow suppression due to antirheumatic (Methotrexate) overdose (Medical Safety Information No.2, No.45 (1st Follow-up Report))
		74	Administration of 10 times proper dosage to pediatric patients (Medical Safety Information No.29)
		73	Administration of Contraindicated Drug (Medical Safety Information No.86)

5. Requests for Provision of Follow-up Information and On-site Visits

This project focuses on the collection of information by means of documents or on-site visits, in the event that the secretariat or Expert Analysis Group deems it necessary to gather information concerning reported events. In 2016, we made 133 requests to medical institutions, asking them to provide documentation and other follow-up information concerning medical adverse events, and received 120 responses. Moreover, we asked 5 medical institutions to permit us to carry out on-site visits regarding 8 events, and all of these institutions offered us their cooperation.

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 reported by inquiring about the content of deliberations conducted within the institution after the report and, as a result, to acquire knowledge that it was not possible to glean at the time of the report. The medical institutions visited have also found the content of the discussions at the time of the on-site visit useful. A summary of the events regarding which on-site visits have been conducted is published for reference purposes on p.79-88, along with the main staff members present during the survey, as well as the survey findings and opinions on the events. In the 2011 Annual Report, 1-2 pages were written about each event, but in the 2012 Annual Report, we increased the quantity of information provided and in the 2016 Annual Report, we have sought to make the information easier to read by positioning the details of the event as reported first, followed by the findings from the visit. We hope that you will find this useful. The summaries of events that were the focus of on-site visits are shown in Table 8.

Using the information gathered in this way, we are striving to further enhance the content of the Quarterly Reports, Annual Reports and Medical Safety Information; we would greatly appreciate your continued cooperation with these information-gathering activities.

Figure 14 Page Composition of the Overview of On-site Visits

Visit 2 **Event in which the senior physician ordered a diluted drug, but the resident prepared and administered the drug undiluted**

Event as reported

Summary of event	Background and causal factors	Improvement measures
At 11:18, the physician began the patient's upper gastrointestinal endoscopy. At 12:12, the patient roused while the procedure was still underway, so it was decided to administer additional sedation and the physician performing the endoscopy gave the resident (3rd year) the verbal order "Draw up Rohypnol 2cc and bring it to me." The resident took Rohypnol (2mg/mL/A) from the safe, prepared 2mL (2A) of Rohypnol in a 2.5mL syringe, and passed it to the senior physician. The senior physician administered 1mL (2mg) of the syringe's contents. When the nurse was tidying up later on, they began to harbor doubts because there was a 2.5mL syringe rather than the 5mL syringe usually used, the tape affixed to the syringe differed from the usual type, and the adhesive label from the ampoule was affixed to it. When the contents of the safe in the endoscopy department were checked, it was discovered that undiluted Rohypnol had been administered, when diluted Rohypnol would usually be used.	Drugs used in endoscopies are usually prepared by nurses. In the morning, the Rohypnol and Dormicum Injection 10mg to be used that day are diluted and placed in the safe, for use on multiple patients. On this occasion, the safe containing psychoactive drugs had not been locked. In the endoscopy department, a tenfold dilution of Rohypnol is prepared every morning, but the resident did not know that. The senior physician intended to order the resident to bring 2mL (0.4mg) of diluted Rohypnol (0.2mg/mL).	• Where verbal orders are unavoidable, the unit used when ordering medication quantity will be mg in all cases. • A rule will be instituted stipulating a mandatory check by a physician and a nurse when administering additional drugs and guidance will be provided to all members of the endoscopy department. • Before beginning clinical practice, all residents will be required to attend a mandatory orientation session covering basic knowledge of sedation methods in the endoscopy departments and sedation methods used at this hospital. • Adherence to the process for managing the key to the drugs safe and locking it will be thoroughly enforced. • The hospital has decided to dilute Rohypnol each time it is used, to avoid the need for verbal orders due to additional administration, as far as possible. • A conference concerning the event and measures taken in response was held, attended primarily by physicians, nurses, and technologists, and the event was also examined at a meeting of physicians in the endoscopy department.

Event as reported

Attendees from the medical institution during the on-site visit

Deputy Hospital Director & Director of the Medical Safety Management Department (physician), Director of the Medical Safety Management Office (physician), 2 physicians from the endoscopy department, Pharmaceuticals Management Officer (pharmacist), 2 GRMs from the Medical Safety Management Office (nurses), endoscopy room charge nurse, endoscopy room chief nurse, 2 members of clerical staff from the Medical Safety Management Office

Attendees from the medical institution during the on-site visit

Findings from the visit

1. Lead-up to the event: Explained by the medical institution (set of documents provided by the medical institution)
- The senior physician administered Rohypnol 0.5mg to sedate the patient before starting the examination. The senior physician discarded the syringe used at that time. Subsequently, when using additional sedation, the senior physician ordered the resident to prepare Rohypnol.

2. Background and causal factors
- Usually, nurses prepare the drugs used in the endoscopy department, but there was no nurse nearby, so the resident prepared it themselves.
- When preparing Rohypnol for use in the endoscopy department, nurses prepared a tenfold dilution, then divided it into two 5mL syringes, to each of which was affixed a special sticker stating "Rohypnol 1mg/5mL." The use of diluted Rohypnol was a rule common to both physicians and nurses in the endoscopy department.
- Both ampoules of Rohypnol and syringes containing a tenfold dilution of Rohypnol were stored in the same safe, with the ampoules in a box at the back and the syringes placed at the front.
- The diluted Rohypnol was made up twice a day: once for patients undergoing procedures in the morning and once for patients undergoing them in the afternoon.
- The nurse carried the key to the safe, unlocking it and locking it again each time it was used, but at the time of this event, the safe was unlocked while the diluted Rohypnol was being made up for use that afternoon.

○ Senior physician
- Physicians were hardly ever involved in preparing drugs, so when using the Rohypnol, the senior physician did not give the resident a specific order about the preparation of the drug.
- The senior physician said, "Draw up 2cc and bring it to me," meaning 2mL of a tenfold dilution of Rohypnol.

○ Resident
- The resident did not know the endoscopy department's rule about diluting Rohypnol or that syringes of the diluted drug had been prepared.
- The resident had no previous experience of using Rohypnol. Neither was the resident particularly aware of the drugs managed using the safe.
- The resident was able to take the Rohypnol ampoule out of the safe because it was unlocked.

○ Nurse
- The nurse was assigned to multiple patients and was not near the patient at the time of the event.

3. Main improvement measures introduced after reporting the event
- Verbal orders for drugs will be given in milligrams. The physician giving the order will do so in specific terms and the person receiving the order will repeat the correct order back to them.
- It will be the responsibility of the physician giving the order to strictly enforce the check back process, so that they can determine whether or not their intended order has been understood.
- Ampoules of Rohypnol will be stored in a separate safe from syringes containing diluted Rohypnol.
- A tenfold dilution of Rohypnol will be prepared for each patient as it is needed.
- Steps will be taken to avoid the need for verbal orders due to additional administration of Rohypnol, as far as possible. If a verbal order is issued, a memo will be taken and a physician and a nurse will carry out a double-check.

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

○ The senior physician was not aware that the resident did not know the rule about diluting Rohypnol. The rule was understood well enough that ordering "Rohypnol 2cc" was usually sufficient, but there appears to have been no awareness that a resident would not know the rule. It would seem to be important to think about risk that arises when a person who does not know about a common rule (resident) is involved in duties that are usually carried out smoothly on the basis of a common rule.

○ The senior physician possibly thought that the resident would ask a nurse to prepare the Rohypnol, rather than preparing it themselves.

○ It might be advisable to decide on ways of ensuring that there is only one option for use, such as by changing the locations in which undiluted and diluted Rohypnol are kept and the way in which they are managed, thereby ensuring that only a tenfold dilution of Rohypnol can be used in procedures. It might also be wise to consider reviewing the specified quantities of stock drugs.

● The pharmaceutical department uses a management register to check the drugs managed using the safe, checking narcotics daily and psychoactive drugs three times a week. We plan to examine the specified quantities.

○ The idea of increasing the number of safes for managing drugs is under consideration, but it might be advisable to think about separating drugs into those like narcotics, which are managed using a safe, and those like psychoactive drugs, which are managed under lock and key.

Findings from the visit and discussion during the visit

Table 8 Summary of Events on Which On-site Visits Focused

Visit	The type of event	Summary of event
1	Drug	Event in which Atonin-O Injection was meant to be administered via a peripheral vein to induce labor, but was instead administered via the epidural route
2		Event in which the senior physician ordered a diluted drug, but the resident prepared and administered the drug undiluted
3		Event in which Adriacin Injection was administered in excess of the total dose
4		Event in which Thyradin powder was prescribed instead of Thyradin S Powder, resulting in an overdose
5		Event in which the nurse prepared and administered Atropine Sulfate Injection when the physician ordered "ATP" (Adesinon-P)
6	Treatment/procedure	Event in which the patient suffered a cerebral infarction after their anticoagulant drug holiday was started five days too early
7	Medical device, etc.	Event in which the patient suffered pacing failure after the cable of their external pacemaker broke
8	Nursing care	Event in which a film dressing was affixed to the patient's permanent tracheostomy, affecting the patient's respiratory condition

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

6. Status of Access to Information Provided on the Website

In July 2010, we began to implement a division of roles between the Quarterly Reports and the website for this project, and increased the quantity of information published on the web. As a result, including information that was already published there, the website currently provides information including the List of Voluntarily Participating Medical Institutions, the List of Medical Institutions Receiving Medical Safety Information by Fax, Event Search, Medical Safety Information, Quarterly and Annual Reports, Analysis Themes, Analysis of Recurrent and Similar Events, Statistics Menu (Web Data), Quarterly/Annual Report Full Text Search, Quarterly/Annual Report Table Search, and Relevant Documents (such as guides concerning how to register to participate and how to use the reports of events, themes in the information about events, and examples of the use of the event search system). Following on from last year, we have conducted a study of changes in the number of times the following three sections have been accessed over the last few years.

Table 9 Survey Items Relating to the Number of Times Information Has Been Accessed

	Item	Content of Information Provided
1)	Published Data Search Note 1)	Reports concerning medical adverse event information and medical near-miss event information can be viewed and printed out from PDF or downloaded as CSV files.
2)	Medical Safety Information	Information Medical Safety Information published in the past can be viewed, downloaded as PDF files, and printed out.
3)	Quarterly and Annual Reports	Quarterly and Annual Reports published in the past can be viewed, downloaded as PDF files, and printed out.

Note 1) Corresponds to the Event Search button on the current website.

1) Changes in Access Frequency by Year

The following shows changes in the number of times information has been accessed by year. This data shows the number of times that visitors have clicked on the Homepage, Published Data Search (corresponds to Event Search on the current website), Medical Safety Information, and Quarterly and Annual Reports buttons on the website. Statistics have been compiled since 2009, but the method used to calculate access frequency was changed in 2014, so the figures shown here only show data from 2014 onward. Figures for the period 2009–2013 can be found on p.28 of the 2015 Annual Report.

Access to the Homepage of the website has been increasing since 2014; in 2016, it was accessed 270,425 times.

Access to Published Data Search (corresponds to Event Search on the current website) also has been increasing since 2014, reaching 50,789 in 2016.

Similarly, access to Medical Safety Information has been increasing since 2014, reaching 70,203 in 2016.

Access to Quarterly and Annual Reports has been increasing since 2014, as well, reaching 27,312 in 2016.

Thus, access to the Homepage, Published Data Search, Medical Safety Information, and Quarterly and Annual Reports pages is growing.

Table 10 Number of Times the Homepage, Published Data Search, Medical Safety Information, and Quarterly and Annual Reports Pages Have Been Accessed

	Number of Times Accessed		
	2014	2015	2016
Homepage[Note 1)]	240,165	263,075	270,425
Published Data Search[Note 2)]	37,906	42,495	50,789
Medical Safety Information	59,156	65,834	70,203
Quarterly and Annual Reports	24,400	25,420	27,312

Note 1) Access to http://www.med-safe.jp/index.html or http://www.med-safe.jp/.
Note 2) Corresponds to the Event Search button on the current website.

Figure 15 Homepage Access Frequency

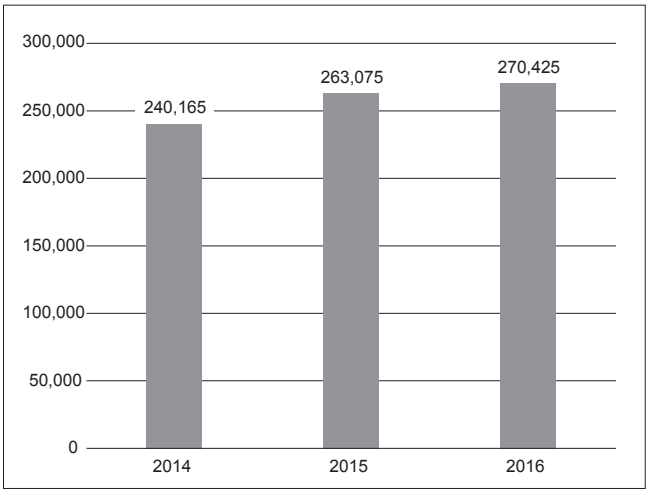
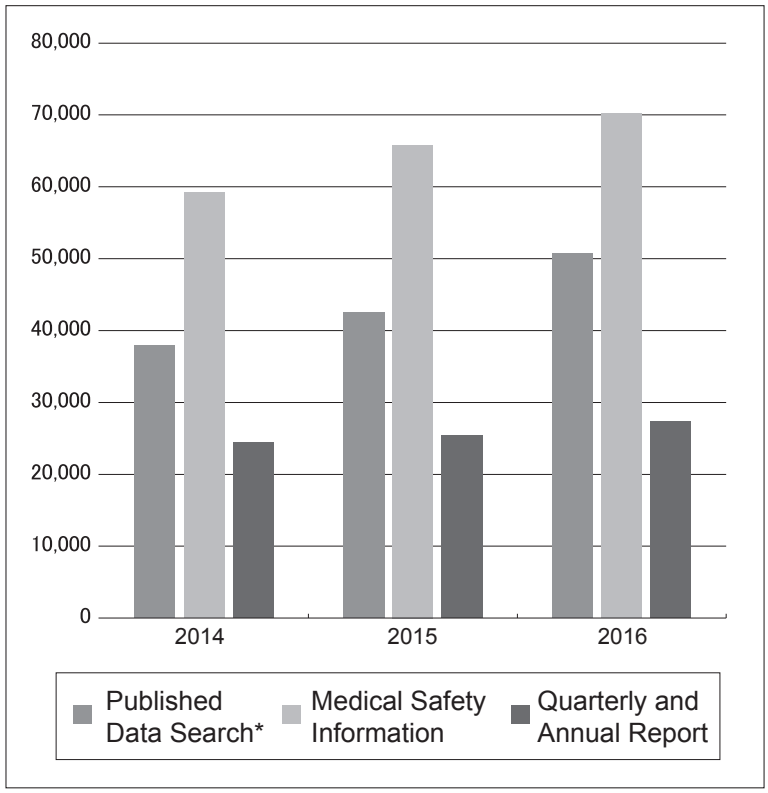


Figure 16 Published Data Search, Medical Safety Information, and Quarterly and Annual Report Page Access Frequency



*Corresponds to the Event Search button on the current website.

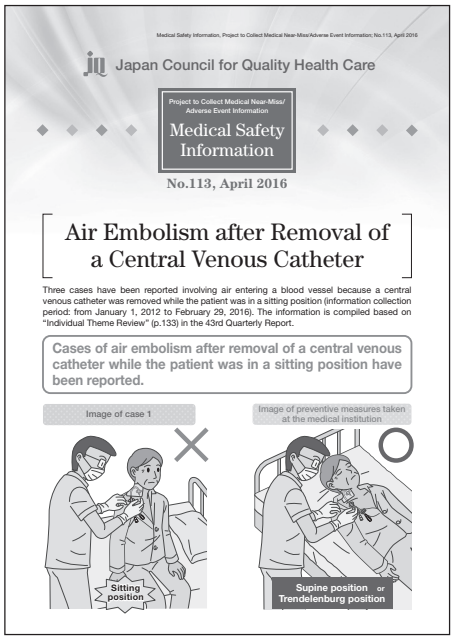
2) Medical Safety Information Accessed the Most

We investigated how many times each issue of Medical Safety Information (from No.50 to No.121) was accessed in the period 2015–2016; Table 11 shows which issues of Medical Safety Information were accessed the most during that period. In many cases, the number of times an issue is accessed increases over the course of the month of publication and the following month, and then gradually declines from the third month after publication. Consequently, it is necessary to bear in mind such matters as (1) the fact that the number of times that Medical Safety Information published outside the period studied (that is to say, issues published up to and including December 2014) was accessed (viewed) during its month of publication and immediately thereafter is not recorded, so the figures are lower than the actual total; (2) the fact that although the survey focused on a two-year period, the length of the collection period differs according to the month and year of publication; and (3) the fact that the overall upward trend in the number of times that Medical Safety Information is accessed could possibly be influencing the number of times that each issue of Medical Safety Information is accessed. Accordingly, these results cannot be taken to indicate the issues of Medical Safety Information that have been perused the most overall, but we hope that they will serve as a useful reference, bearing these points in mind. The issue that was accessed the most in 2015 was Medical Safety Information No.98 “Wrong Method of Administering a Potassium Preparation,” while in 2016 it was Medical Safety Information No.113 “Air Embolism after Removal of a Central Venous Catheter” (Figure 17), both of which were prepared and published in the respective year under consideration. When figures for the two-year period were totaled, Medical Safety Information No. 98 “Wrong Method of Administering a Potassium Preparation” (Figure 18) was the issue most frequently accessed in 2015 and 2016.

Table 11 Medical Safety Information Accessed the Most in 2015 and 2016

	2015	Number of events	2016	Number of events
1	No.98: Wrong Method of Administering a Potassium Preparation	21,032	No.113: Air Embolism after Removal of a Central Venous Catheter	18, 911
2	No.101: Wrong Drug Administration Route	16,902	No.114: Forgetting to Resume Anticoagulants/Antiplatelet Drugs	15, 361
3	No.102: Misinterpretation of a Verbal Order	15,892	No.111: Delays in Urgent Contact Regarding Panic Values	15, 004
4	No.104: Wrong Weight When Prescribing an Antineoplastic Agent	13,928	No.110: Blood Transfusion to Wrong Patient (1st Follow-up Report)	14, 567
5	No.100: Medical Safety Information released in 2014	12,382	No.116: Patient Mix-up in Drug Administration	14, 372
6	No.103: Medical Safety Information released from 2011 to 2013	12,137	No.118: Drug Mix-up Due to Similar Appearance	13, 562
7	No.105: Forgetting to Open/Close a T-shaped Stopcock	12,065	No.115: Medical Safety Information released from 2012 to 2014	12, 338
8	No.106: Wrongly Prepared Drug for a Pediatric Patient	11,118	No.112: Medical Safety Information released in 2015	12, 168
9	No.99: Left-Right Mix-Up When Inserting a Thoracostomy Tube	10,662	No.119: Incorrect Setting of Medication Quantity or Solution Volume on a Syringe Pump	11, 879
10	No.107: Surgical Fire Due to Ignition of a Flammable Drug by an Electrosurgical Pencil (1st Follow-up Report)	10,229	No.117: Inadequate Checks of Meal Type Information from Other Facilities	11, 125

Figure 17 Medical Safety Information Accessed the Most in 2016: Medical Safety Information No.113 “Air Embolism after Removal of a Central Venous Catheter”



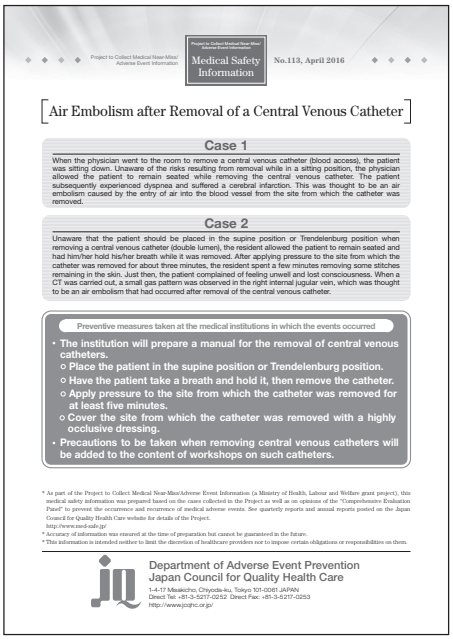
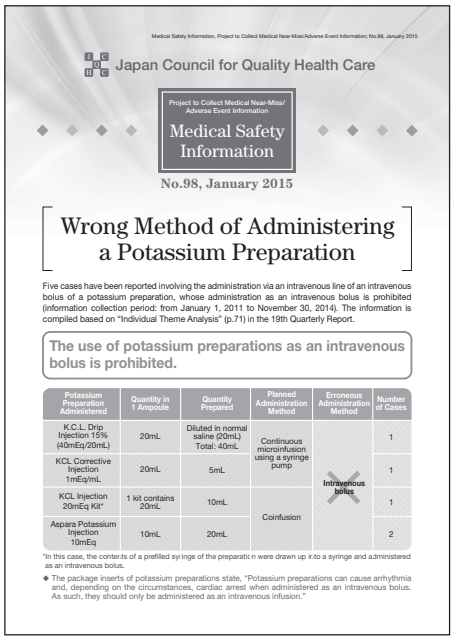


Table 12 Medical Safety Information Accessed the Most in Total in the Period 2015-16

	Total (2015+2016)	Access Frequency
1	No.98: Wrong Method of Administering a Potassium Preparation	30, 230
2	No.101: Wrong Drug Administration Route	20, 945
3	No.102: Misinterpretation of a Verbal Order	20, 589
4	No.113: Air Embolism after Removal of a Central Venous Catheter	18, 911
5	No.104: Wrong Weight When Prescribing an Antineoplastic Agent	16, 414
6	No.105: Forgetting to Open/Close a T-shaped Stopcock	15, 669
7	No.114: Forgetting to Resume Anticoagulants/Antiplatelet Drugs	15, 361
8	No.108: Incorrect Concentration of Adrenaline	15, 069
9	No.111: Delays in Urgent Contact Regarding Panic Values	15, 004
10	No.103: Medical Safety Information released from 2011 to 2013	14, 856

Figure 18 Medical Safety Information Accessed the Most in 2015 and 2016: Medical Safety Information No.98 “Wrong Method of Administering a Potassium Preparation”



Medical Safety Information, Project to Collect Medical Near-Miss/Adverse Event Information; No.98, January 2015

Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.98, January 2015

Wrong Method of Administering a Potassium Preparation

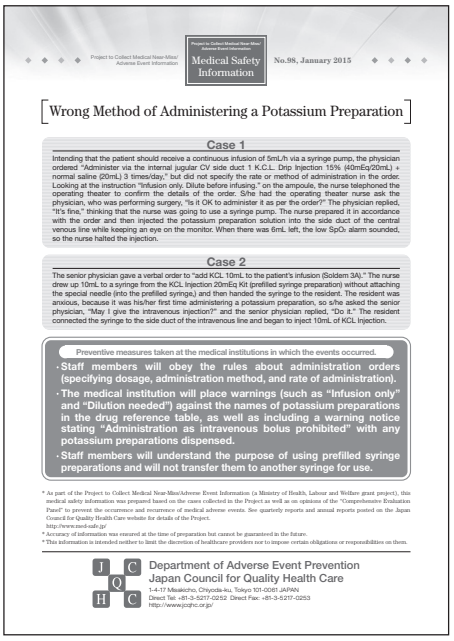
Five cases have been reported involving the administration via an intravenous line of an intravenous bolus of a potassium preparation, whose administration as an intravenous bolus is prohibited (information collection period: from January 1, 2011 to November 30, 2014). The information is compiled based on “Individual Theme Analysis” (p.71) in the 19th Quarterly Report.

The use of potassium preparations as an intravenous bolus is prohibited.

Potassium Preparation Administered	Quantity in 1 Ampoule	Quantity Prepared	Planned Administration Method	Erroneous Administration Method	Number of Cases
K.C.L. Drip Injection 15% (40mEq/20mL)	20mL	Diluted in normal saline (20mL) Total: 40mL	Continuous microinfusion using a syringe pump	Intravenous bolus	1
KCL Corrective Injection 1mEq/mL	20mL	5mL			1
KCL Injection 20mEq Kit*	1 kit contains 20mL	10mL	Coinfusion		1
Aspara Potassium Injection 10mEq	10mL	20mL			2

*In this case, the contents of a prefilled syringe of the preparation were drawn up in to a syringe and administered as an intravenous bolus.

◆ The package inserts of potassium preparations state, “Potassium preparations can cause arrhythmia and, depending on the circumstances, cardiac arrest when administered as an intravenous bolus. As such, they should only be administered as an intravenous infusion.”



Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.98, January 2015

Wrong Method of Administering a Potassium Preparation

Case 1

Intending that the patient should receive a continuous infusion of 5mL/h via a syringe pump, the physician ordered “Administer via the internal jugular CV side duct 1 K.C.L. Drip Injection 15% (40mEq/20mL) + normal saline (20mL) 3 times/day,” but did not specify the rate or method of administration in the order. Looking at the instruction “Infusion only. Dilute before infusing.” on the ampoule, the nurse telephoned the operating theater to confirm the details of the order. S/he had the operating theater nurse ask the physician, who was performing surgery, “Is it OK to administer it as per the order?” The physician replied, “It’s fine,” thinking that the nurse was going to use a syringe pump. The nurse prepared it in accordance with the order and then injected the potassium preparation solution into the side duct of the central venous line while keeping an eye on the monitor. When there was 6mL left, the low SpO_2 alarm sounded, so the nurse halted the injection.

Case 2

The senior physician gave a verbal order to “add KCL 10mL to the patient’s infusion (Soldem 3A).” The nurse drew up 10mL to a syringe from the KCL Injection 20mEq Kit (prefilled syringe preparation) without attaching the special needle (into the prefilled syringe,) and then handed the syringe to the resident. The resident was anxious, because it was his/her first time administering a potassium preparation, so s/he asked the senior physician, “May I give the intravenous injection?” and the senior physician replied, “Do it.” The resident connected the syringe to the side duct of the intravenous line and began to inject 10mL of KCL injection.

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

- Staff members will obey the rules about administration orders (specifying dosage, administration method, and rate of administration).
- The medical institution will place warnings (such as “Infusion only” and “Dilution needed”) against the names of potassium preparations in the drug reference table, as well as including a warning notice stating “Administration as intravenous bolus prohibited” with any potassium preparations dispensed.
- Staff members will understand the purpose of using prefilled syringe preparations and will not transfer them to another syringe for use.

* 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 quarterly reports and annual reports posted on the Japan Council for Quality Health Care website for details of the Project.
http://www.med-safe.jp/
* Accuracy of information was ensured at the time of preparation but cannot be guaranteed in the future.
* This information is intended neither to limit the discretion of healthcare providers nor to impose certain obligations or responsibilities on them.

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

7. Workshops

Every year, this project holds workshops on the analysis of medical adverse events, to promote high-quality reporting. The workshops held to date have focused on the use of root cause analysis (RCA) as an analytical technique and the preparation of process flows. In FY2016, the project held the 8th Workshop on Process Flows and the Project to Collect Medical Near-miss/Adverse Event Information in February 2017.

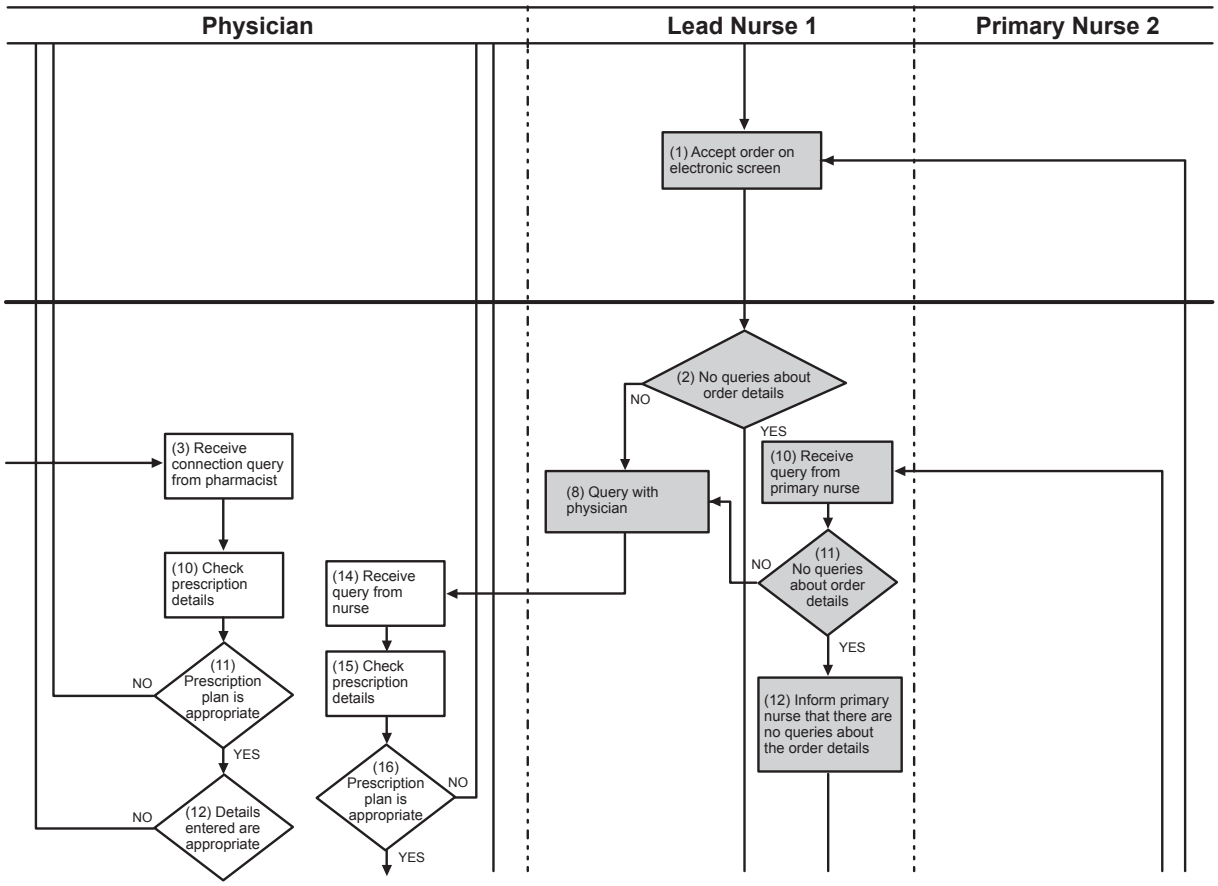
Duties are usually carried out via various operational processes in such areas as medical care, nursing care, and drug dispensing at medical institutions. However, one cannot really say that optimal, standardized operational processes have been established in practice at medical institutions. Accordingly, it seems that operational processes differ between medical personnel and that they vary considerably from one medical institution to another, even for the same medical procedure. In quite a few cases, it is unclear whether or not those processes were designed with consideration for eliminating waste and excess, as well as minimizing the risk of a medical adverse event. Answering such questions is an exercise in drawing up a process flowchart.

The workshop was attended by 36 people from 12 medical institutions, including 7 physicians, 1 dentist, 17 nurses, 6 pharmacists, and 5 clerical staff members. The call for participants specified that participation by staff in a range of occupations was preferable, including those in roles related to medical safety, those tasked with managing information systems, and those with experience of analyzing medical adverse events.

In terms of the main content of the program, the morning session featured an explanation of the current status of this project by the Division of Adverse Event Prevention. After that, Dr. Yoji Nagai, Director of Hitachi, Ltd. Hitachinaka General Hospital, spoke on the subject "What is a Process Flow?" The Division of Adverse Event Prevention then gave an explanation entitled "Drawing up Process Flows and their Importance in Medical Safety," which was followed by a lecture by Dr. Shigeru Fujita of the Department of Social Medicine at Toho University's Faculty of Medicine provided a commentary on "Improving Operational Processes Based on Medical Adverse Events and Points to Remember When Drawing up Process Flows." In the afternoon, each group from a single medical institution formed a team and reviewed and revised the process flows for regular and occasional injections at their facility, exploring the vulnerabilities of the operational processes at their facility and examining what revisions could be made.

In the post-workshop questionnaire, 97.2% of respondents replied "I understood the content of the exercise (well)." Feedback regarding the training exercise included "Working with people in other occupations and from other hospitals helped to expand the breadth of my knowledge," "It starkly highlighted our vulnerability out-of-hours. In addition, I realized that we have a problem with the time slots allocated for physicians to issue orders during working hours," and "I began to think about what is being compared with what in the process of carrying out checks." One can see how motivated the participants were, from these questionnaire responses alone. Regarding future workshops, feedback included such requests as "It was difficult for me to visualize problems and improvements that would enable me to work out how to link what I've learned to operational improvements starting tomorrow. I would have liked to have time for reflection and feedback by each team after the group exercise" and "Perhaps there is not enough time, but I wish that we could have discussed things after learning about the size of the participating hospitals and their role in the communities that they serve." We will take this feedback into account when planning future workshops.

Figure 19 Excerpt from a Process Flow From Ordering an Injection to Administration and Observation (Example)



8. Cooperation with the Project to Collect and Analyze Pharmaceutical Near-miss Event Information

1) The Current Status of the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information

(1) The Number of Participating Pharmacies and Reported Events

In October 2008, the Department of Adverse Event Prevention launched a project to collect and analyze medical near-miss event information from pharmacies, based on events occurring or discovered at pharmacies, with reports of near-miss events being accepted from April 2009. The 2015 Annual Report was published in November 2016, while the 15th and 16th Aggregate Reports were published in November 2016 and March 2017, respectively. The 2016 Annual Report is currently being prepared.

The number of pharmacies participating is continuing to increase, even now, and has reached 8,700 as of the end of 2016. The number of events reported is tracking at around 340–450 each month.

Although described as “pharmaceutical near-miss” events, there are also prescription form errors that have occurred at medical institutions, which are discovered through prescription queries by pharmacies; such events are also the subject of reports by pharmacies. 51,718 such events have already been published on the website for this project. Moreover, if you click on the Event Search button on the website, you can enter keywords to search the events in the database (http://www.yakkyoku-hiyari.jcqhc.or.jp/phsearch/SearchReport.action). In addition, particularly important events are selected as “Events to Be Shared” and published with comments from experts on individual events (http://www.yakkyoku-hiyari.jcqhc.or.jp/pdf/sharing_case_index.pdf).

This method of providing information began with the Project to Collect and Analyze Pharmaceutical Near-miss Event Information, ahead of the Project to Collect Medical Near-miss/Adverse Event Information, and this method of providing information has subsequently been adopted for the latter project as well.

(2) 2016 Annual Report

Through the Project to Collect and Analyze Pharmaceutical Near-miss Event Information, 4,939 events have been tabulated and analyzed between January and December 2016, and we are aiming to publish the 2016 Annual Report in due course. The 2010 Annual Report was the first full-scale Annual Report after registration of pharmacies began in April 2009, so it is intended that the forthcoming Annual Report will be the seventh volume that enables comparisons to be made. In compiling the outcomes of the project in the form of Aggregate Reports, Annual Reports, Events to Be Shared and Pharmacy Near-miss Analysis Tables, the same methodology is used as that employed in regard to the Quarterly and Annual Reports and Medical Safety Information in the Project to Collect Medical Near-miss/Adverse Event Information: the aggregate results and analyses of themes are presented, along with a few specific examples with condensed information, and they are created in a format that takes legibility into consideration, in regard to such matters as color and design. Furthermore, starting with the 2015 Annual Report, we have begun publishing a color edition entitled "Learning From Events," which describes typical events and highlights key points identified by members of the Comprehensive Evaluation Panel regarding those events.

The themes due to be taken up in the 2016 Annual Report are shown below and we hope that, once published, this information will be of use to hospital pharmaceutical departments as well.

Table 13 Analysis Themes in the 2016 Annual Report

	Details of Themes
1	Events related to similar drug names
2	Events related to prescriptions featuring generic names
3	Events related to a change to a generic drug
4	Events related to high-risk drugs — Events related to anticoagulants —
5	Events related to inquiries about prescriptions
6	Recurrence of Events to Be Shared or similar events — Events related to refilling errors —
7	Events related to the continuation of prescriptions at discharge, etc.

Many of the near-miss events that occur at pharmacies relate to dispensing; the breakdown shows that "wrong quantity," "wrong specification/dosage form," and "drug mix-up" are the most frequent, so one can see that there are many points in common with medical adverse events and medical near-miss events at medical institution. Thus, the JQ will make use of the advantages of gathering information about events occurring at medical institutions and pharmacies in an integrated fashion, and will provide an abundance of information concerning the prevention of medical adverse events relating to medications in particular.

2) Collaboration with the Project to Collect Medical Near-miss/Adverse Event Information

Approximately 70% of the pharmaceutical near-miss events reported in the Project to Collect and Analyze Pharmaceutical Near-miss Event Information are events relating to dispensing, most of which are events that also arise in the pharmaceutical departments of medical institutions, such as wrong quantity or wrong specification/dosage form. Consequently, of the Quarterly Reports, Annual Reports, and Medical Safety Information that have been compiled and published hitherto as part of the Project to Collect Medical Near-miss/Adverse Event Information, most of the content relating to medications is information that is useful for

pharmacies as well. Accordingly, the website of the Project to Collect and Analyze Pharmaceutical Near-miss Event Information has a page outlining results of the Project to Collect Medical Near-miss/Adverse Event Information (http://www.yakkyoku-hiyari.jcqhc).

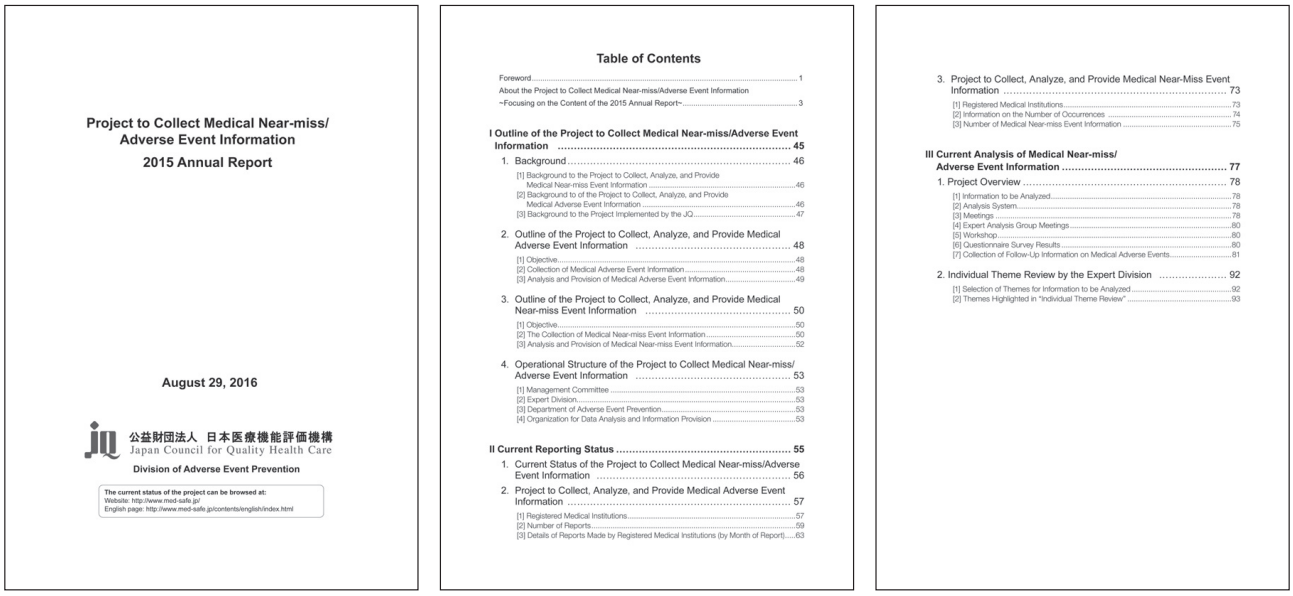
We are striving to disseminate information and educate people using this page, in order to ensure that pharmacists at pharmacies, registered seller (sales clerk qualified to sell over-the-counter drugs), and those involved in the clerical administration of pharmacies can discover at pharmacies errors that have occurred at medical institutions, and thereby strive to prevent medical adverse events.

9. Publication of the English-language Editions of the Project to Collect Medical Near-miss/Adverse Event Information 2015 Annual Report and Medical Safety Information No.108-119 and Dissemination of Information via the Global Patient Safety Alerts Project of the Canadian Patient Safety Institute (cpsi-icsp)

As part of the Project to Collect Medical Near-miss/Adverse Event Information, an English-language version of the Annual Report has been created each year since the 2005 Annual Report; published via the website, it has been used to publicize the content of the project and its outcomes, with copies being given to visitors from overseas.

At the end of March 2017, we published the English translation of this project's 2015 Annual Report, entitled "Project to Collect Medical Near-miss/Adverse Event Information 2015 Annual Report" (Figure 20). It can be viewed and downloaded from our website.

Figure 20 Cover Page and Table of Contents of the Project to Collect Medical Near-miss/Adverse Event Information 2015 Annual Report (English Edition)



Project to Collect Medical Near-miss/
Adverse Event Information
2015 Annual Report

August 29, 2016

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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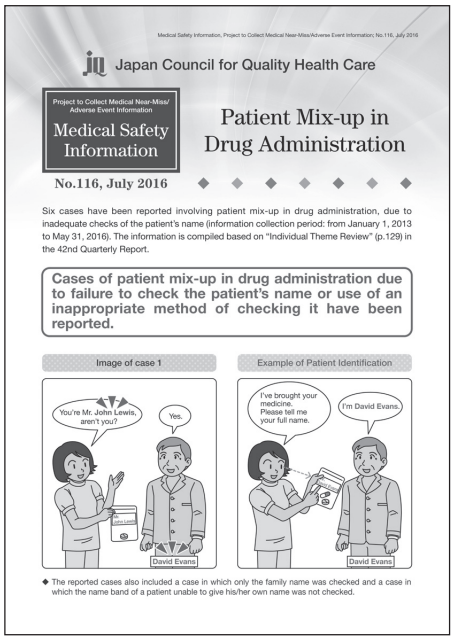
We publish English-language versions of the Medical Safety Information, which we provide to various organizations overseas. The latest English editions of Medical Safety Information, No.108-No.119, were published at the end of March 2017 (Figure 21). They are published on the project website and we hope that you will make use of them.

The Canadian Patient Safety Institute (cpsi-icsp) (http://www.patientsafetyinstitute.ca/en/Pages/default.aspx),

which is a WHO collaborating center, continues to disseminate the English-language editions of our Medical Safety Information to a global audience through the Global Patient Safety Alerts project that it is implementing jointly with the WHO (http://www.patientsafetyinstitute.ca/en/NewsAlerts/Alerts/Pages/default.aspx).

Specifically, the project website provides a summary of the information contained in each English-language edition of each Medical Safety Information, additional details, and related recommendations, along with a link to the full bulletin (in English) on the same page. The JQ's name is listed on the project website's as a contributing organization. A Global Patient Safety Alerts app is also available, enabling users to view the material on their mobile device. The project website (http://www.patientsafetyinstitute.ca/en/NewsAlerts/Alerts/Pages/default.aspx) features a video outlining the project. In a sign of the ongoing contribution to this project made by the Medical Safety Information bulletins prepared by our project on the basis of events that have occurred in Japan, the video explains the project's approach to sharing information internationally with the example of Medical Safety Information bulletins created in Japan being used in the U.S.A., along with the example of safety information from the UK being used in Canada (this video can also be viewed on YouTube: https://www.youtube.com/watch?v=4to0B25Nb9Q). (Figure 22)

Figure 21 Medical Safety Information No.116 (English Version)



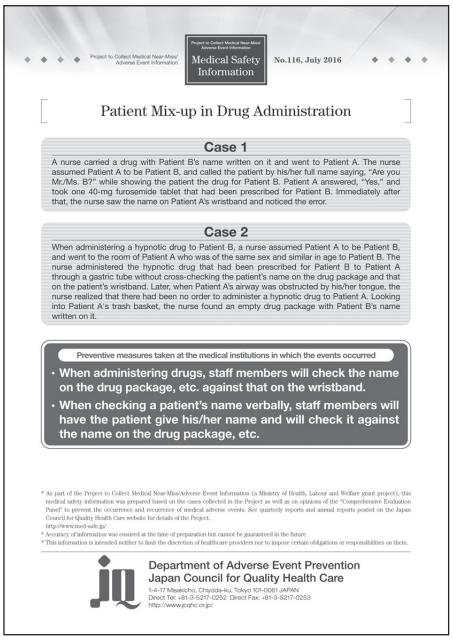
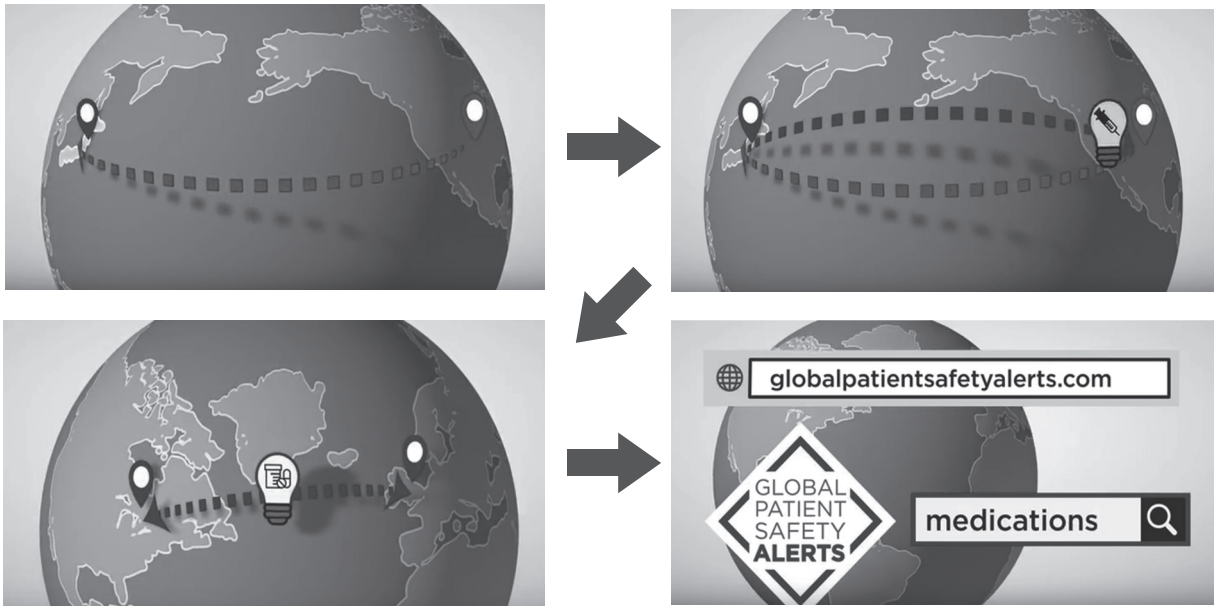


Figure 22 Video on the International Sharing of Medical Safety Information Featured on the Canadian Patient Safety Institute Website



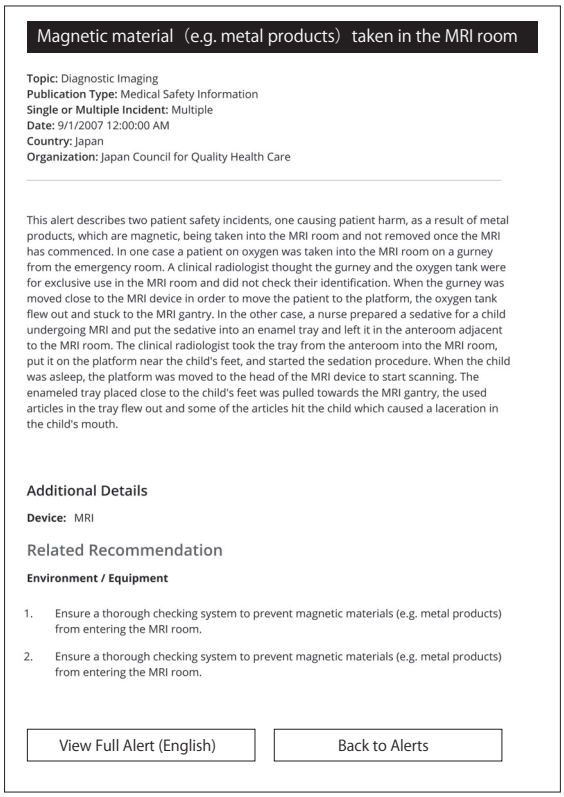
At the WHO Inter-regional Consultation on Patient Safety Incident Reporting and Learning Systems held in Colombo, which is described in further detail below, Ioana Popescu of the Canadian Patient Safety Institute gave a speech entitled "International Perspective: Canada." In her speech, Ms. Popescu outlined the institute's projects, including Global Patient Safety Alerts, and mentioned our project's Medical Safety Information several times. For example, she said, "Global Patient Safety Alerts includes many alerts from Japan. We extract information from the Japanese alerts and adjust it to our own format for publication. Naturally, we also link to the website that carries the Japanese alert. The Japanese adverse events reporting system website has a page with English-language versions of the alerts." During the Q&A session that followed her speech, the delegate representing this project said, "I recall that it was in 2011 that you asked our project to provide you with the English-language versions of our Medical Safety Information. I would like to know how frequently these alerts are viewed as part of your project. Even if they are being viewed reasonably frequently, there are many people who still do not know about them, so we would be grateful if you would make further efforts to raise awareness of them." In response, Ms. Popescu replied, "Our alerts are accessed about 40,000 times per year and this figure is increasing annually. We will continue to spread awareness of them. We have also created an app to make them more user-friendly." Accordingly, our delegate said, "We mention your project and the app in our Quarterly and Annual Reports on Japan's Project to Collect Medical Near-miss/Adverse Event Information. We have mentioned them in every Quarterly Report. We will continue to provide English versions of our Medical Safety Information bulletins, so we would appreciate it if you would continue to use and publicize them." After listening to the speech and subsequent Q&A session, the representative of the WHO, which organized the WHO Inter-regional Consultation in Colombo, said that they wished to strengthen links between Global Patient Safety Alerts and the WHO's own activities and output. After the meeting ended, we got in touch with Ioana Popescu and the Global Patient Safety Alerts coordinator to let them know that the most recent English-language versions of the Medical Safety Information (up to No.107 at that stage) were available on our website and to ask them to make use of them. They told us that they were in the process of redesigning their website so that it would provide not only an outline of the alert, but also additional details. The redesign of the website was subsequently completed and users can view not only the Medical Safety Information, but also additional details relevant to the theme.

At the WHO Expert Consultation on Establishing Patient Safety Incident Reporting and Learning Systems, which is described in further detail below, we exchanged views with Stephen Routledge, who, further to the aforementioned Q&A exchange with Ioana Popescu, informed us that the Global Patient Safety Alerts website

receives 40,000 views annually from more than 100 countries worldwide and that page views were up 42% year on year. At the Second Global Ministerial Summit on Patient Safety, which was held in March 2017 in Bonn, Germany, the delegate from the Canadian Patient Safety Institute, who served as Canada's representative at the meeting, outlined the Global Patient Safety Alerts project. We had the opportunity to exchange views with Chris Power, the institute's CEO, and reaffirmed our commitment to future collaboration.

Thus, in addition to the English-language website for the Project to Collect Medical Near-miss/Adverse Event Information, the content of the English editions of Medical Safety Information is being viewed worldwide via the contributing organizations page of the Global Patient Safety Alerts website, as well as the site's search function and the dedicated app.

Figure 23 Global Patient Safety Alerts Page for Medical Safety Information No.10 "Magnetic material (e.g. metal products) taken in MRI room" and Additional Details



10. Development of the WHO Minimal Information Model for Patient Safety (MIM PS)

The WHO is undertaking a project focused on the development of a system for reporting adverse events and analyzing and learning from them to prevent their recurrence, an approach to promoting international medical safety similar to the methodology of this project. The WHO Draft Guidelines for Adverse Event Reporting and Learning Systems (currently in the process of revision), which were compiled and published in 2005 and are very familiar to those working in the medical safety field, set out the core principles for learning systems based on the systematic collection of data on adverse events. These guidelines highlight this project as Japan's adverse event reporting and learning system.

As described below, the Conceptual Framework for the International Classification for Patient Safety (ver.1.1) has been compiled and published to serve as one of the basic systems for gaining an understanding of adverse events. This framework proposes a variety of classes of information needed to gain an understanding of incidents, including contributing factors/hazards, patient characteristics, incident characteristics, catalysts for

detection, ameliorating actions, patient outcomes, organizational outcomes, and actions taken to reduce risk. Based on the outcomes of this, the Minimal Information Model for Patient Safety (MIM PS) was developed as a system for going beyond the institutional level by promoting learning and information-sharing at the global level. The details of MIM PS were explained at the WHO International Consultation on European Validation of the Minimal Information Model for Patient Safety in Warsaw, Poland on May 12–13, 2015. Japanese participants in the meeting gave a speech explaining this project and its status as Japan's adverse events reporting system. Similarly, the WHO coordinator talked about this project's progress at meetings in February and March 2016, at which speeches concerning this project had been requested. Details of the speech at the WHO Inter-regional Consultation on Patient Safety Incident Reporting and Learning Systems in Africa and the Asia Pacific Regions, which was held in Colombo on March 22–24, can be found in the 47th Quarterly Report (p.28–31).

Table 14 MIM PS Reporting Categories

MIM PS: Standard Version	MIM PS: Expanded Version
(1) Patient information (age, sex) (2) Time of incident (3) Location of incident (4) Agent(s) involved (persons, devices, etc.) (5) Incident type (6) Incident outcome(s) (7) Resulting action(s) (8) Reporter's role	(1) Patient information (age, sex) (2) Time of incident (3) Location of incident (4) Cause (5) Contributing factor (6) Mitigating factor (7) Incident type (8) Incident outcome(s) (9) Resulting action(s) (10) Reporter's role

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

ISQua (the International Society for Quality in Health Care) (http://www.isqua.org/) is an international society dedicated to improving the quality of healthcare, which was established in 1985 and currently has its headquarters in Dublin (Ireland). It is funded by the membership fees of individual and institutional members in around 70 countries, as well as by contributions from the Irish government. In addition to the JQ's institutional membership of ISQua, 24 members of the JQ hold individual membership of the society. JQ Executive Board member Yuichi Imanaka is a member of the ISQua Board and contributes to the society's running in that capacity.

ISQua's main activities are as follows:

- The International Accreditation Programme (IAP)

- Publication of the International Journal for Quality in Health Care

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

- Holding the International Conference

In 2016, the JQ and ISQua co-hosted the International Conference at Tokyo International Forum from Sunday, October 16 to Wednesday, October 19 (http://jcqhc.or.jp/isqua.html). Table 15 lists the main presentations about this project, followed by a summary of the main points.

Table 15 Overview of Presentations

Date	Category	Title, Chair, Speakers
October 18	**Plenary 3 (55 min.)**	Japan's Quality Improvement Body -Its Achievement And Future Role in Public Healthcare Service As Private Sector Entity Chair: BK Rana; India Speaker: Shin Ushiro; Japan
October 19	**Session C10 (60 min.)**	Improvement Science for Quality and Safety Chair: Sir Liam Donaldson; WHO Speakers: Sheila Leatherman; USA, Cliff Hughes; Australia, Shin Ushiro; Japan
October 17-19	**Poster**	Utilization of Medical Safety Information in Medical Institutions Presenter: Misa Sakaguchi, Hiromi Sakai, Junko Inoue, Shin Ushiro; Japan

1) Plenary 3: Japan's Quality Improvement Body -Its Achievement And Future Role in Public Healthcare Service As Private Sector Entity, Chair: BK Rana, India; Speaker: Shin Ushiro, Japan

In his explanation during the plenary session on October 18, Ushiro covered such topics as the background to the founding of this project; its anonymous, non-disciplinary approach; the increase in the number of reports; details of its quantitative and theme-based analysis; and the fact that making the database available has led to the withdrawal of brand names involved in the mix-up of drugs with similar names. He also described the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information, which is a similar system, and emphasized the importance of seamless safety measures from drug prescription through to dispensing and administration. Following this, Ushiro outlined the Japan Obstetric Compensation System for Cerebral Palsy, the key features of which are no-fault compensation, detailed analysis, and fulfillment of the duty of accountability to families. Regarding fatal events, he briefly mentioned the fact that Japan's medical adverse event investigation system was launched in 2015 and that consideration is being given to a third-party hospital evaluation system for advanced treatment facilities and the like, to address the medical adverse events that have recently occurred during the provision of advanced medical treatment at university hospitals. The Q&A session that followed included comments, questions, and information about a range of topics. These included medication safety — specifically, the linkage of information about medication collected as part of the Project to Collect Medical Near-miss/Adverse Event Information and the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information to medication safety measures implemented by the government; the need for improvements in South Korea, because the voluntary reporting system guaranteeing protection under the law that has been launched there still receives few reports; the extent to which use of the WHO's surgical checklist has become widespread in Japan; and the impact of this project's outcomes on medical device package inserts, which are currently complex.

2) Session C10: Improvement Science for Quality and Safety, Chair: Sir Liam Donaldson, WHO; Speakers: Sheila Leatherman, USA; Cliff Hughes, Australia; Shin Ushiro, Japan

A session planned by the WHO was held on October 19. As described below, this project's output has attracted the attention of the WHO, so we were asked to speak at this session. A key factor behind the planning of this session was the awareness of the need to achieve qualitative improvements at the same time as the quantitative enhancement in medical care expected to result from the positioning of universal health coverage as a key issue on the agenda at the U.N. and various economic summits. In addition, the WHO is considering measures aimed mainly at low- and middle-income countries, so this session was held with the aim of offering an insight into the state of deliberations at this stage and also in the hope that Japan and Australia could provide advice. The JQ's presentation started by describing how the JQ had been founded by a large number of medical and administrative bodies after a preparatory period of about 10 years and went on to cover (1) the establishment of public and private sector leadership at the national and local level to improve the quality and safety of

medical care; (2) the spontaneous improvements in quality and safety that result from medical institutions undergoing Hospital Accreditation by a third-party organization in addition to the medical supervision carried out by the government; (3) the creation of a culture of learning from errors through the operation of facility- and national-level reporting systems that adopt an anonymous, non-disciplinary approach, based on the experiences of the Project to Collect Medical Near-miss/Adverse Event Information; (4) the importance of ensuring widespread use of clinical practice guidelines that have been evaluated on the basis of global standards, based on the experiences of the Medical Information Network Distribution Service (MINDS), which assists with the preparation of clinical practice guidelines and evaluates them; and (5) the importance of standardizing quality indicators (QIs) to facilitate benchmarking at the national level. Speaker Sheila Leatherman offered a commentary providing an overview of the Global Quality Report, which the WHO is currently preparing in partnership with the World Bank and the OECD and which will be the WHO's first full-scale report on the quality of medical care. Prof. Leatherman's explanation covered the current situation in low- and middle-income countries; the importance of policymaking at the national level and specific topics related to this; the specific roles of government, medical personnel, and other relevant individuals; and the action plan. ISQua President Cliff Hughes then gave a speech about the concept of measuring services. Questions and comments during the Q&A session covered such topics as the need to use the still-little-known report on quality prepared by the WHO in 2003 and the necessity of refining the focus of quality and safety, given that they are perceived by some groups and academic societies as being very broad in scope. Asked by session chair Sir Liam Donaldson to comment on how trust — which had not been mentioned by any of the speakers — could be formed, Ushiro stated that in most of the JQ's projects, the committee members include those who can offer the patient's perspective and that while conflicts of opinion sometimes occurred, this made it possible to run a more balanced project that was trusted by the public. Similarly, many world leaders and advanced organizations in the field of quality and safety expressed the view that the perspective of patient participation and, beyond that, proactive involvement by patients is required.

In taking advantage of opportunities such as these to deepen its partnership with ISQua, the JQ is striving to ensure that it does not merely put into practice initiatives that accord with international trends, but also actually participates in shaping those trends. Recently, the JQ has been redoubling its efforts to disseminate information, running webinars (online seminars) covering the same topics in both Japanese and English on the ISQua website.

12. Dissemination of Information at International Conferences

The Project to Collect Medical Near-miss/Adverse Event Information publishes English-language versions of the Annual Report and Medical Safety Information on the project's website and uses them to publicize the project's activities and achievements.

The ongoing dissemination of such information has led to requests from overseas for lectures about the JQ's projects focused on the quality and safety of health care, including this one, almost every year since FY2010. In addition, the JQ continues to give presentations on similar matters at ISQua's annual conference, as part of its efforts to strengthen its partnership with ISQua.

Recently, we have received a number of requests to give lectures and presentations at WHO conferences to explain this project and other JQ projects focused on the quality and safety of medical care. In 2015, we gave speeches at the WPRO Policy Round Table on Quality in Health Services, which was hosted by the WHO West Pacific Region in Hong Kong in September (an outline of the speech can be found in the 44th Quarterly Report, p.34–36), and at the WHO Strategic Expert Working Group Meeting Developing Vision and Strategic Directions for Improving Patient Safety and Quality of Care, which was held at WHO headquarters in Geneva, Switzerland in November (an outline of the speech can be found in the 44th Quarterly Report, p.39). In 2016–2017, we gave speeches about the current status of the project and publicized its outcomes at the meetings hosted by the WHO and the German Federal Ministry of Health, as well as the Healthcare Accreditation Thailand National Forum, as described below. In addition, we participated in discussions while attending

meetings concerning the planning of the next project to be undertaken by the WHO-led World Alliance for Patient Safety and the revision of draft guidelines concerning patient safety incident reporting and learning, in which this project is involved. The following provides an outline of these conferences. Further details can be found in the 49th Quarterly Report.

Table 16 International Conferences Attended

	Conference	Date	City
1	WHO Inter-regional Consultation Conference	08-10 Feb 2016	Muscat, Oman
2	WHO Inter-regional Consultation Conference	22-24 Mar 2016	Colombo, Sri Lanka
3	Working Groups Meeting WHO Global Patient Safety Challenge Medication Safety	22-24 Aug 2016	WHO headquarters, Geneva, Switzerland
4	WHO Global Consultation	26-28 Sep 2016	Florence, Italy
5	WHO Expert Consultation on Establishing Patient Safety Incident Reporting and Learning Systems	15-16 Dec 2016	WHO headquarters, Geneva, Switzerland
6	18th Healthcare Accreditation Thai National Forum	15-17 Mar 2017	Bangkok, Thailand
7	2nd Ministerial Summit on Patient Safety in Bonn	29-30 Mar 2017	Bonn, Germany

1) Inter-Regional Technical Consultation on Best Practices in Patient Safety and Quality of Care, 8-10 February 2016 in Muscat, Oman

On February 8-10, 2016, WHO headquarters and the WHO Eastern Mediterranean Regional Office jointly organized a meeting in Muscat, Oman, in collaboration with the Governments of Japan and Oman. Its aim was to promote partnerships between four WHO regions (the African, Eastern Mediterranean, South-East Asian and Western Pacific Regions). The consultation was part of the initiative for establishing the WHO Global Patient Safety and Quality Network, in response to an increasing high-level interest in strengthening patient safety and quality of care across the world. The 120 participants from 22 countries included experts in the field of safety and quality of care, such as policymakers from health ministries, as well as representatives of key facilities and organizations, and other stakeholders.

In the morning of the first day, Ushiro gave a lecture about this project (30 minutes). Specifically, he explained Japan's medical safety measures (national level: Project to Collect Medical Near-miss/Adverse Event Information, the no-fault obstetric compensation for cerebral palsy / causal analysis and recurrence prevention system, and Hospital Accreditation; institutional level: internal incident reporting systems and responses to disputes). In addition, he served as moderator for the Panel Discussion on Selected Evidence Based Interventions for Patient Safety and Quality of Care (one hour) on the afternoon of the first day, as well as contributing his views and comments to other discussions.

2) WHO Inter-Regional Consultation Patient Safety Incident Reporting and Learning Systems in Africa and Asia Pacific Regions, 22-24 March 2016, Colombo, Sri Lanka

On March 22-24, 2016, WHO headquarters and the WHO South-East Asian Regional Office jointly organized a meeting in Colombo, Sri Lanka, with the support of the Governments of Japan and Sri Lanka. Its aim was to promote partnerships between four WHO regions (the African, Eastern Mediterranean, South-East Asian and Western Pacific Regions). The participants from 21 countries included experts in the field of safety and quality of care, such as policymakers from health ministries, as well as representatives of key facilities and

organizations, and other stakeholders.

To assist member countries that had expressed a desire to establish incident reporting systems at the national level, the WHO established the first edition of its draft guidelines in 2005 and has been developing the Minimal Information Model for Patient Safety Incident Reporting and Learning System (MIM PS), which is a streamlined and functional set of items to be reported. The WHO intends to utilize the fruits of these discussions in preparing the WHO Implementation Guidelines on Patient Safety Incident Reporting and Learning Systems.

In the afternoon of the first day, Ushiro gave a lecture about this project (15 minutes). Specifically, he explained the reporting method used in the Project to Collect Medical Near-miss/Adverse Event Information, as well as outlining the results of analysis and providing examples of the way in which project outcomes are used (such as in eliminating drugs with similar names). In addition, he served as moderator and summarizer for the group exercise in "Developing WHO Guidance on Patient Safety Incident Reporting and Learning Systems" (two hours) on the afternoon of the first day, as well as contributing his views and comments to other discussions.

3) WHO Global Patient Safety Challenge on Medication Safety: Working Groups Meeting, 22-24 August 2016, Steering Board Meeting, 25 August 2016, Geneva, Switzerland

In the past, the WHO has led two global patient safety challenges, which are initiatives focused on the quality and safety of medical care. The first focused on hand hygiene and the second on the use of a surgical checklist. Following on from these, the WHO has selected medication safety as the focus of its third patient safety challenge. Accordingly, the WHO held a meeting to discuss the specific content of the challenge on August 22–24, 2016.

A plenary session in the morning of August 22 was followed by group sessions and presentations that went on until August 24. The themes of the working group meetings were: (1) Patient and public; (2) Health care professionals; (3) Medicines; (4) Systems and practices; and (5) Monitoring and evaluation. The delegate from the JQ commented that the outcomes of the Project to Collect Medical Near-miss/Adverse Event Information and the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information could assist in promoting the new patient safety challenge of medication safety.

At the Steering Board meeting on August 25, participants gave a summary of the discussions over the previous three days and talked about future plans until the launch of the new patient safety challenge.

4) WHO Global Consultation Setting Priorities for Global Patient Safety, 26-28 September 2016, Florence, Italy

This meeting was held on September 26–28, 2016 in Florence, Italy, hosted by the Centre for Clinical Risk Management and Patient Safety, Department of Health of the Tuscany Region, which has recently been designated as the WHO Collaborating Centre in Human Factors and Communication for the Delivery of Safe and Quality Care. A total of 140 delegates from 30 countries — both developed and developing — took part.

Almost all of the three-day program consisted of lectures by experts. During Session 6 "Patient Safety Incident Reporting and Learning Systems, Chair: Dr Ross Baker," in the morning of the second day, the delegate from the JQ gave a 20-minute lecture that focused primarily on this project, as well as mentioning the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information, the Japan Obstetric Compensation System for Cerebral Palsy, and the medical adverse event investigation system. In addition, the JQ delegate participated in the group session "Recommendations on Priorities for Global Patient Safety" in the afternoon of the third day, emphasizing the importance of learning from errors and giving their views on promoting the introduction of reporting systems at the national and institutional levels.

Topics covered in the meeting included education and training; strengthening leadership; teamwork and communication; scientific approaches for ensuring effectiveness; patient involvement; comprehensive system handling and integrated approaches; sharing examples of success; medication safety; diagnostic errors; hospital-acquired infections; and ensuring organizational transparency to learn from errors and foster a culture of safety. Focusing primarily on learning from errors, the speech concerning this project would seem to have been relevant to a number of those topics.

One of the recommendations that emerged from the speeches at the meeting was support for sharing the WHO Global Knowledge Sharing Platform for Patient Safety, which the WHO is preparing to launch. The WHO Global Knowledge Sharing Platform for Patient Safety is currently being developed in partnership with Tuscany's WHO Collaborating Centre in Human Factors and Communication for the Delivery of Safe and Quality Care, which hosted the meeting. The platform incorporates both the sharing of best practices and learning from incident reports. Discussion of this topic in even greater depth during the meeting resulted in the consensus that the WHO needs to build a network to facilitate the exchange of knowledge between states or organizations.

5) Expert Consultation on Establishing Patient Safety Incident Reporting and Learning Systems, 15-16 December 2016, Geneva, Switzerland

In 2005, the WHO published the WHO Draft Guideline for Adverse Event Reporting and Learning Systems, which highlighted this project as a Japanese initiative in this area. Although it is positioned as a draft guideline, it has been translated into several languages and has influenced the design of medical adverse event reporting systems and the promotion of medical safety in many countries. About ten years have passed since the publication of the draft guideline, so member countries are calling for it to be incorporated into an official guideline, along with revisions that take account of technical advances over the last decade.

Accordingly, the WHO held a meeting attended by experts in the field of medical safety from various WHO regions on December 15–16, 2016, to discuss and revise a new draft guideline prepared by the WHO. A delegate from the JQ attended this meeting and outlined the knowledge amassed through the running of this project.

At this meeting, the new draft guideline was discussed during a number of group sessions. The main points covered in the discussions were as follows:

- Awareness of the current situation in low- and middle-income countries.
- Some issues have remained unresolved ever since the 2005 publication of the draft guideline. For example, these include fostering a culture that does not criticize those who submit reports, the issue of under-reporting, and the small number of reports concerning events in primary care and childbirth.
- The scope of reporting is unclear, gathering information requires money and labor, and there is a lack of resources to devote to analysis, which results in little feedback being provided.
- Examples illustrating the positive effects of reporting/learning systems are necessary.
- Guidance to assist in creating a high-level reporting/learning system (clarifying the scope of reporting, fostering a culture free from criticism, providing feedback, etc.)
- Guidance aimed at ensuring that the occurrence of reportable events is noticed and recorded (ensuring that medical personnel are conscious of their responsibility to report events, reporting particularly critical phenomena by telephone, participation of patients and their family members, etc.)
- The significance of analyzing and tallying a large number of events and the significance of analyzing individual events in depth.

- ○ Guidance concerning the review and investigation of individual incidents (developing human resources and investing resources, examining deficiencies in the system that are common to other facilities and sectors, clarifying policies on reporting at the national level and reporting to learning systems, protecting the persons involved in incidents, etc.)
- ○ Guidance about using the incident data amassed and analyzed to gain insights into the content of the system (analyzing systems that have safety standards and guidelines in light of those standards and guidelines, formulating methods of using data to identify factors that could pose new risks, etc.)
- ○ Guidance aimed at providing support for learning, practice, and improvement (the awareness that formulating improvement measures requires intensive discussion and expert advice, the effective use of alerts issued at the national level, the creation of reporting and learning mechanisms in specific specialized areas, the protection of reported data, etc.)

During the discussion, the JQ's delegate outlined the knowledge that we have gained from running this project. Another participant expressed the high esteem in which they hold this project, which reports a variety of medical adverse events and near-miss events at Japanese medical institutions. The following provides a summary of the discussion:

- ○ In discussing items for inclusion in adverse event reports and the development of legislation, it should be recognized that motivating medical institutions to report to an external body is critical to the success of the system in this project.
- ○ Regarding items to be included in reports, descriptive information is also important, because there are limits to the extent to which events can be broken down to their constituent elements by using menus of options from which to select.
- ○ One example of a positive effect of a reporting/learning system can be seen in Japan, where this project highlighted the fact that mix-ups between specific drugs with similar brand names were occurring, as a result of which the companies scrapped the brand names concerned for the sake of medical safety. The JQ would like the outcomes of Japan's reporting and learning system to be highlighted as an example of best practice in the new guideline as well.
- ○ An Australian participant expressed the view that Japan's mechanism is functioning well in terms of the number of reports, analysis, and feedback, as described in the presentation at ISQua's International Conference in Tokyo 2016.

At the end of the meeting, the WHO explained that it would continue to work on revising the draft guideline further, while summarizing and reflecting the discussions that had just taken place. The WHO also stated that, in the process of this revision work, it would seek the opinions of participants in the aforementioned WHO Inter-Regional Consultation on Patient Safety Incident Reporting and Learning Systems held in Colombo, Sri Lanka, on March 22–24, 2016, and that it was giving consideration to ways of ensuring that the guidelines would also be practical for low- and middle-income countries and countries where reporting and learning systems do not yet exist.

6) 18th Healthcare Accreditation Thai National Forum, Bangkok, Thailand

The 18th National Forum hosted by the Healthcare Accreditation Institute, which runs a third-party hospital appraisal program in Thailand, was held at Impact Muangthong Thani, Nonthaburi on March 15–19, 2017. As well as representatives of Thailand's Ministry of Public Health, the more than 6,000 participants included hospital staff, most of whom were representing the 200 or so facilities accredited by the body last year.

At the forum's request, the JQ gave a speech about the Project to Collect Medical Near-miss/Adverse Event Information and the Japan Obstetric Compensation System during the international session on March 15. This request came in the wake of previous interactions with senior representatives of the organization. The Thai accreditation body's president Dr. Supachai Kunaratanapruk, CEO Dr. Anuwat Supachutikul, and Deputy CEO Dr. Piyawan Limpanyalert became interested in the JQ after attending the 33rd ISQua International Conference 2016, which the JQ co-hosted with ISQua in October 2016. In addition, Dr. Piyawan Limpanyalert developed a deeper interest in this project at WHO meetings, asking questions following our speeches and discussing adverse event reporting systems in general. The following provides an overview of the speech and Q&A session.

(1) National Reporting and Learning System: Learn from Japan experience to initiative in Thailand, 10:30-12:00, 15 Mar.
Moderator: Dr. Piyawan Limpanyalert

This speech focused on the Project to Collect Medical Near-miss/Adverse Event Information, providing an outline of the system and the way in which the Quarterly Reports, Annual Reports and Medical Safety Information are prepared and distributed to readers both within Japan and overseas. The following provides an overview of the questions, answers, and comments.

○ In Thailand, medical personnel still have a negative attitude to reporting adverse events, due to the risk of being held liable. Accordingly, it might be better to take things slowly in moving forward with the introduction of an external reporting system like Japan's.

○ It is an ongoing struggle here, due to constant under-reporting. What is the situation in Japan? In response, the JQ speaker explained that this project regards the current situation, in which the number of reported events is increasing year-on-year, as being the result of the practice of reporting becoming firmly established, rather than representing a rise in the actual number of medical adverse events. In that sense, we recognize that there is ongoing under-reporting. In our experience, it takes time to gain the understanding of medical institutions and get this kind of system running successfully.

○ The Moderator asked members of the audience to raise their hands if their facility operates some kind of reporting system. In response, 70–80% of the audience raised their hands. The Moderator expressed a wish to create a reporting system at the national level going forward, using the Japanese initiative as a point of reference.

○ In Thailand, medical adverse events can result not only in civil trials, but also in criminal trials. This is particularly common in the field of obstetrics and gynecology. In the event of maternal death, it is frequently the case that both civil and criminal suits are lodged. Consequently, medical personnel fear being held liable.

○ The speech about Japanese experiences offered some very useful pointers. Thailand too must operate an external reporting system and learn from errors.

○ Asked to outline the key message that can be taken from Japan's success, the JQ speaker replied that it would be the fact that the system operates on the basis of an anonymous, non-disciplinary approach.

(2) Japan Compensation System: Adverse Event of Obstetric, 15:00-16:30, 15 Mar.
Moderators: Dr. Supachai Kunaratanapruk, Prof. Pisake Lumbiganon (President, Royal Thai College of Obstetricians and Gynaecologists)

The JQ speaker described the Japan Obstetric Compensation System for Cerebral Palsy, explaining the background to its creation and outlining the system itself (review and compensation, causal analysis, and

prevention of recurrence), and also talked about the status of disputes in the field of obstetrics and gynecology.

7) 2nd Global Ministerial Summit on Patient Safety in Bonn, Germany

The 2nd Global Ministerial Summit on Patient Safety was held on March 29–30, 2017, hosted by the German Federal Ministry of Health and co-hosted by the WHO. This followed on from the first summit, which was held in the UK last year. The summit took place in Bonn, Germany, and was attended by around 350 people from 45 countries, including high-level representatives, experts, and representatives of international organizations including the WHO, the EU, the World Bank (WB), and the OECD. Cabinet-level ministers attended from the UK, Italy, the Netherlands, Switzerland, Qatar, Oman, Sri Lanka, Lithuania, Saudi Arabia, and Luxembourg, among others.

The first day featured discussions of six areas by expert working groups. The six areas were as follows: (1) Economy and Efficiency of Patient Safety; (2) Global Patient Safety — Perspectives from Low- and Middle-income Countries; (3) Patient Safety and mHealth, Big Data, and Handheld Devices; (4) Prevention and Control of Infectious Diseases; (5) Increased Safety of Diagnostics and Treatment — Checklists and Other Tools; and (6) Safety of Medication Therapy and the Launch of the WHO Global Patient Safety Challenge on Medication Safety. The conclusions were summarized in the Core Messages to the Ministers.

The ministerial summit took place on the second day. The proceedings got underway with opening remarks from Hermann Gröhe, Germany's Minister of Health, and Jeremy Hunt, Britain's Secretary of State for Health. This was followed by a welcome address from WHO Director General Margaret Chan and a keynote speech by Dr. Victor Dzau, President of the U.S. National Academy of Medicine (49th Quarterly Report, p.48-51). The health ministers from each country and representatives of organizations such as the WB and the OECD then exchanged remarks concerning their respective approaches to involvement in medical safety.

In the course of this, the Canadian delegate outlined the initiatives of the Canadian Patient Safety Institute, with particular reference to Global Patient Safety Alerts. The institute has been designated the WHO Collaborating Centre for Patient Safety and Patient Engagement. The delegate stressed that the Global Patient Safety Alerts from across the globe — including this project's Medical Safety Information — distributed by the institute make it possible to learn from other countries' experiences, so there is no need to start from scratch when devising measures, thereby ensuring swifter progress. Also taking part in the summit was Canadian Patient Safety Institute CEO Chris Power, so the JQ took the opportunity to express our thanks for her organization's use of Japan's Medical Safety Information and confirmed that the two organizations would continue to work together going forward.

WHO Director General Margaret Chan was overwhelmed with support from participating countries for a World Patient Safety Day to be celebrated annually on September 17. In the words of keynote speaker Victor Dzau, President of the U.S. National Academy of Medicine, "this journey of a thousand miles begins with a first step – an official WHO World Patient Safety Day." Acting on that, the German Federal Minister of Health in agreement with the UK Secretary of State for Health stepped up and announced, "Together with our colleagues from the United Kingdom, we will draft a resolution for the 2018 World Health Assembly and will be counting on your support."

The Ministers of Health and high level delegates from all 45 countries who attended the Summit, all displayed great compassion and commitment to this cause, sharing stories of tragic patient harm in their countries as they pledged to drive forward this agenda at the political level. Next year's summit — the third — is due to be held in Japan.

13. Meeting With the Ministry of Health and Welfare of the Republic of Korea and the Korea Institute of Healthcare Accreditation (KOIHA)

On December 6, 2016, the JQ was visited by four representatives of the Korea Institute of Healthcare Accreditation (KOIHA) — South Korea's third-party appraisal body — including KOIHA President Suk Seung Han, as well as Jeong Young Hun from the Ministry of Health and Welfare and Lee Sook Ja of Korean Hospital Accreditation.

When representatives of KOIHA previously visited the JQ in May 2015, we took the opportunity to explain and discuss Hospital Accreditation. On this visit, we focused on the Project to Collect Medical Near-miss/Adverse Event Information, as well as explaining the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information, EBM Medical Information Network Distribution Service, and Patient Safety Promotion initiatives. This was followed by a Q&A session.

The visiting guests told us that a nationwide adverse event reporting system similar to the Project to Collect Medical Near-miss/Adverse Event Information had been launched as a governmental initiative following the January 2015 enactment of South Korea's Patient Safety Act. The Patient Safety Act includes a guarantee of anonymity in respect of information about reporters and reporting medical institutions. However, the number of reports remains low, which is an issue also noted by a South Korean participant in a question following the keynote speech about this project at last year's ISQua conference in Tokyo. The visitors from the Ministry of Health and Welfare also inquired about the current status of the medical adverse event investigation system launched in Japan in 2015, asking about such matters as trends in the number of reports.

The meeting got underway with an explanation of the Project to Collect Medical Near-miss/Adverse Event Information and the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information. We explained the Project to Collect Medical Near-miss/Adverse Event Information in detail, providing the latest information in simple terms, including the nature of serious medical adverse events that have occurred at advanced treatment facilities and the resultant revision of the requirements for advanced treatment facilities, as well as revisions of the Hospital Accreditation system. Regarding the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information, we explained that the project involves collecting examples of inquiries about prescriptions. The Q&A session then took place. Questions about the Project to Collect Medical Near-miss/Adverse Event Information included the following: "Did anyone express dissatisfaction about the fact that only university hospitals and national hospitals are subject to mandatory reporting?" "Is there any penalty for failure to report?" "Are IDs and names of medical institutions attached to reports? If so, are they subsequently deleted? If they are not deleted and continue to be preserved in the data held by the JQ, has there been any pressure from society to make that information public?" "Was there any resistance from medical institutions about publishing details of events in the Quarterly Reports?" There were no questions about the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information. We explained that while there are cases in which medical institutions do not respond to inquiries from pharmacies, we do not believe that this is acceptable in this day and age. The situation appears to be the same in South Korea, as the visitors nodded in agreement. Regarding the medical adverse event investigation system, one guest asked, "I've heard that a system imposing a mandatory requirement to report medical adverse events was created by an amendment to the law in Japan in 2015. Could you please provide us with a brief overview?"

14. Responding to Lecture Requests ~ Increasing Number of Requests for Lectures on Topics Including the Medical Adverse Event Investigation System ~

In response to requests from medical institutions, pharmacies, and related groups, we give lectures explaining the current status of the project and the content of its output, such as the Quarterly Reports, Annual Reports and Medical Safety Information. Each year, we give around 50 lectures, both within Japan and overseas. Figure 24 shows Japan's nationwide adverse event investigation, collection, analysis, and learning projects. The JQ is in charge of a large number of projects, so Table 17 shows the content explained in lectures, including the relationship between the various projects. As shown in the table, we mostly explain the overall nature of the project and its outcomes, but a new specialist physician system is currently being put together with a view to being launched sometime in FY2018, so we have recently started to receive requests from a variety of academic societies involved in running that system. When giving lectures in those cases, we provide a detailed explanation of medical adverse event information and medical near-miss events as they relate to the area of specialism of the academic society in question.

The JQ is a support organization under the medical adverse event investigation system, which was launched in October 2015, so we also give lectures about the system as part of our role in that system.

We aim to respond to as many requests as possible, so if any medical institutions participating in this project would like us to give a lecture, please do contact us.

Figure 24 Nationwide Systems/Projects for Adverse Event (Medical Near-miss/Adverse Events) Investigation, Collection, Analysis, and Learning

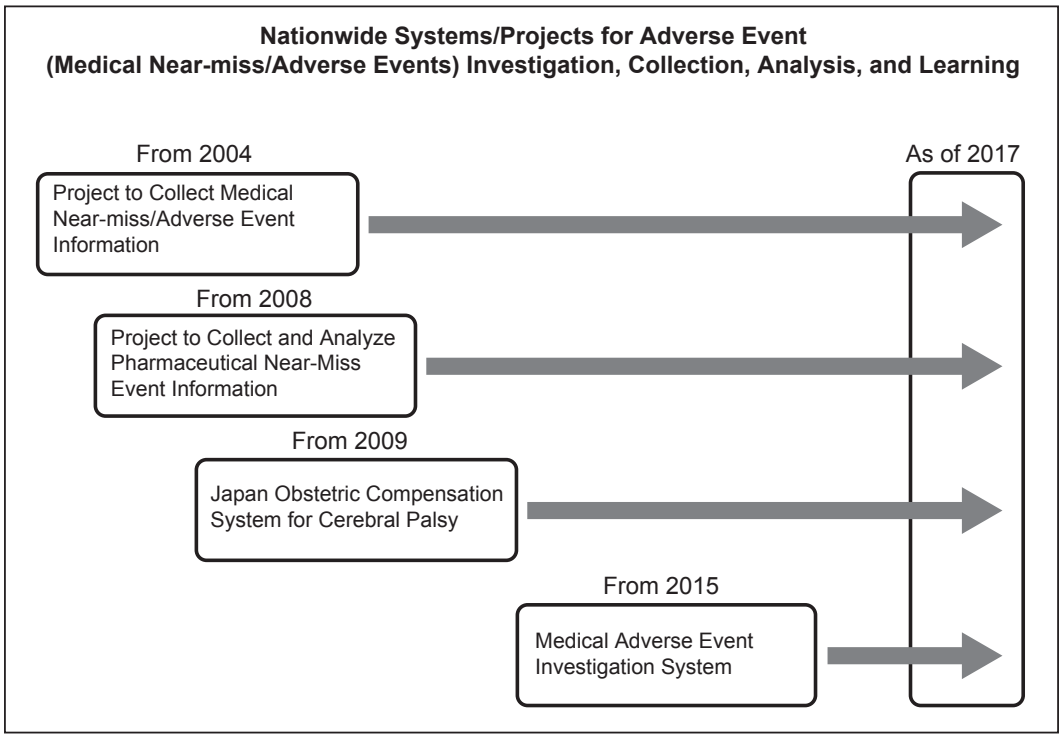


Table 17 Examples of the Content of Lectures

1. Project to Collect Medical Near-miss/Adverse Event Information

2. Project to Collect and Analyze Pharmaceutical Near-miss Event Information

1) Reporting System for Medical Institutions — Project to Collect Medical Near-miss/Adverse Event Information

- Significance of the collection of medical near-miss/adverse event information
- Purpose and overview of the project
- Content of Quarterly Reports (content of aggregate results and theme analysis)
- Medical Safety Information (e.g. Air Embolism after Removal of a Central Venous Catheter, Events related to anticoagulants, etc.)
- Utilization of the Website
- Causal analysis significance and methods
- Dissemination of information overseas

2) Reporting System for Pharmacies — Project to Collect and Analyze Pharmaceutical Near-Miss Event Information

- Significance of the collection of reports of medical near-miss/adverse events
- Purpose and overview of the project
- Content of Aggregate Reports and Annual Reports (aggregate results, increase in the number of inquiries about prescriptions, and content of theme analysis)
  (i) Introduction to events involving similar names, combinations of similar brand names, improvement measures, etc.
  (ii) Introduction to events involving inquiries about prescriptions, nature of events (deletion of drug from prescription, change in dosage, etc.), cases in which no inquiry was made about the prescription but it was later queried
  (iii) Introduction to events related to a change to a generic drug, etc.
- Importance of working in partnership with pharmacies and medical institutions (introduction to medical adverse events that occurred as a result of inadequate inquiries about a prescription and to improvement measures, etc.)
- How to use Pharmaceutical Near-miss Information Analysis Tables (events related to a change to a generic drug, etc., events related to combination drugs, etc.)
- Utilization of the Events to Be Shared
- Utilization of the Website

3) Medical Adverse Event Investigation System

- Background to the system's creation
- Overview of the system
- Definition of medical adverse events under the system and their judgment and reporting
- Internal investigation of medical adverse events
- How explanations are provided to bereaved families
- Prevention of recurrence, similarity to the Project to Collect Medical Near-miss/Adverse Event Information
- June 2016 revision of the system
- Actual achievements of the system

3. No-fault Compensation System for Medical Adverse Events in Childbirth — Japan Obstetric Compensation System for Cerebral Palsy

- Social security system and the private sector compensation system that supplements it
- The concept of no-fault compensation and the need for this
- Purpose and overview of the project
- Approach to compensation criteria based on a no-fault premise and the current status of screening
- Current status of the analysis of causes
- Approaches to the analysis of causes
- Current status of the prevention of recurrence
- Current status of disputes in the field of obstetrics and gynecology

4. Others

- Overseas initiatives to promote medical safety about which we have learned through meetings such as the ISQua International Conference and WHO interregional meetings

15. Role as a Support Organization in the Medical Adverse Event Investigation System

On October 1, 2015, the Medical Care Act governing the medical adverse event investigation system entered into force and the system began operating. On August 6, 2015, the JQ was officially announced by the Ministry of Health, Labour and Welfare to be a "medical accident investigation support organization" under this law. Specifically, this support takes the form of responding to requests from medical institutions to give lectures that include explanations of the system and we have already given many lectures of this kind. Taking advantage of the fact that the JQ runs a number of similar projects, these lectures not only provide an overview of the system, but also explain its achievements after the first year; the number of reported events after its launch and other matters concerning its current status; its similarity to the Project to Collect Medical Near-miss/Adverse Event Information and the Japan Obstetric Compensation System for Cerebral Palsy in terms of content and the methods that it uses, such as causal analysis and efforts to prevent recurrence; and the current status of medical adverse events in clinical practice. In addition, the lectures also cover the judgment and investigation of medical adverse events at advanced treatment facilities, and the fact that the June 2016 revision of the ministerial ordinance revising the requirements for advanced treatment facilities incorporated a mechanism for identifying all fatalities within a hospital and conducting the requisite verification.

In terms of recent topics relating to the medical adverse event investigation system, it was reported at a meeting of the Medical Care Subcommittee of the Social Security Council on June 9, 2016 that the law could not be amended by the deadline specified in the law and that the necessary improvement measures would be made on the operational side. In June 2016, the revisions that the Medical Care Act stipulated should be carried out within two years of promulgation were implemented. These revisions and clarifications covered such matters as positioning support organization liaison committees within the system at the central and local levels; ensuring that systems are capable of enabling managers to identify all deaths within their institution, without omission; dealing with queries from bereaved families and communicating the content of their queries to medical institutions; enhancing training and sharing examples of best practice; and checking and querying medical institutions' internal adverse event investigation reports by the Medical Accident Investigation and Support Center.

The Japan Medical Association organized a meeting of the central-level Support Organization Liaison Committee on December 28, 2016. As a support organization undertaking a nationwide project, the JQ attends these meetings as a member of the committee. During the meeting, the background to the committee's formation was explained, the committee's terms of reference were agreed, and the chair and vice chair were elected. To facilitate flexible operation going forward, a steering committee was established to consider proposals for activities. The views and explanations offered by the support organizations that attended the meeting are summarized below.

- ○ An overview was provided concerning the status of activities by the local committee in Tokyo.
- ○ The Japan Medical Safety Research Organization explained the number of reports under the medical adverse event investigation system and the current status of internal investigations of medical adverse events.
- ○ In some prefectures, the burden of providing support at the prefectural medical association level is heavy. It would be desirable for the central-level committee to provide support as well.
- ○ Managers simply do not understand the system at present. Guidance is required at the level of municipal and county medical associations, to enable them to play an active role in tackling this situation.
- ○ Would it be possible to work in partnership with the Japanese Coalition for Patient Safety.
- ○ The Japanese Society for Quality and Safety in Healthcare has previously provided external members for internal medical adverse event investigation committees and will continue to do so.

○ The medical community has been entrusted with the running of the system, so it must spare no effort in enhancing the system.

The JQ is keen to make a contribution, both as a member of the committee and as the organization that operates this project and a third-party program that analyzes the causes of severe cerebral palsy and seeks to prevent their recurrence.

In March 2017, the Medical Adverse Event Investigation and Support Center Report (2016 Annual Report) was published, providing a summary of reports on medical adverse events over the 15-month period from October 2015 to December 2016, reports on the results of internal investigations of medical adverse events, and investigations by the Center itself. As a related initiative, Analysis of Deaths From Complications Arising From Central Venous Catheterization —1st Report— was published, with the aim of providing a first set of recommendations for preventing the recurrence of medical adverse events, which is the goal of this system. Data from this project is cited in this analysis.

16. Dissemination of Information via Facebook

The Division of Adverse Event Prevention has set up an official Facebook page, through which it disseminates information. As of the time of writing, this project's Facebook page had been "Liked" by 2,038 Facebook users.

Figure 25 The Facebook Page for the Project to Collect Medical Near-miss/Adverse Event Information (URL: https://www.facebook.com/medsafe.jcqhc)

17. Conclusion

We would be most grateful if the medical institutions participating in this project would continue to provide us with reports about medical adverse event information and medical near-miss event information. Moreover, by developing an environment that is more conducive to reporting than before, we hope that medical institutions that had previously hesitated to participate in this project due to the burden of reporting will now agree to take part. In the future, the project will increase its efforts to enhance the content of Quarterly Reports and Annual Reports, in order to ensure that this project contributes to the prevention of medical adverse events and the promotion of medical safety in Japan.

I

Outline of the Project to Collect Medical Near-miss/ Adverse Event Information

I Outline of the Project to Collect Medical Near-miss/ Adverse Event Information

Based on the collection of medical near-miss/adverse event information, this project seeks to foster an ever-improving culture of safety in medical care.

This project 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. An overview of these two projects and their operational structure is provided below.

1. Background

[1] Background to the Project to Collect, Analyze, and Provide Medical Near-miss Event Information

In October 2001, the Ministry of Health, Labour and Welfare (MHLW) launched the "Network for Medical Safety Measures (Project to Collect Medical Near-miss Event Information)," which was focused on collecting and analyzing medical near-miss event information and providing information that would contribute to medical safety, such as improvement measures. Under the initial project framework, the Organization for Pharmaceutical Safety and Research [OPSR: currently the Pharmaceuticals and Medical Devices Agency (PMDA)] collected information from registered medical institutions concerning medical near-miss events; this information was reported to the MHLW and a study group at the Ministry then tabulated and analyzed the data. Medical near-miss event information was collected on the basis of this framework and the Ministry of Health, Labour and Welfare published overviews of the tabulated results, in order to provide information about medical near-miss events.(Note 1)

In FY2004, the JQ took over the project for the collection of medical near-miss event information from the Organization for Pharmaceutical Safety and Research [OPSR: currently the Pharmaceuticals and Medical Devices Agency (PMDA)], and has been implementing the Project to Collect, Analyze, and Provide Medical Near-Miss Event Information. The tabulation results and analysis are published on the project's website.(Note 2)

[2] Background to the Project to Collect, Analyze, and Provide Medical Adverse Event Information

In April 2002, the Investigation Committee for Medical Treatment Safety Measures, a body established by the MHLW, compiled and published a report entitled "Comprehensive Measures for Promoting the Safety of Medical Treatment"(Note 3). In regard to the Network for Medical Safety Measures (Project to Collect Medical Near-miss Event Information), which had begun in October 2001, this report stated that, "In analyzing such events, there is a need to study the building of a system to collect even more accurate analytical and study results from an even greater number of institutions, as well as gathering the results of analyzing and studying improvement measures." In addition, the report introduced opinions that called for the utilization of medical adverse events through the gathering and analysis of information and the establishment of a system for compulsory research and reporting concerning such events; moreover, it pointed out the need to conduct further studies, including the legal issues associated with the reporting of medical adverse events.

(Note1) See MHLW website "Medical Safety Measures" (http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryou/i-anzen/index.html).
(Note2) See the Japan Council for Quality Health Care "Project to Collect Medical Near-miss/Adverse Event Information" website (http://www.med-safe.jp/).
(Note3) "Comprehensive Measures for Promoting the Safety of Medical Treatment" proposed the following as challenges that should be addressed: "safety measures at medical institutions," "improving safety relating to medications and medical devices," "education and training concerning medical safety," and "developing an environment for promoting medical safety."
See the MHLW website ("Report" in "3. Comprehensive Measures for Promoting the Safety of Medical Treatment") (http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/houkoku/index.html).

Subsequently, on September 21, 2004, the MHLW promulgated a ministerial ordinance that partially amended the Medical Care Act Enforcement Ordinance(Note 1), which obliged Special Functioning Hospitals to report medical adverse events. Having become a registered analysis center conducting projects to analyze adverse events as stipulated in the ministerial ordinance concerned under Public Notice of the Ministry of Health, Labour and Welfare No.372, dated October 1, 2004 (actual date of registration: September 30, 2004), the JQ launched the Project to Collect Medical Adverse Event Information. As a registered analysis center, under Article 12 (5) of the Ordinance for Enforcement of the Medical Care Act, the JQ is required to renew its registration every five years. Accordingly, the JQ renewed its registration for a second term in 2009 and a third term in 2014.

[3] Background to the Project Implemented by the JQ

On July 1, 2004, the Center for Medical Adverse Event Prevention (currently the Department of Adverse Event Prevention) was established as a body affiliated to the JQ; on October 7, 2004, it began the statutory collection of medical adverse event information. This department comprehensively analyzes medical near-miss/adverse event information and compiles quarterly reports following summarization of the data by the Comprehensive Evaluation Panel(Note 2), which is composed of various experts, based on the policy of the Management Committee(Note 3) of this department. Since FY2006, Medical Safety Information has been compiled and distributed regarding events that the JQ feels should be common knowledge. In FY2010, the project began analyzing more specific individual themes, publishing these analyses in its quarterly reports.

Moreover, in 2008, this project's Management Committee and Comprehensive Evaluation Panel discussed revisions of the reporting system, from the perspective of reducing the reporting burden for medical institutions and creating an environment that makes reporting easier than before, while continuing to gather the information required in order to promote medical safety. Their findings were translated into reality, and medical adverse event information and medical near-miss event information began to be gathered using the new method and provided online in 2010.

As well as sending quarterly reports and Medical Safety Information to medical institutions participating in this project, and related groups and government bodies, the project publishes details of its work more widely to society by such means as posting information on the project website(Note 4).

(Note1) MHLW Ordinance No.133.
(Note2) Composed of experts in various fields, this committee undertakes comprehensive evaluation and deliberations concerning the quarterly reports. Moreover, it provides technical support relating to analytical techniques and methods.
(Note3) Composed of general experts, as well as experts in fields such as general medicine and safety measures, this committee considers policies concerning the activities of the division, as well as evaluating the content of its activities. Moreover, it provides technical support relating to analytical techniques and methods.
(Note4) See the Japan Council for Quality Health Care "Project to Collect Medical Near-miss/Adverse Event Information" website (http://www.med-safe.jp/).

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

[1] Objective

The objective is to share with a wide range of medical institutions information that will be useful in formulating medical safety measures by collecting, analyzing and providing medical adverse event information reported by medical institutions subject to reporting requirements and voluntarily participating medical institutions, as well as further promoting medical safety measures through sharing information with the public.

[2] Collection of Medical Adverse Event Information

(1) Medical Institutions(Note 1)

The medical institutions included in the initiative are the following medical institutions subject to reporting requirements and voluntarily participating medical institutions.

i) Medical Institutions Subject to Reporting Requirements(Note 2)

a) National Research and Development Agencies and National Hansen's Disease Sanatorium

b) Hospitals run by the National Hospital Organization

c) Hospitals affiliated to universities governed by the School Education Act (not including their branch hospitals)

d) Special Functioning Hospitals

ii) Voluntarily Participating Medical Institutions

Medical institutions other than medical institutions subject to reporting requirements, which have expressed a desire to participate in the Project to Collect, Analyze, and Provide Medical Adverse Event Information

(2) Information Reported as Medical Adverse Event Information

The medical adverse event information subject to reporting is as follows:

a) 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.

b) 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).

c) Other than those described in a) and b), information conducive to the prevention of medical adverse events and their recurrence at medical institutions.

(Note1) For details of the medical institutions concerned, see the "List of Medical Institutions Participating in Each Project" on the Japan Council for Quality Health Care Project to Collect Medical Near-miss/Adverse Event Information website (http://www.med-safe.jp/contents/register/index.html).

(Note2) On September 21, 2004, the Ministry of Health, Labour and Welfare promulgated a ministerial ordinance to partially revise the enforcement ordinance for the Medical Care Act (Ministry of Health, Labour and Welfare Ordinance No. 133, 2004) to require National Research and Development Agencies, National Hansen's Disease Sanatorium, hospitals run by the National Hospital Organization, hospitals affiliated with universities (not including their branch hospitals) governed by the School Education Act No. 26, 1947, and Special Functioning Hospitals to report medical adverse event information.

Reports of medical adverse event information contain 28 report items, including "month, year and time period of occurrence," "severity of event," "overview of the event," "the number of patients involved, their age(s) and their gender(s)," and "details of the event, background and causal factors, and improvement measures." The reports must, as a general rule, be made within two weeks of the adverse event in question occurring or within two weeks of becoming aware of the adverse event.

Moreover, the following events a) to h) are stipulated as being events that particularly require a report to be made, based on Article 14-2(Note 1) of the Outline of the Project to Collect Medical Near-miss/Adverse Event Information.

a) Accident due to use of contaminated drug/material/biologic product

b) Death or disability due to nosocomial infection

c) Suicide or attempted suicide of patient

d) Disappearance of inpatient

e) Burn of patient

f) Electric shock of patient

g) Death or disability of patient due to facility fire

h) Handling over of infant to wrong parent

(3) Reporting Methods

Reports on adverse events are submitted via the internet (SSL encrypted communication), using the dedicated online reporting screen. There are two reporting methods: direct input using the online reporting screen and reports submitted as a file in the designated format (XML file). The direct input method involves two types of form: a selection form, requiring the respondent to select the relevant item from a checklist or pull-down list, and a description form, which requires the response to be entered into free-text boxes(Note 2).

[3] Analysis and Provision of Medical Adverse Event Information

(1) Tabulation and Analysis

This was carried out by the Department of Adverse Event Prevention, Japan Council for Quality Health Care.

(2) Publication of the Tabulated and Analyzed Results

Information is made available to interested parties and the general public through this report and via the project website(Note 3).

(Note1) Outline of the Project to Collect Medical Near-miss/Adverse Event Information Article 14-2 This department can stipulate the requisite reporting topics, in order to appropriately collect information concerning events that correspond to the scope of adverse events as prescribed in each item of the preceding paragraph.

(Note2) For details of "Report Input Items (Medical Adverse Event Information)," see the "Relevant Documents" section of the Japan Council for Quality Health Care Project to Collect Medical Near-miss/Adverse Event Information website (http://www.med-safe.jp/pdf/accident_input_item.pdf).

(Note3) See the Japan Council for Quality Health Care "Project to Collect Medical Near-miss/Adverse Event Information" website (http://www.med-safe.jp/).

3. Outline of the Project to Collect, Analyze, and Provide Medical Near-miss Event Information

[1] Objective

The objective of this project is to share with a wide range of medical institutions information that will be useful in formulating medical safety measures by collecting, analyzing and providing near-miss event information reported by medical institutions that wish to participate, as well as further promoting medical safety measures through sharing information with the public.

[2] The Collection of Medical Near-miss Event Information

(1) Medical Institutions(Note)

The medical institutions included in the initiative are medical institutions which have expressed a desire to participate in the Project to Collect, Analyze, and Provide Medical Near-miss Event Information. Medical near-miss event information includes two types of information: "information on the number of occurrences" and "medical near-miss event information."

i) Medical institutions reporting "information on the number of occurrences" (Participating medical institutions)

These are all medical institutions that wish to participate in the Project to Collect, Analyze, and Provide Medical Near-Miss Event Information.

ii) Medical institutions reporting "medical near-miss event information" (Participating medical institutions for medical near-miss event information reporting)

These are medical institutions that wish to participate in the Project to Collect, Analyze, and Provide Medical Near-Miss Event Information and have also stated that they wish to report information about events.

(2) Scope of Information Reported as Medical Near-miss Event Information

i) Definition of "medical near-miss event information"

a) Erroneous medical procedures that were identified before actually being performed on patients.

b) Erroneous medical procedures that were performed but were not deemed to have had an effect on the patient, or which required only minor treatment. However, minor treatment is defined as procedures such as disinfection, application of a compress, or administration of an analgesic.

c) Erroneous medical procedures that were performed, where the effect on the patient is unknown.

ii) Content of reports

(a) Reports of "information on the number of occurrences"

Information on the number of occurrences is classified into categories of near-miss event that provide an overview, namely "drug," "blood transfusion," "treatment/procedure," "medical device, etc.," "drainage tube or other tube," "examination," "nursing care," and "others." At the same time,

(Note) For details of the medical institutions concerned, see the "List of Medical Institutions Participating in Each Project" on the Japan Council for Quality Health Care Project to Collect Medical Near-miss/Adverse Event Information website (http://www.med-safe.jp/contents/register/index.html).

the events are categorized based on whether or not any erroneous medical procedures were carried out and, if not, are further categorized according to impact, in terms of what kind of effect would the medical procedure in question have had on the patient if carried out (see the input screen for information on the number of occurrences); the number of occurrences in each category is reported.

The reporting period for information on the number of occurrences is the beginning to the end of the month after the end of each quarter (January - March, April - June, July - September, October - December).

[Input Screen for Information on the Number of Occurrences]

Items	Erroneous medical procedures				Total
	Not performed			Performed	
	Effects if actions in question had been done				
	Patients would have died or had serious conditions	Patients would have required intensive procedure/ treatment	Patients would have required minor procedure/ treatment or would not have required any procedure/ treatment		
(1) Drug					
(2) Blood transfusion					
(3) Treatment/procedure					
(4) Medical device, etc.					
(5) Drainage tube or other tube					
(6) Examination					
(7) Nursing care					
(8) Others					
Total					
Re-posted					
[1] Events involving name or dosage form of drug					
[2] Events caused by drug					
[3] Events caused by medical device, etc.					
[4] Current theme					

Note) "Current theme" refers to events that correspond to the theme stipulated for each collection period.

(b) Reports of "medical near-miss event information"

Medical near-miss event information that corresponds to items (i) - (v) below (see the section marked with a thick line on the [Input Screen for Information on the Number of Occurrences]) is collected.

(i) Events that it is thought would have resulted in death or a serious situation if the treatment had actually taken place

(ii) Events involving the name or dosage forms of drug

(iii) Events involving the drug

(iv) Events involving medical device, etc.

(v) Events corresponding to the theme stipulated for each collection period

The theme for 2016 is "Medical Near-miss Events Related to Antineoplastic Agents."

There are 24 report items in regard to medical near-miss event information, including "month, year and time period of occurrence," "overview of the event," "whether or not the medical procedure was actually carried out," "the degree of treatment involved in the event or the effect on the patient," "the location of the occurrence," "the number of patients involved, their age(s) and their gender(s)," and "details of the event, background and causal factors, and improvement measures."

The reporting period for medical near-miss event information is within one month after the date on which the event occurred or within one month after the date of becoming aware that the event occurred.

(3) Reporting method

Reports on near-miss events are submitted via the internet (SSL encrypted communication), using the dedicated online reporting screen.

i) Reports of "information on the number of occurrences"

The number of occurrences is entered directly, using the online reporting screen.

ii) Reports of "medical near-miss event information"(Note 1)

This can be submitted in either of two ways: direct input using the online reporting screen or as a file in the designated format (XML file). The direct input method involves two types of form: a selection form, requiring the respondent to select the relevant item from a checklist or pull-down list, and a description form, which requires the response to be entered into free-text boxes.

[3] Analysis and Provision of Medical Near-miss Event Information

(1) Tabulation and Analysis

This was carried out by the Department of Adverse Event Prevention, Japan Council for Quality Health Care.

(2) Provision of the Tabulated and Analyzed Results

Information is made available to interested parties and the general public through this report and via the project website(Note 2).

(Note1) For details of "Report Input Items (Medical Near-miss Event Information)," see the "Relevant Documents" section of the Japan Council for Quality Health Care Project to Collect Medical Near-miss/Adverse Event Information website (http://www.med-safe.jp/pdf/hiyarihatto_input_item.pdf).
(Note2) See the Japan Council for Quality Health Care "Project to Collect Medical Near-miss/Adverse Event Information" website (http://www.med-safe.jp/).

4. Operational Structure

In order to guarantee the project's neutrality and impartiality as a third-party organization gathering medical adverse event information, and ensure the smooth running of the project, we have established the following committee and divisions.

[1] Management Committee

Composed of 16 members (as of December 31, 2016), including medical professionals with expertise in such fields as general medicine and medical safety measures, along with general advisors, this body considers policies concerning the activities of this department, as well as evaluating the content of its activities. It has been established as a subcommittee, in accordance with the articles of endowment of the JQ.

[2] Expert Division

(1) Comprehensive Evaluation Panel

Consisting of 11 experts (as of December 31, 2016) in fields including medical safety and safety measures, this panel undertakes comprehensive evaluation and deliberations concerning the Medical Safety Information (drafts) and Quarterly Reports (drafts) compiled by the "Expert Analysis Group" mentioned below. Moreover, it provides technical support relating to analytical techniques and methods.

(2) Expert Analysis Groups

Consisting of 28 medical professionals involved in medical safety and experts in safety management (as of December 31, 2016), these groups check and analyze the reported events, and compile Quarterly Reports (drafts) and Medical Safety Information (drafts). If necessary, they gather the information required to conduct analysis, and conduct on-site visits.

[3] Department of Adverse Event Prevention

The Japan Council for Quality Health Care's Department of Adverse Event Prevention runs the Project to Collect Medical Near-miss/Adverse Event Information. This department deploys people with medical qualifications and visiting researchers to accept medical adverse event information and medical near-miss event information, gather information that is useful from a medical safety perspective, and formulate and publish Medical Safety Information and reports concerning this project. Moreover, if necessary, they conduct on-site visits in partnership with Expert Analysis Group members, in order to gather additional information.

[4] Organization for Data Analysis and Information Provision

The staff who handle the primary information that is reported are employees, visiting researchers and Expert Analysis Group members who are subject to this department's confidentiality regulations. The primary information is anonymized by our staff and forms the basis of analysis by the Expert Analysis Groups.

If necessary, the Expert Analysis Groups collect additional information and conduct studies of prior research, as well as checking the practice of medical institutions implementing advanced initiatives relating to relevant events. The Expert Analysis Groups synthesize this information and summarize the results of their analyses as quarterly reports (drafts) and Medical Safety Information (drafts), before submitting them to the Comprehensive Evaluation Panel. The Comprehensive Evaluation Panel considers the quarterly reports (drafts) submitted to it from an expert standpoint and finalize the reports and Medical Safety Information so that they can be published widely throughout society by the JQ.

II

Current Reporting Status

II Current Reporting Status

1. Current Status of 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, 2016 are shown below.

Fig. II-1-1 (YI-01)(Note) 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	124	477	82	301	70	253	276	1,031
	Voluntary	Participating	353		219		183		755	
		Not participating	164		252				416	
Total			641		553		253		1,447	
			1,194							

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

(Note) The numbers in parentheses written with each figure indicate the number for that figure that is posted on the website.

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

The number of registered medical institutions participating in the Project to Collect, Analyze, and Provide Medical Adverse Event Information and the number of reported events as of December 31, 2016 are shown below.

[1] Registered Medical Institutions

The number of medical institutions subject to reporting requirement and voluntarily participating medical institutions participating in the Project to Collect, Analyze, and Provide Medical Adverse Event Information as of December 31, 2016 is shown below. Reasons for the fluctuation in the number of medical institution include opening/closure and consolidation of hospitals as well as change of classification of the parent organization.

Fig. II-2-1 (YA-01) Number of Medical Institutions Subject to Reporting Requirement and Voluntarily Participating Medical Institutions

Parent organization		Medical institutions subject to reporting requirement(Note 1)	Voluntarily participating medical institutions(Note 2)
Government	National University Corporation, etc.	45	1
	National Hospital Organization	143	0
	National Research and Development Agencies	8	0
	National Hansen's Disease Sanatorium	13	0
	Japan Organization of Occupational Health and Safety	0	31
	Japan Community Health care Organization	0	40
	Other national organizations	0	0
Municipality	Prefecture	2	20
	City/village	0	84
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	9	2
	Local independent administrative institutions	1	21
Parent organization of public medical institution other than municipality	Japan Red Cross	0	56
	Saiseikai Imperial Gift Foundation	0	19
	Hokkaido Social Welfare Association	0	1
	National Welfare Federation of Agricultural Cooperatives	0	18
	National Health Insurance Association Federation	0	1
	Health Insurance Union and their associations	0	1
	Mutual Aid Associations and their associations	0	11
	National Health Insurance Society	0	0
Corporation	School juridical organization	54	13
	Healthcare corporation	0	306
	Charitable organization	1	46
	Company	0	12
	Other corporation	0	29
Individual practitioner		0	43
Total		276	755

(Note 1) As of the end of December 2016, details of the medical institutions subject to reporting requirement (276 institutions) are as follows:
A. National Research and Development Agencies and National Hansen's Disease Sanatorium 21 institutions
B. National Hospital Organizations 143 institutions
C. University hospitals governed by the School Education Act (not including branch hospitals) 108 institutions
D. Special Functioning Hospitals (including those categorized as A, B or C above) 84 institutions
(Note 2) Voluntarily participating medical institutions are those participating in the project other than medical institutions subject to reporting requirement.

[2] Number of Reports

(1) Number of Monthly Report

The number of monthly reports made by medical institutions subject to reporting requirement and voluntarily participating medical institutions between January 1 and December 31, 2016 is shown below.

Fig. II-2-2 (YA-03) Number of Monthly Reports Made by Medical Institutions Subject to Reporting Requirement and Voluntarily Participating Medical Institutions

	2016												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of reports made by medical institutions subject to reporting requirement	316	228	321	281	244	288	298	278	290	294	239	351	3,428
Number of reports made by voluntarily participating medical institutions	50	16	19	33	11	39	74	33	26	61	61	31	454
Number of medical institutions subject to reporting requirement	275	275	275	275	276	276	276	276	276	276	276	276	-
Number of voluntarily participating medical institutions	746	751	751	753	755	755	755	756	756	756	755	755	-

(2) Medical Adverse Event Reporting Status

A. Reporting status of medical institutions subject to reporting requirement

Among medical institutions subject to reporting requirement, the number of reporting medical institutions subject to reporting requirement and the number of reports made between January 1 and December 31, 2016 are shown in Fig. II-2-3, tabulated numbers of reports made since the launch of the project by the parent organization are shown in Fig. II-2-4, those by the number of beds are shown in Fig. II-2-5, and those by region are shown in Fig. II-2-6. In addition, tabulated numbers of reporting medical institutions in the same period by number of reports are shown in Fig. II-2-7. Figures for the number of medical institutions subject to reporting requirements may not correspond to those shown in other tables, due to changes during the collection period, such as the accreditation of medical institutions as Special Functioning Hospitals or the abolition of medical institutions. As of December 31, 2016, the number of medical institutions subject to reporting requirement was 276, and the total number of beds at those institutions was 141,182.

Fig. II-2-3 (YA-04) Number of Reporting Medical Institutions Subject to Reporting Requirement and Reports Made by the Parent Organization

Parent organization		Number of medical institutions (as of December 31, 2016)	Number of reporting medical institutions	Number of reports
			January to December, 2016	January to December, 2016
Government	National University Corporation, etc.	45	42	857
	National Hospital Organization	143	131	1,403
	National Research and Development Agencies	8	7	97
	National Hansen's Disease Sanatorium	13	10	31
Municipality	Prefecture	12	11	282
	City/village			
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities			
	Local independent administrative institutions			
Corporation	School juridical organization	54	39	750
	Charitable organization	1	1	8
Total		276	241	3,428

Fig. II-2-4 (QA-05) Number of Reports Made by Medical Institutions Subject to Reporting Requirement (Accumulated Total)

Parent organization		Number of reports
		October 2004 to December 2016
Government	National University Corporation, etc.	6,308
	National Hospital Organization	11,316
	National Research and Development Agencies	1,045
	National Hansen's Disease Sanatorium	300
Municipality	Prefecture	1,791
	City/village	
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	
	Local independent administrative institutions	
Corporation	School juridical organization	6,051
	Charitable organization	44
Total		26,855

Fig. II-2-5 (YA-05) Number of Reporting Medical Institutions Subject to Reporting Requirement and Reports Made by Number of Beds

Number of beds	Number of medical institutions (As of December 31, 2016)	Number of reporting medical institutions	Number of reports
		January to December, 2016	January to December, 2016
0-19 beds	0	0	0
20-49 beds	15	5	9
50-99 beds	5	1	1
100-149 beds	8	6	15
150-199 beds	7	5	32
200-249 beds	16	14	79
250-299 beds	16	14	105
300-349 beds	28	26	158
350-399 beds	16	14	172
400-449 beds	27	26	319
450-499 beds	19	18	272
500-549 beds	10	7	70
550-599 beds	9	9	168
600-649 beds	26	25	508
650-699 beds	7	7	162
700-749 beds	11	11	151
750-799 beds	3	3	20
800-849 beds	11	10	293
850-899 beds	5	4	99
900-999 beds	11	11	206
1000 beds or more	26	25	589
Total	276	241	3,428

Fig. II-2-6 (YA-06) Number of Reporting Medical Institutions Subject to Reporting Requirement and Number of Reports by Region

Region	Number of medical institutions (As of December 31, 2016)	Number of reporting medical institutions	Number of reports
		January to December, 2016	January to December, 2016
Hokkaido	10	9	47
Tohoku	25	21	179
Kanto/Koshinetsu	87	72	1,131
Tokai/Hokuriku	38	35	555
Kinki	35	29	364
Chugoku/Shikoku	35	34	586
Kyushu/Okinawa	46	41	566
Total	276	241	3,428

Fig. II-2-7 (YA-07) Number of Medical Institutions Subject to Reporting Requirement by Number of Reports

Number of reports	Number of reporting medical institutions
	As of December 31, 2016
0	35
1	18
2	16
3	18
4	13
5	19
6	14
7	17
8	5
9	12
10	11
11-20	49
21-30	17
31-40	16
41-50	5
51-100	9
101-150	1
151-200	1
200 or above	0
Total	276

B. Reporting status of voluntarily participating medical institutions

The number of voluntarily participating medical institutions as of December 31, 2016 and reports made by those institutions between January 1 and December 31, 2016 are shown in Fig. II-2-8 and tabulated number of reports made since the launch of the project by parent organization is shown in Fig. II-2-9.

Fig. II-2-8 (YA-08) Number of Reporting Voluntarily Participating Medical Institutions and Number of Reports

Parent organization	Number of medical institutions (As of December 31, 2016)	Number of reporting medical institutions	Number of reports
		January to December, 2016	January to December, 2016
Government	72	10	38
Municipality	127	26	150
Public medical institution	107	19	52
Corporation	406	43	214
Individual practitioner	43	0	0
Total	755	98	454

Fig. II-2-9 (QA-10) Number of Reports Made by Voluntarily Participating Medical Institutions (Accumulated Total)

Parent organization	Number of reports
	October 2004 to December 2016
Government	159
Municipality	802
Public medical institution	804
Corporation	1,564
Individual practitioner	6
Total	3,335

[3] Details of Reports Made by Registered Medical Institutions (by Month of Report)

The "Statistics Menu (Web Data)" section of the project website contains the following three types of statistical table.
(http://www.med-safe.jp/contents/report/html/StatisticsMenu.html)

Table Type	Category	Tabulation
Type A	Reports Made by Medical Institutions Subject to Reporting Requirement	by Month of Report
Type B	Reports Made by Medical Institutions Subject to Reporting Requirement	by Month of Occurrence
Type C	Reports Made by Registered Medical Institutions (from all participating medical institutions)	by Month of Report

This Annual Report carries some of the results compiled on the basis of medical adverse event information reports from registered medical institutions (medical institutions subject to reporting requirement and voluntarily participating medical institutions) (table type C) between January 1 and December 31, 2016. The suffixes A, B, and C in the table number in parentheses indicate whether the table is type A, B, or C. Each table is compiled on the basis of the options available in the Medical Adverse Event Information Report Input Items(Note).

Fig. II-2-10 (YA-28-C) Job Title of the Person Involved

Job title of the person involved	Number of event
Doctor	2,280
Dentist	66
Nurse	2,409
Assistant nurse	25
Pharmacist	27
Clinical engineer	36
Midwife	10
Nursing assistant	23
Radiological technologist	40
Clinical technologist	10
Registered dietitian	2
Dietitian	3
Cook/kitchen staff	5
Physical therapist (PT)	40
Occupational therapist (OT)	11
Speech -language -hearing therapist (ST)	1
Medical technologist	0
Dental hygienist	1
Dental technologist	0
Others	69
Total	5,058

* 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.

(Note) For details of "Report Input Items (Medical Adverse Event Information)," see the "Relevant Documents" section of the Japan Council for Quality Health Care Project to Collect Medical Near-miss/Adverse Event Information website (http://www.med-safe.jp/pdf/accident_input_item.pdf).

Fig. II-2-11 (YA-35-C) Summary of Event

Summary of event	Number of event	%
Drug	270	7.0
Blood transfusion	9	0.2
Treatment/procedure	1,168	30.1
Medical device, etc.	105	2.7
Drainage tube or other tube	266	6.9
Examination	155	4.0
Nursing care	1,430	36.8
Others	479	12.3
Total	3,882	100.0

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

Fig. II-2-12 (YA-37-C) Severity of Event

Severity of event	Number of event	%
Death	338	8.7
High potential of residual disability	398	10.3
Low potential of residual disability	1,101	28.4
No potential of residual disability	1,008	26.0
No disability	882	22.7
Unknown	155	4.0
Total	3,882	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 (YA-40-C) Clinical Department

Clinical department	Number of event	%
Internal medicine	323	6.8
Anesthesiology	143	3.0
Cardiovascular medicine	267	5.6
Neurology	111	2.3
Respiratory medicine	224	4.7
Gastrointestinal medicine	301	6.3
Hematology	85	1.8
Circulatory surgery	29	0.6
Allergy	3	0.1
Rheumatism	17	0.4
Pediatrics	196	4.1
General surgery	432	9.0
Orthopedics	614	12.8
Plastic surgery	42	0.9
Cosmetic surgery	0	0
Neurosurgery	230	4.8
Respiratory surgery	82	1.7
Cardiovascular surgery	192	4.0
Pediatric surgery	17	0.4
Pain clinic	3	0.1
Dermatology	53	1.1
Urology	128	2.7
Venereology	0	0
Proctology	2	0
Gynecology/Obstetrics	79	1.7
Obstetrics	24	0.5
Gynecology	41	0.9
Ophthalmology	53	1.1
Otolaryngology	116	2.4
Psychosomatic medicine	6	0.1
Psychiatry	286	6.0
Rehabilitation	41	0.9
Radiology	59	1.2
Dentistry	20	0.4
Orthodontics	0	0
Pediatric dentistry	1	0
Dental/oral surgery	51	1.1
Unknown	7	0.1
Others	505	10.6
Total	4,783	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.

Fig. II-2-14 (YA-41-C) Cause of Event

Cause of event	Number of event	%
Action of the person involved		
Neglect to check	1,167	11.3
Neglect to observe	1,090	10.5
Delayed (neglected) reporting	105	1.0
Inadequate documentation	87	0.8
Inadequate coordination	542	5.2
Inadequate (neglected) explanation to patient	496	4.8
Misjudgment	995	9.6
Human factors		
Lack of knowledge	610	5.9
Deficiency of technique/skill	667	6.4
Busy working condition	402	3.9
Under unusual physical condition	53	0.5
Under unusual psychological condition	93	0.9
Others	310	3.0
Environment/facilities and devices		
Computerized system	54	0.5
Drug	104	1.0
Medical device	172	1.7
Facility	153	1.5
Other items	86	0.8
Patient side	1,164	11.2
Others	164	1.6
Others		
Education/training	730	7.0
System	174	1.7
Inadequate rules	265	2.6
Others	678	6.5
Total	10,361	100.0

* Cause of event may have been more than one.
* Regarding percentages, the totals may not become 100.0 due to rounding to the first decimal place.

Fig. II-2-15 (YA-42-C) Events Encouraged to Be Reported

Events encouraged to be reported	Number of event	%
Accident due to use of contaminated drug/ material/biologic product	7	0.2
Death or disability due to nosocomial infection	3	0.1
Suicide or suicide attempt of patient	62	1.6
Disappearance of inpatient	14	0.4
Burn of patient	30	0.8
Electric shock of patient	0	0
Death or disability of patient due to facility fire	2	0.1
Handling over of infant to wrong parent	0	0
No applicable option	3,764	97.0
Total	3,882	100.0

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

Fig. II-2-16 (YA-68-C) Clinical Department and Summary of Event

Clinical department × Summary of event	Drug	Blood transfusion	Treatment/ procedure	Medical device, etc.	Drainage tube or other tube	Examination	Nursing care	Others	Aggregate total
Internal medicine	41	0	43	6	20	11	153	49	323
Anesthesiology	13	1	95	8	15	0	1	10	143
Cardiovascular medicine	13	0	104	13	14	8	77	38	267
Neurology	2	0	11	1	8	1	78	10	111
Respiratory medicine	14	0	21	10	14	19	130	16	224
Gastrointestinal medicine	15	1	110	4	19	24	87	41	301
Hematology	19	2	13	0	8	3	32	8	85
Circulatory surgery	1	0	11	1	8	1	4	3	29
Allergy	0	0	0	0	0	0	3	0	3
Rheumatism	4	0	3	0	0	1	8	1	17
Pediatrics	19	1	21	7	34	4	93	17	196
General surgery	31	0	184	8	37	21	105	46	432
Orthopedics	6	1	129	8	11	6	373	80	614
Plastic surgery	1	0	21	2	0	2	11	5	42
Cosmetic surgery	0	0	0	0	0	0	0	0	0
Neurosurgery	11	0	74	2	20	7	81	35	230
Respiratory surgery	4	0	38	0	10	6	18	6	82
Cardiovascular surgery	12	2	113	13	17	5	15	15	192
Pediatric surgery	4	0	5	0	2	1	3	2	17
Pain clinic	0	0	2	0	0	1	0	0	3
Dermatology	5	0	6	0	6	0	29	7	53
Urology	12	1	61	4	5	5	29	11	128
Venereology	0	0	0	0	0	0	0	0	0
Proctology	0	0	2	0	0	0	0	0	2
Gynecology/Obstetrics	7	0	40	5	2	3	10	12	79
Obstetrics	2	0	13	0	1	1	1	6	24
Gynecology	5	0	18	3	4	1	5	5	41
Ophthalmology	1	0	27	3	0	2	13	7	53
Otolaryngology	12	0	49	7	9	5	22	12	116
Psychosomatic medicine	0	0	0	0	0	0	3	3	6
Psychiatry	3	0	5	2	1	1	231	43	286
Rehabilitation	0	0	9	0	1	0	26	5	41
Radiology	6	0	19	1	6	18	6	3	59
Dentistry	0	0	12	0	0	1	3	4	20
Orthodontics	0	0	0	0	0	0	0	0	0
Pediatric dentistry	0	0	0	0	0	0	1	0	1
Dental/oral surgery	3	0	27	1	5	1	10	4	51
Unknown	1	0	1	0	0	0	0	5	7
Others	41	1	152	13	42	43	142	71	505
Total	308	10	1,439	122	319	202	1,803	580	4,783

* Clinical department may be more than one.

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. The event information is collected by those that wish to report. A summary of the project as of December 31, 2016 is reported herein.

[1] Registered 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, 2016 is shown below. Reasons for the fluctuation in the number of medical institution include opening/closure and consolidation of hospitals as well as change of classification of the parent organization.

Fig. II-3-1 (YH-01) Number of Participating Medical Institutions in the Project to Collect, Analyze, and Provide Medical Near-Miss Event Information

Parent organization		Participating medical institutions	Participating medical institutions for medical near-miss event information reporting
Government	National University Corporation etc.	29	18
	National Hospital Organization	118	69
	National Research and Development Agencies	5	3
	National Hansen's Disease Sanatorium	11	4
	Japan Organization of Occupational Health and Safety	31	26
	Japan Community Health care Organization	44	24
	Other national organizations	0	0
Municipality	Prefecture	27	17
	City/village	130	72
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	9	5
	Local independent administrative institutions	24	11
Parent organization of public medical institution other than municipality	Japan Red Cross	80	45
	Saiseikai Imperial Gift Foundation	20	10
	Hokkaido Social Welfare Association	0	0
	National Welfare Federation of Agricultural Cooperatives	20	8
	National Health Insurance Association Federation	2	0
	Health Insurance Union and their associations	1	0
	Mutual Aid Associations and their associations	20	12
	National Health Insurance Society	1	1
Corporation	School juridical organization	47	33
	Healthcare corporation	413	202
	Charitable organization	53	23
	Company	12	3
	Other corporation	45	22
Individual practitioner		52	33
Total		1,194	641

[2] Information on the Number of Occurrences

The reports of the information on the number of occurrences between January 1 and December 31, 2016 are shown below.

Fig. II-3-2 (YNR-01) Information on the Number of Occurrences

Items	Erroneous medical procedures				Total
	Not performed			Performed	
	Effects (if actions in question had been done)				
	Patients would have died or had serious conditions	Patients would have required intensive procedure/treatment	Patients would have required minor procedure/treatment or would not have required any procedure/treatment		
(1) Drug	1,041	5,076	83,422	188,837	278,376
(2) Blood transfusion	114	214	1,701	3,097	5,126
(3) Treatment/procedure	419	1,929	12,670	34,759	49,777
(4) Medical device, etc.	256	764	10,338	17,144	28,502
(5) Drainage tube or other tube	410	1,673	25,266	99,970	127,319
(6) Examination	384	1,670	27,016	48,507	77,577
(7) Nursing care	691	3,152	50,620	133,165	187,628
(8) Others	532	1,962	47,746	52,257	102,497
Total	3,847	16,440	258,779	577,736	856,802
Re-posted					
[1] Events involving name or dosage form of drug	168	590	5,519	13,018	19,295
[2] Events caused by drug	743	2,817	31,019	78,692	113,271
[3] Events caused by medical device, etc.	220	593	4,439	10,958	16,210
[4] Current theme	188	576	3,392	8,250	12,406

Number of reporting medical institutions	608
Total number of beds	237,814

[3] Number of Medical Near-miss Event Information

The number of monthly reports for medical near-miss event information between January 1 and December 31, 2016 is shown below.

Fig. II-3-3 (YH-03) Number of Monthly Reports for Medical Near-miss Event Information

	2016												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of medical near-miss event information	4,206	1,422	1,937	3,758	1,500	1,535	4,571	2,050	945	3,770	2,348	2,276	30,318
Number of participating medical institutions for medical near-miss event information reporting	644	643	642	641	642	643	644	645	644	644	641	641	-

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 information reported through this project to gain an overview of them. They then exchange opinions about new themes for analysis and consider the direction of analysis in respect of themes already under analysis, as well as providing advice.

Theme-specific Expert Analysis Groups are established to conduct analysis if deemed necessary, based on the number of events or level of expertise involved. In some cases, rather than establishing a theme-specific Expert Analysis Group, visiting researchers and administrative staff from this department conduct analysis of a theme, with advice from the Expert Analysis Groups.

Finally, based on the opinions of the Expert Analysis Groups and theme-specific Expert Analysis Groups, this department compiles the findings from the analyses and, after review by the Comprehensive Evaluation Panel, publishes those findings.

[3] Workshop

The following workshop was held for medical institutions participating in this project. As well as an update on the current status of the project, it featured a process flow preparation exercise, which was intended to assist in enhancing the quality of reports.

(1) 8th Workshop on Process Flows and the Project to Collect Medical Near-miss/ Adverse Event Information

1) Overview of the Workshop

a) Workshop date: Sunday February 5, 2017

b) Workshop venue: Lecture Hall, JQ

c) Target participants:

Staff from medical institutions, based on the following conditions i) – iii)

i) Teams to consist of 2-3 people, primarily the person in charge of the Medical Safety Management Division, the Medical Safety Manager, and people who play a part in medical safety at the medical institution, such as members of the Medical Safety Committee and Medical Safety Officers, as well as those involved in the management of IT systems at the medical institution.

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

iii) Participation by those in a range of occupations is preferable.

d) Program

i) Lecture :
1) The Current Status of the Project to Collect Medical Near-miss/Adverse Event Information and its Challenges
2) What is a Process Flow?
3) Drawing up Process Flows and their Importance in Medical Safety
4) Improving Operational Processes Based on Medical Adverse Event Information and Points to Remember When Drawing up Process Flows

ii) Practice: Examining Problems in Processes at Your Own Facility and Revising the Process Flows

2) Participation Status

Number of participants: 36 people (12 medical institutions)

[4] Collection of Follow-Up Information on Medical Adverse Events

When an Expert Analysis Group determines that further detailed event information from the medical institution is necessary for analysis, it makes written inquiries to the reporting medical institution or, if the institution agrees to cooperate, visits the institution to collect follow-up information. The follow-up information obtained is used for the development of medical safety measures.

(1) Collection of Follow-Up Information in Writing

In 2016, 133 written inquiries concerning medical adverse events were made to medical institutions and 120 responses were received. The breakdown of these is shown in Fig. III-1-1.

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

Overview of the event	Number of events
Drugs	58
Blood transfusions	2
Treatment/procedure	21
Medical device, etc.	16
Drainage tubes or other tubes	8
Examination	5
Nursing care	10
Others	13
Total	133

Written requests for follow-up information mainly involve asking for more detailed facts and information about background factors to enable the Expert Analysis Group concerned to analyze the content of the original report of the event. However, written inquiries are also sent to medical institutions when there are omissions in the information about the person involved that is to be reflected in the various tables, as well as information such as the name of the drug or medical device involved in an event.

(2) Collection of Follow-Up Information via On-site Visits

Medical institutions where eight medical adverse events occurred were asked to cooperate in conducting on-site visits, and they all did so. A list of on-site visits conducted in 2016 is provided in Fig. III-1-2, while details of a few of these visits are provided in Fig. III-1-3.

Fig. III-1-2 List of On-site Visits

Visit	The type of event	Summary of event
1	**Drugs**	Event in which Atonin-O Injection was meant to be administered via a peripheral vein to induce labor, but was instead administered via the epidural route
2		Event in which the senior physician ordered a diluted drug, but the resident prepared and administered the drug undiluted
3		Event in which Adriacin Injection was administered in excess of the maximum cumulative dose
4		Event in which Thyradin powder was prescribed instead of Thyradin S Powder, resulting in an overdose
5		Event in which the nurse prepared and administered Atropine Sulfate Injection when the physician ordered “ATP” (Adesinon-P)
6	**Treatment/ procedure**	Event in which the patient suffered a cerebral infarction after their anticoagulant drug holiday was started five days too early
7	**Medical device, etc.**	Event in which the patient suffered pacing failure after the cable of their external pacemaker broke
8	**Nursing care**	Event in which a film dressing was affixed to the patient’s permanent tracheostomy, affecting the patient’s respiratory condition

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

Fig. III-1-3 Overview of On-site Visits

Visit 2 **Event in which the senior physician ordered a diluted drug, but the resident prepared and administered the drug undiluted**

Event as reported

Summary of event	Background and causal factors	Improvement measures
At 11:18, the physician began the patient's upper gastrointestinal endoscopy. At 12:12, the patient roused while the procedure was still underway, so it was decided to administer additional sedation and the physician performing the endoscopy gave the resident (3rd year) the verbal order "Draw up Rohypnol 2cc and bring it to me." The resident took Rohypnol (2mg/mL/A) from the safe, prepared 2mL (2A) of Rohypnol in a 2.5mL syringe, and passed it to the senior physician. The senior physician administered 1mL (2mg) of the syringe's contents. When the nurse was tidying up later on, they began to harbor doubts because there was a 2.5mL syringe rather than the 5mL syringe usually used, the tape affixed to the syringe differed from the usual type, and the adhesive label from the ampoule was affixed to it. When the contents of the safe in the endoscopy department were checked, it was discovered that undiluted Rohypnol had been administered, when diluted Rohypnol would usually be used.	Drugs used in endoscopies are usually prepared by nurses. In the morning, the Rohypnol and Dormicum Injection 10mg to be used that day are diluted and placed in the safe, for use on multiple patients. On this occasion, the safe containing psychoactive drugs had not been locked. In the endoscopy department, a tenfold dilution of Rohypnol is prepared every morning, but the resident did not know that. The senior physician intended to order the resident to bring 2mL (0.4mg) of diluted Rohypnol (0.2mg/mL).	• Where verbal orders are unavoidable, the unit used when ordering medication quantity will be mg in all cases. • A rule will be instituted stipulating a mandatory check by a physician and a nurse when administering additional drugs and guidance will be provided to all members of the endoscopy department. • Before beginning clinical practice, all residents will be required to attend a mandatory orientation session covering basic knowledge of sedation methods in the endoscopy departments and sedation methods used at this hospital. • Adherence to the process for managing the key to the drugs safe and locking it will be thoroughly enforced. • The hospital has decided to dilute Rohypnol each time it is used, to avoid the need for verbal orders due to additional administration, as far as possible. • A conference concerning the event and measures taken in response was held, attended primarily by physicians, nurses, and technologists, and the event was also examined at a meeting of physicians in the endoscopy department.

Attendees from the medical institution during the on-site visit

Deputy Hospital Director & Director of the Medical Safety Management Department (physician), Director of the Medical Safety Management Office (physician), 2 physicians from the endoscopy department, Pharmaceuticals Management Officer (pharmacist), 2 GRMs from the Medical Safety Management Office (nurses), endoscopy room charge nurse, endoscopy room chief nurse, 2 members of clerical staff from the Medical Safety Management Office

Findings from the visit

1. Lead-up to the event: Explained by the medical institution (set of documents provided by the medical institution)
- The senior physician administered Rohypnol 0.5mg to sedate the patient before starting the examination. The senior physician discarded the syringe used at that time. Subsequently, when using additional sedation, the senior physician ordered the resident to prepare Rohypnol.

2. Background and causal factors
- Usually, nurses prepare the drugs used in the endoscopy department, but there was no nurse nearby, so the resident prepared it themselves.
- When preparing Rohypnol for use in the endoscopy department, nurses prepared a tenfold dilution, then divided it into two 5mL syringes, to each of which was affixed a special sticker stating "Rohypnol 1mg/5mL." The use of diluted Rohypnol was a rule common to both physicians and nurses in the endoscopy department.
- Both ampoules of Rohypnol and syringes containing a tenfold dilution of Rohypnol were stored in the same safe, with the ampoules in a box at the back and the syringes placed at the front.
- The diluted Rohypnol was made up twice a day: once for patients undergoing procedures in the morning and once for patients undergoing them in the afternoon.
- The nurse carried the key to the safe, unlocking it and locking it again each time it was used, but at the time of this event, the safe was unlocked while the diluted Rohypnol was being made up for use that afternoon.

○ Senior physician
- Physicians were hardly ever involved in preparing drugs, so when using the Rohypnol, the senior physician did not give the resident a specific order about the preparation of the drug.
- The senior physician said, "Draw up 2cc and bring it to me," meaning 2mL of a tenfold dilution of Rohypnol.

○ Resident
- The resident did not know the endoscopy department's rule about diluting Rohypnol or that syringes of the diluted drug had been prepared.
- The resident had no previous experience of using Rohypnol. Neither was the resident particularly aware of the drugs managed using the safe.
- The resident was able to take the Rohypnol ampoule out of the safe because it was unlocked.

○ Nurse
- The nurse was assigned to multiple patients and was not near the patient at the time of the event.

3. Main improvement measures introduced after reporting the event
- Verbal orders for drugs will be given in milligrams. The physician giving the order will do so in specific terms and the person receiving the order will repeat the correct order back to them.
- It will be the responsibility of the physician giving the order to strictly enforce the check back process, so that they can determine whether or not their intended order has been understood.
- Ampoules of Rohypnol will be stored in a separate safe from syringes containing diluted Rohypnol.
- A tenfold dilution of Rohypnol will be prepared for each patient as it is needed.
- Steps will be taken to avoid the need for verbal orders due to additional administration of Rohypnol, as far as possible. If a verbal order is issued, a memo will be taken and a physician and a nurse will carry out a double-check.

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

○ The senior physician was not aware that the resident did not know the rule about diluting Rohypnol. The rule was understood well enough that ordering "Rohypnol 2cc" was usually sufficient, but there appears to have been no awareness that a resident would not know the rule. It would seem to be important to think about risk that arises when a person who does not know about a common rule (resident) is involved in duties that are usually carried out smoothly on the basis of a common rule.

○ The senior physician possibly thought that the resident would ask a nurse to prepare the Rohypnol, rather than preparing it themselves.

○ It might be advisable to decide on ways of ensuring that there is only one option for use, such as by changing the locations in which undiluted and diluted Rohypnol are kept and the way in which they are managed, thereby ensuring that only a tenfold dilution of Rohypnol can be used in procedures. It might also be wise to consider reviewing the specified quantities of stock drugs.

● The pharmaceutical department uses a management register to check the drugs managed using the safe, checking narcotics daily and psychoactive drugs three times a week. We plan to examine the specified quantities.

○ The idea of increasing the number of safes for managing drugs is under consideration, but it might be advisable to think about separating drugs into those like narcotics, which are managed using a safe, and those like psychoactive drugs, which are managed under lock and key.

Visit 3 **Event in which Adriacin Injection was administered in excess of the maximum cumulative dose**

Event as reported

Summary of event	Background and causal factors	Improvement measures
Suffering from endometrial cancer, the patient had undergone a total hysterectomy, bilateral salpingo-oophorectomy, pelvic and paraaortic lymphadenectomy, and an omentectomy three years and four months before the event. Six courses of TC (Paclitaxel + Carboplatin) therapy were subsequently carried out. Due to the recurrence of peritoneal dissemination two years before the event, the patient then underwent six courses of AP therapy (Adriacin Injection (Doxorubicin) with a total dose of 310mg/m2 at this point). Following recurrence at the vaginal stump, the patient underwent tumor resection a year before the event. Three courses of AP (Doxorubicin + Cisplatin) therapy (Adriacin Injection with a total dose of 470mg/m2 at this point) were then carried out. Despite knowing that there was a risk of serious cardiomyopathy if the total dose of Adriacin Injection administered was in excess of 500mg/m2, the physician decided to carry out additional AP therapy, which had previously been effective. The physician's reasoning was that the patient had undergone surgery as a recurrent case and that chemotherapy could be expected to extent the patient's prognosis. In most cases of chemotherapy, six courses are usually administered. No consideration was given to the question of whether the total dose would be exceeded during those six courses. While undergoing chemotherapy, the patient had no subjective symptoms and the scheduled number of courses was completed six months before the event (total dose: 620mg/m2). The patient subsequently suffered heart failure triggered by an upper respiratory tract infection. She was admitted to the department of cardiovascular medicine and an endomyocardial biopsy was carried out, resulting in a diagnosis consistent with drug-induced cardiomyopathy.	Although the physician knew about the risk of cardiomyopathy due to overdose of Adriacin Injection, they proceeded with the planned number of courses of chemotherapy for fear of recurrence. As a result, insufficient attention was paid to the total dose. Although there is a total dose screen when entering the regimen on the electronic medical record, the total dose is not calculated automatically. Nor was there a mechanism for anyone other than the physician to check drugs that pose a problem in the event of an overdose. The pharmacist failed to check the total dose when checking the regimen and the problem could therefore not be spotted.	• The hospital instituted the following measures concerning the administration of drugs subject to limits on the total dose. 1) Physicians will provide a full explanation of the nature of the treatment and its attendant risks before starting a course of treatment. 2) Physicians will contact the pharmacist by phone or other means when entering the regimen. 3) The pharmacist will specify the upper dose limit on the instruction sheet used when explaining the treatment to the patient when starting the regimen. 4) A box for the total dose will be added to the pharmacist's Regimen Check Sheet, which will be completed and explained to the patient each time. 5) The electronic medical record's regimen system will be upgraded so that a caution notice is displayed when issuing orders, warning that caution is required concerning the total dose. 6) The electronic medical record's regimen system will be upgraded so that the total dose is calculated automatically and a caution notice is displayed if the total dose exceeds the upper limit.

Attendees from the medical institution during the on-site visit

Obstetrician-gynecologist, Director of the Pharmaceutical Department (pharmacist), Deputy Director of the Pharmaceutical Department (pharmacist), Medical Safety Manager (nurse), clerical staff from the Planning Office

Findings from the visit

1. Lead-up to the event: Explained by the medical institution (set of documents provided by the medical institution)

2. Background and causal factors

○ Obstetrician-gynecologist

• In addition to endometrial cancer, the patient also had an advanced case of breast cancer and the physician added AP therapy because it could be expected to extend the patient's prognosis.

- The physician was aware of the total dose of Adriacin, but because there were no precise records, the physician relied on their memory regarding the amount administered to the patient and thought that six courses would be fine. The total doses specified in the summary of the event were calculated retroactively after the event occurred.
- Because six courses are usually administered in most chemotherapy regimens, the physician assumed that six courses would be fine in this case, but looking back, it is clear that insufficient consideration was given to the total dose received by this patient.
- The physician was fully aware of the possibility of cardiomyopathy due to Adriacin overdose and would not have deliberately administered Adriacin in excess of the total dose if they had been able to spot that the total dose was an overdose.

○ Pharmaceutical department
- There are 31 pharmacists assigned to the pharmaceutical department, including ward pharmacists (each ward pharmacist handles two wards). Duties such as dispensing anticancer drugs and providing explanations to patients in the chemotherapy room are handled by 5–7 pharmacists.
- Information about the total dose administered to patients was not shared with them and was managed by physicians alone.
- When preparing anticancer drugs, they were supposed to be checked the day before and on the day of use itself by a total of three pharmacists from the section in charge of dispensing them, but the procedure regarding checks of the total dose was ambiguous. No check was carried out in this event.

○ System
- Although the regimen input screen has a screen to display total dose, what it shows is the number of vials ordered, with no indication of the total dose actually administered, so the total dose screen was not used.

○ Chemotherapy Committee
- This event involved the administration of chemotherapy without realizing that the total dose administered was an overdose. If a physician puts together an off-label treatment plan, it needs to be reviewed and approved by the Chemotherapy Committee. To date, the committee has never reviewed an anticancer drug treatment plan.

○ Other
- Including both inpatients and outpatients, around 20 patients receive chemotherapy each day, on average.

3. Main improvement measures introduced after reporting the event
- The electronic medical record system was upgraded so that the electronic medical record can display a screen showing "Total dose (cumulative total dose) mg/m2" for anthracyclines and also displays a warning screen if the upper limit specified in the package insert is exceeded.
- Physicians will check the total dose on the electronic medical record.
- Pharmacists will check the total dose once the drugs have been gathered together the day before and then contact the physician by e-mail.
- The pharmaceutical department has put together a checklist called the Regimen Check Sheet, on which the total dose is to be noted and then checked by the pharmacist auditing the prescription, the dispensing pharmacist, and the pharmacist conducting the accuracy check.
- Physicians have been notified that they must reply to pharmacists' inquiries about prescriptions and the pharmaceutical department has reconfirmed the procedure to be used to check the details of the response when dispensing the drugs.
- To ensure that patients are informed about drugs that have an upper limit on their total dose, the hospital has decided to include information about the total dose in the chemotherapy pamphlet by adding the statement "At this hospital, the upper dose limit is ○○."

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

○ As in this event, it is hard for someone to spot a situation in which the prescription for each individual course is fine, but increasing the number of times that the drug is administered results in the upper limit on the total dose being exceeded. The involvement of a pharmacist to serve as a stopper is crucial. Some medical institutions have a rule that a prescription cannot proceed to the dispensing process unless it has not only the physician's signature, but also the signature of the auditing pharmacist.

○ Although the electronic medical record is a system that displays a warning screen if the upper limit on the total dose is exceeded, it is already too late if a warning is only provided when ordering a prescription that will exceed the total dose. It would be more user-friendly if the system had some kind of mechanism that brought this issue to the physician's attention at an earlier stage.

○ The total dose box on the Regimen Check Sheet is completed by hand and one can see cases in which the units and other details vary according to who completed it. It would be advisable to clearly specify how the sheet should be completed.

○ It would be helpful to know how the total dose on the electronic medical record and the Regimen Check Sheet are checked.

● This event was the catalyst for instituting a check of the total dose by the pharmaceutical department section in charge of dispensing chemotherapy drugs as part of the process of gathering together the drugs the day before. Checks are now carried out by pharmacists three times.

○ Patient pamphlets are a good tool for providing information.

● When considering this event, there was a comment along the lines that although physicians know the total dose for patients who began their treatment at this hospital and have continued to be treated here, there are limits to the information that can be gathered from patient referral documents and referral letters in the case of patients who are receiving treatment at multiple medical institutions. The deliberations looked at the importance of patients themselves being in possession of information to ensure safe treatment and the decision was taken to explain total doses to patients who are aware that they are being treated with anticancer drugs.

○ All medical institutions struggle with events like this, but this medical institution's organizational climate is such that it responded swiftly, starting with the safety measures that it could implement, such as upgrades to the system, which is excellent. We would like this medical institution to maintain its positive approach to reporting events, including sentinel events.

Visit 7 **Event in which the patient suffered pacing failure after the cable of their external pacemaker broke**

Event as reported

Summary of event	Background and causal factors	Improvement measures
At 18:00, when surgery ended, the external pacemaker belonging to the operating theater was replaced with one belonging to the Heart Center. At the entrance to the operating theater, while the patient was being transferred from the operating theater to the Heart Center, the patient suffered pacing failure and went into cardiac arrest. The attending physician carried out chest compressions and the heartbeat restarted, but a pacing failure occurred again. The operating theater's pacemaker, was hurriedly brought out and attached to the patient. At 18:15, the patient entered the Heart Center. The pacing failure was thought to have been caused by a broken myocardial lead, so at 18:40, a different lead was inserted percutaneously and the operating theater's pacemaker was used for pacing. Subsequently, when the Heart Center pacemaker that had been used after surgery was connected to the percutaneously inserted lead, pacing could not be carried out. It was then thought that the Heart Center pacemaker unit itself was the cause of the problem, so the operating theater's pacemaker was connected to the percutaneously inserted lead. No pacing failures were observed thereafter. The percutaneously inserted lead was removed three days later and pacemaker implantation was carried out. The following day, the situation was reported to the ME Department. Suspecting that the cable on the pacemaker side had broken, the ME Department replaced it with a new cable. The ME Department asked the manufacturer to inspect the cable that had been used and the pacemaker unit itself. As a result, while performance tests showed no abnormalities in the pacemaker unit, a break was found on the ventricular cable (+) side. There were nine external pacemakers at the hospital, four of which were deployed in the Heart Center. The ME Department used to go around each department to conduct regular monthly inspections. The pacemaker used had been inspected about a month earlier.	In the Heart Center, pacemakers were stored with the cables still connected and wound around them, so it is possible that the cable broke after developing a kink. Although Heart Center staff checked pacemaker batteries before surgery, they did not check the cables. The ME Department only checked for broken cables during the regular monthly inspection and the Heart Center did not know how those checks were carried out. 16 days before this operation, the cables had been replaced after an event occurred in which an atrial cable was unable to carry out pacing following pediatric cardiac surgery and had to be replaced with a ventricular cable. However, this event was reported neither to the person in charge of the ME Department nor to the person in charge of the Heart Center. It was not highlighted in an incident report, either. When fitting an external pacemaker in the operating theater, the Heart Center's pacemaker is brought into the operating theater on the bed to be used after surgery. The pacemaker is replaced in the operating theater and the patient is transferred immediately afterwards, so there is no time to check that the pacing is functioning normally. There is no replacement device that can be used in the event of a pacemaker malfunction during patient transfer.	• The ME Department's pacemaker check process will be checked. • The ME Department will check both the pacemaker unit and the cables each time they are to be used for a patient. • To prevent cables from breaking due to excessive twisting, a cable fastener will be attached to the pacemaker unit (by the manufacturer). • Once the methods used by the manufacturer and the ME Department to check pacemakers have been confirmed, the manual for pacemaker check procedures in each department will be revised. • A replacement device will be obtained in case of problems during patient transfer.

Attendees from the medical institution during the on-site visit

Director of the Medical Safety Department (physician), Director of the Medical Safety Management Office (physician), Assistant Director of the Medical Safety Management Office (nurse), Director of the Medical Safety Division, Assistant Director of the Medical Safety Division, supervisor from the ME Department

Findings from the visit

1. Lead-up to the event: Explained by the medical institution (set of documents provided by the medical institution)

2. Background and causal factors

○ Pacemaker deployment and models

- The hospital has nine pacemakers: four in the Heart Center, two in the cardiac catheterization room, two in the department of cardiovascular medicine, and one in the operating theater.

- The hospital has not standardized the pacemakers that it uses; the pacemaker used in this event in the operating theater was a different model from the Heart Center's pacemaker that was involved.
- Of the four pacemakers deployed in the Heart Center, three are Fukuda Denshi 3077 SSI portable pacemakers, while one — the device involved in this event — is a Medtronic 5388 DDD external pacemaker.
- The pacemaker deployed in the operating theater is a Biotronik EDP 30/AX external cardiac pacemaker.

○ Pacemaker management in the ME Department
- The ME Department is not staffed 24 hours a day, so it cannot check both the pacemaker unit and the cables each time they are to be used for a patient.
- The regular monthly inspection is carried out using a checklist.
- The items on the inspection checklist are as follows: check for damage to / breakage of the outer casing; check for loosening of screws; check connections of connectors; check whether the main Power On lamp works; check whether each switch functions well; check that the extension lead is not broken; check that output is normal; check that there are spare consumables in stock; check battery condition; check the battery replacement date; check that there is an instruction manual.
- Pacemaker battery checks are carried out by using a tester to check the output in amperes. The manufacturer carries out an annual check of output accuracy.

○ Pacemaker management in the Heart Center
- To prevent misconnection of pacemakers and cables, pacemakers were stored with the cables connected and wound around them.
- Pacemakers were stored lying flat on a shelf, in spaces demarcated by plastic tape.
- In the Heart Center, battery levels were checked by turning on the pacemaker's power switch and checking whether the battery indicator lamp lit up.
- Battery changes while a pacemaker is in use are carried out in the presence of a physician.
- 16 days before this event, an event occurred in which an atrial cable was unable to carry out pacing and had to be replaced with a ventricular cable. However, this event was not reported to the people in charge of the ME Department and the Heart Center, nor was it highlighted in an incident report.

○ Pacemaker operation in the operating theater
- There is only one pacemaker in the operating theater, so if it is removed from the operating theater, it is not available if needed in emergency surgery. Accordingly, after surgery, patients are switched from the operating theater's pacemaker to the Heart Center's pacemaker before being returned to their room.

3. Main improvement measures introduced after reporting the event
- While patients will still be switched to one of the Heart Center's pacemakers in the operating theater after surgery, the hospital has decided that the operating theater's pacemaker will also be taken with the patient during transfer as a spare.
- Pacemakers were stored with the cable wrapped around them, but the hospital decided to have its pacemakers fitted with cable fasteners and transparent covers covering the main unit and the cable connection, to prevent cables from breaking.
- The Heart Center decided to store each pacemaker with an unused battery as a set, and to replace the battery with an unused one before using the pacemaker.
- The item "Replace the battery if 7.2V or below" was added to the Heart Center's manual for pacemaker check procedures.
- The Medical Safety Management Office held a review meeting with the relevant clinical departments, the Heart Center, and the ME Department to inform them about this event.

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

○ It might be advisable to rethink the deployment of the hospital's nine pacemakers. Currently, four pacemakers are deployed in the Heart Center and one in the operating theater, but this could be changed to three in the Heart Center and two in the operating theater, for example. Alternatively, it might be wise to consider using the same model of pacemaker in both the operating theater and the Heart Center, so that they can be used in both.

● The Medical Safety Management Office has requested that new pacemakers be purchased and that the model used be standardized.

○ Changing the pacemaker during the busy interval between the end of surgery and the patient's transfer poses a high risk to the patient. Rather than changing the pacemaker over in the operating theater, it might be advisable to wait until the patient has returned to the Heart Center and their condition has stabilized before doing so.

○ At present, pacemakers are stored with the cables still connected and wound around them, but this makes the cables prone to breakage due to being bent. To prevent cables from being damaged, it might be wise to remove the cables and store the pacemaker unit, the cables, and an unused battery together in a tray.

○ Looking at a photograph of the pacemakers in storage, it is hard to tell whether batteries are unused, because they have been removed from their individual plastic packaging. It might be helpful to leave the batteries in their packaging or in plastic bags, so that anyone can tell that they are unused.

○ The Heart Center manual for pacemaker check procedures mixes items to be covered in pre-use checks and post-use checks together, making it hard to understand. It might be advisable to revise the manual to make the sequence of procedures understandable.

○ The fact that the incident 16 days earlier was not reported or dealt with demonstrates that not all events that occur at the time of surgery are highlighted as incident reports. At the medical institution to which the visitor belongs, all operations performed in all departments within the last year where reoperation was required within 100 days undergo a review. Reconfirming whether or not there was a problem with surgery reveals cases in which events went unreported but should have been examined; this has led to a change in attitude, with staff more inclined to conduct reviews of events associated with surgery.
○ Some medical institutions draw up a checklist aimed at gaining an understanding not only of major adverse events during surgery, but also events such as device defects, which is submitted in all cases. This enables the ME Department to swiftly obtain information about and deal with device defects such as the one in this event, so it might be worth considering.
● The list of surgical events to be reported was drawn up two years ago, but is not used very much, so the hospital plans to consider an occurrence-based system involving the submission of a report list for all cases, in the same way as for time outs.

2. Individual Theme Review by the Expert Division

[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 generality/universality, event frequency, effect on patients, preventability, and ability to serve as an object lesson.

Individual theme analysis in the quarterly reports for this project involves two types of theme: (1) themes subject to comprehensive analysis in conjunction with medical adverse event information, while continuing to collect details of relevant medical near-miss event information over the course of a year; and (2) themes selected from medical adverse event information reported during the period under analysis in the quarterly report and then used to identify and analyze details of similar events in the past.

[2] Themes Highlighted in "Individual Theme Review"

Fig. III-2-1 lists the individual themes highlighted for analysis in the 45th to 48th Quarterly Reports, which were published in 2016.

Fig. III-2-1 "Individual Theme Review" Themes Highlighted in 2016

Analysis themes	Quarterly Report
(1) Themes subject to comprehensive analysis in conjunction with medical adverse event information, while continuing to collect details of relevant medical near-miss event information over the course of a year	
Events Related to Antineoplastic Agents	
[1] Overview	45th
[2] Events occurring at the regimen registration, treatment plan, or prescription stage	46th
[3] Events occurring at the order, dispensing, preparation, or explanation/guidance to patient stage	47th
[4] Events occurring at the administration or checks/observation associated with injection stage	48th
(2) Themes selected from medical adverse event information reported during the period under analysis in the quarterly report and then used to identify and analyze details of similar events in the past	
[1] Events Related to Drug Mix-up Due to Similar Appearance	45th
[2] Events Related to Disconnection of Ventilator Circuit	
[3] Events Related to Double Dosing of Medicines Brought in at Hospitalization and Medicines Prescribed in Hospital	46th
[4] Events in Which a Film Dressing Was Affixed to a Permanent Tracheostomy	
[5] Events in Which a Patient Accidentally Ingested/Aspirated a Foreign Substance During Dental Treatment	47th
[6] Events Related to Falls From a Pediatric Bed	
[7] Events in Which Nor-Adrenalin Was Administered Instead of Adrenaline During Resuscitation	48th
[8] Events Related to the Fitting of Elastic Stockings to Patients With Arteriosclerosis Obliterans of the Lower Limbs	

3. Recurrence of Events and Occurrence of Similar Events

The 3rd to 17th Quarterly Reports featured a section entitled Medical Adverse Event Information to Be Shared, which provided a summary of events that the Expert Analysis Groups thought should be shared with a wider audience after consideration of individual medical adverse event information reports. In addition, a section entitled Individual Theme Review has appeared in each quarterly report since the 1st Quarterly Report; highlighting a specific theme, this section analyzes and examines events related to that theme. Based on events previously profiled in the Medical Adverse Event Information to Be Shared or Individual Theme Review sections, the project also publishes Medical Safety Information, which provides information that should be common knowledge.

[1] Content Highlighted in Recurrence of Events and Occurrence of Similar Events

The Recurrence of Events and Occurrence of Similar Events section of the 45th to 48th Quarterly Reports, which were published in 2016, 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-3-1 lists the contents of each quarterly report.

Fig. III-3-1 Content Highlighted in Recurrence of Events and Occurrence of Similar Events in 2016

Quarterly Report	Title
45th	Specimen mix-up at pathological diagnosis (Medical Safety Information No.53)
	Medical Adverse Event Information to Be Shared: Event Related to intraocular lenses (15th Quarterly Report)
46th	Provision of Food to Which the Patient was Allergic (Medical Safety Information No.69)
	Patient Mix-up during Radiological Examinations (Medical Safety Information No.73)
47th	Drug mix-up (Medical Safety Information No.4, 1st Follow-up Report: No.68)
	Urethral Damage Caused by an Indwelling Bladder Catheter (Medical Safety Information No.80)
48th	Wrong site surgery (right/left) (Medical Safety Information No.8, 1st Follow-up Report: No.50) — Wrong site surgery (right/left) in neurosurgical procedures—
	Events Related to Reactivation of Hepatitis B Due to Immunosuppression/Chemotherapy (34th Quarterly Report)

IV

Provision of Medical Safety Information

IV Provision of Medical Safety Information

In December 2006, in addition to providing information via Quarterly and Annual Reports, the Project to Collect Medical Near-miss/Adverse Event Information began to provide information by fax, etc. not only to medical institutions participating in the project but also to the public. These Medical Safety Information bulletins focus on information about which knowledge should be particularly widespread.

Medical safety information was provided 12 times in total between January and December 2016.

1. Summary of the Medical Safety Information

[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 collected in the Project to Collect Medical Near-miss/Adverse Event Information, in order to promote the prevention of the occurrence/recurrence of medical adverse events.

[2] Medical Institutions

1. Medical institutions subject to reporting requirements as well as voluntarily participating medical institutions in the Project to Collect, Analyze, and Provide Medical Adverse Event Information
2. Participating medical institutions in the Project to Collect, Analyze, and Provide Medical Near-miss Event Information
3. Medical institutions that have requested that information be provided by fax

In addition, medical institutions that have never previously received Medical Safety Information have been contacted five times to ask whether they wish to receive information by fax. Medical Safety Information bulletins are provided to approximately 6,000 medical institutions at present.

[3] Information Provision Method

Information is mainly provided by fax. Information is also made available to the general public via the website.

[4] Content of the Information Provided

Medical Safety Information bulletins No.110 to No.121 were issued between January and December 2016 (Fig. Ⅳ-1-1).

Fig. Ⅳ-1-1 Medical Safety Information released in 2016

No.	Month of information supply	Title
No.110	January	Blood Transfusion to Wrong Patient (1st Follow-up Report)
No.111	February	Delays in Urgent Contact Regarding Panic Values
No.112	March	Medical Safety Information released in 2015
No.113	April	Air Embolism after Removal of a Central Venous Catheter
No.114	May	Forgetting to Resume Anticoagulants/Antiplatelet Drugs
No.115	June	Medical Safety Information released from 2012 to 2014
No.116	July	Patient Mix-up in Drug Administration
No.117	August	Inadequate Checks of Meal Type Information from Other Facilities
No.118	September	Drug Mix-up Due to Similar Appearance
No.119	October	Incorrect Setting of Medication Quantity or Solution Volume on a Syringe Pump
No.120	November	Administration of the Wrong Drug From a Syringe Not Labeled With the Drug Name
No.121	December	Wrongly Inserted Nasogastric Feeding Tube

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Japan Council for Quality Health Care
Toyo Building
1-4-17 Misaki-cho, Chiyoda-ku, Tokyo
101-0061, Japan
Tel: +81-3-5217-0252

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