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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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 the end of 2015, we have issued one hundred nine 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 2015 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, and analyses of individual themes; 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.

About the Project to Collect Medical Near-miss/Adverse Event Information Focusing on the Content of the 2015 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 2015, the project has been run during FY2015 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 2015, 1,426 registered medical institutions were participating in the project and we received 3,654 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 surveys 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 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 2015 Annual Report, which summarizes the medical near-miss/adverse event information reported between January and December 2015. 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.

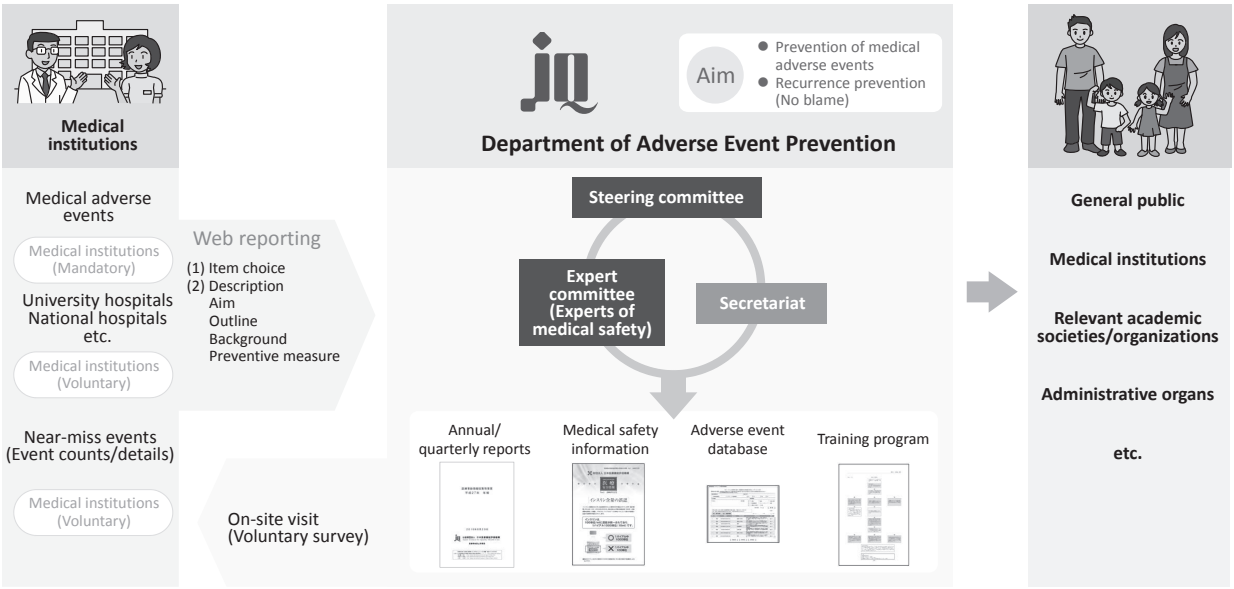
Moreover, the JQ also hopes that, by reading this Annual Report and viewing information published on the project homepage, the general public, as recipients of medical care, will gain an understanding of the various different types of medical adverse events and medical near-misses and the nature thereof, 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. 2015 Project Outline

The project plan for FY2015 was approved at a February 2015 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. 2015 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.

Figure 2 Project Website

2) Number of Registered Medical Institutions Participating in the Project

As of the end of 2015, the number of medical institutions participating in this project has increased slightly, to 1,426 institutions. A breakdown of the number of registered medical institutions participating in the project can be found on p.56. These show the number of medical institutions reporting medical adverse event information, the number of medical institutions reporting medical near-miss event information, and the number of registered 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 2015, the project received 3,654 reports of medical adverse event information, 3,374 of which were reported by medical institutions subject to reporting requirements, with the remaining 280 being reported by voluntarily participating medical institutions (Table 1). These figures exceed the number of events reported in 2014 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-[1]-2 Information Reported as Medical Adverse Events" 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 2015, 784,190 events occurred from 231,981 hospital beds, with information being provided about 30,271 cases from 211,802 hospital beds. Through the introduction of information about the number of events occurring, it is hoped that we will be able to gain more precise information than previously about the relationship between the occurrence of medical near-miss events and the number of 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 Events

Year		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
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
	Voluntary	151	155	179	123	169	521	316	347	341	283	280
	Total	1,265	1,451	1,445	1,563	2,064	2,703	2,799	2,882	3,049	3,194	3,654
Number of Medical Institutions	Mandatory	272	273	273	272	273	272	273	273	274	275	275
	Voluntary	283	300	285	272	427	578	609	653	691	718	743
	Total	555	573	558	544	700	850	882	926	965	993	1,018

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 events reported by voluntarily participating medical institutions rose to 521 in 2010, an increase of around threefold on the figures reported hitherto. However, the number of events has remained around the 300 mark since 2011, with just 283 reported in 2014, and 280 in 2015. On the other hand, we believe that the rise in the number of voluntarily participating medical institutions from 718 (as of the end of 2014) to 743 (as of the end of 2015) 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 events 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.

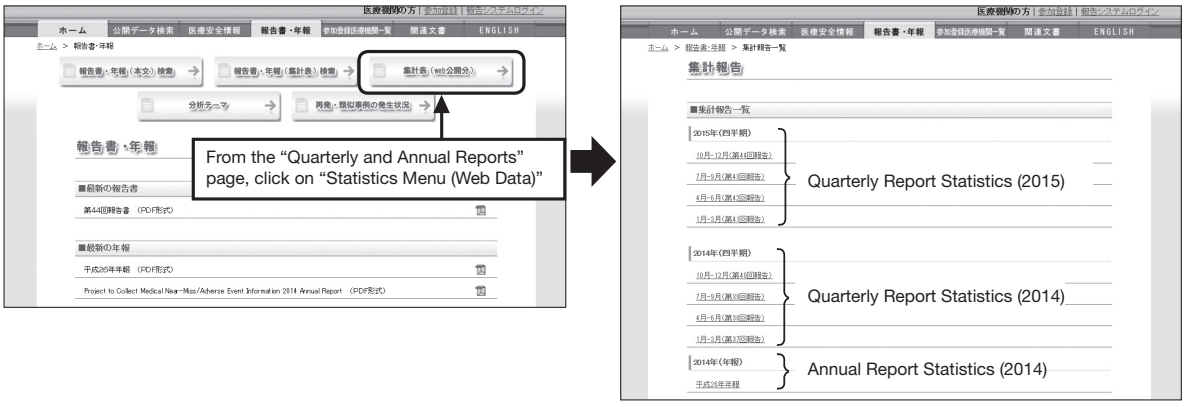
5) Current Reporting Status

“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. 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 in previous annual reports, 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 Analysis

Individual theme analysis takes two forms: prospective analysis and retrospective analysis. As shown in Table 2, a total of nine themes were taken up for analysis in 2015.

Prospective analysis involves first establishing the theme and then continuing to collect details of relevant medical near-miss events, while undertaking a comprehensive analysis of these in conjunction with medical adverse event information. A new theme is chosen each year and information is provided on an ongoing basis. In 2015, analysis throughout the year focused on the theme "Medical Adverse Events Related to Insulin."

In retrospective analysis, a theme is selected from key events reported during the period under analysis in each quarterly report and similar events in the past are highlighted. 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 is provided as appropriate, in the form of an individual theme analysis.

In this Annual Report, an outline of the individual themes highlighted for analysis in 2015 is provided in "2. Individual Theme Review [2] Themes Highlighted in 'Individual Theme Review'" in the chapter "III. Current Analysis of Medical Near-miss/Adverse Event Information." Each quarterly report provides information about specific events, the number of reported events, an analysis of the background and causal factors, and a summary of improvement measures taken to prevent recurrence, so please refer to the 41st to 44th 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

Theme Analyzed
(1) Themes for the Gathering and Analysis of Examples Over the Course of the Year (Prospective Analysis)
Medical Adverse Events Related to Insulin
(2) Themes Analyzed Based on Events That Occurred During the Period Under Analysis in the Quarterly Report (Retrospective Analysis)
[1] Events Related to the Lithotomy Position during Surgery
[2] Events Involving Suicide or Attempted Suicide in Hospital
[3] Events Related to Patient or Drug Mix-up at the Time of Administration
[4] Events Related to Urgent Contact Regarding Panic Values
[5] Events Related to Central Venous Catheter Procedures on Patients in a Sitting Position
[6] Events Related to Wrongly Inserted Gastric Tube
[7] Events Related to Drugs Subject to a Drug Holiday Before an Invasive Procedure
[8] Events Related to Fires Caused by Use of an Electrosurgical Pencil During a Tracheotomy

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, 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 2015 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 in 2015 (Medical Adverse Event Information to Be Shared and 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]	25
Events Related to Burns (Excluding Burns Sustained During Nursing Care)	9th Quarterly Report [Medical Adverse Event Information to Be Shared]	24
Event Involving Facility Management	11th Quarterly Report [Medical Adverse Event Information to Be Shared]	20
Events Related to the Transfer of a Patient from One Bed to Another	13th 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	20th Quarterly Report [Individual Theme Review]	19
Events Involving Failure to Communicate the Content of the Diagnostic Imaging Report	26th Quarterly Report [Individual Theme Review]	18
Events Related to Beds and Other Objects Used in Patient Care	11th Quarterly Report [Medical Adverse Event Information to Be Shared]	15
Events Related to Pathology Test Specimens	15th Quarterly Report [Medical Adverse Event Information to Be Shared]	15
Event Involving Burns Sustained During Nursing Care	5th Quarterly Report [Medical Adverse Event Information to Be Shared]	13
Events Related Wrong-site Treatment in Dental Consultations	12th Quarterly Report [Medical Adverse Event Information to Be Shared]	12
Events Involving Suicide or Attempted Suicide in Hospital	41st Quarterly Report [Individual Theme Review]	12

Table 4 Most Commonly Reported Recurrent and Similar Events in 2015 (Medical Safety Information)

Summary	Information Provided	Number of events
Accidental removal of the endotracheal/tracheostomy tube when changing positions	No.54	12
Mix-up of the tooth extraction site	No.47	11
Accidental ingestion of PTP sheets Accidental ingestion of PTP sheets (1st Follow-up Report)	No.57 No.82	11
Inadequate checks concerning diagnostic imaging reports	No.63	11
Urethral damage caused by an indwelling bladder catheter	No.80	10
Wrong pick-up of syringe containing drug	No.15	8
Accidental removal of a drain/tube during transfer	No.85	7
Extravascular leakage in pediatric patients	No.7	5
Wrong site surgery (right/left) Wrong site surgery (right/left) (1st Follow-up Report)	No.8 No.50	5
Administration of allergic drug to patient with previous known allergy history	No.30	5
Forgetting to check the pathologic diagnosis report	No.71	5

Table 5 shows themes highlighted in the section “Recurrence of Events and Occurrence of Similar Events” in 2015. Each quarterly report provides details of changes in the number of reported events, specific examples, 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 cases, so please refer to the 41st to 44th 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	Information Provided
[1] Bone marrow suppression due to antirheumatic (Methotrexate) overdose Bone marrow suppression due to antirheumatic (Methotrexate) overdose (1st Follow-up Report)	Medical Safety Information No.2 Medical Safety Information No.45
[2] Administration of 10 times proper dosage to pediatric patients	Medical Safety Information No.29
[3] Administration of Contraindicated Drug	Medical Safety Information No.86
[4] Tubing misconnection of ventilator circuit	Medical Safety Information No.24
[5] Insufficient confirmation concerning medical devices implanted into the patient’s body	Medical Safety Information No.62
[6] Failure to implement measures to prevent mother-to-child transmission of Hepatitis B	Medical Safety Information No.49
[7] Event involving Gauze left within the body	14th Quarterly Report [Medical Adverse Event Information to Be Shared]
[8] Contraindicated combined administration of drugs	Medical Safety Information No.61
[9] Events related to management of quantity remaining in oxygen tanks	17th Quarterly Report [Medical Adverse Event Information to Be Shared]

4. Medical Safety Information ~ Number of Facilities Receiving Information by Fax has Increased to 5,932 ~

1) Increase in the Number of Medical Institutions Receiving Medical Safety Information by Fax

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 for maximum visual impact. In 2015, we compiled and published Medical Safety Information (No.98-No.109) once a month between January and December.

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.

After soliciting requests to receive Medical Safety Information by fax in December 2015, the number of medical institutions receiving these faxes rose to 5,932, equating to around 70% of all hospitals nationwide. Requests to receive Medical Safety Information by fax may be submitted at any time. In 2015, we placed a "Request Fax" button on the Medical Safety Information page on the project website, making the request process even more convenient. As such, we would be delighted to receive requests from any hospitals that have not yet submitted one.

2) Concerning the Survey on the Expansion of the Number of Hospitals to Which Medical Safety Information is Provided

We have sought to achieve ongoing increases in the number of medical institutions receiving Medical Safety Information by mentioning it in lectures and conducting surveys of hospitals not currently receiving it by fax to ask whether they would like to do so. As a result of our 2011 survey, we received new requests for Medical Safety Information faxes from 697 hospitals. As this shows, we generally receive a considerable number of requests whenever we conduct a survey of this nature. Accordingly, in December 2015, we conducted a similar survey that also incorporated a questionnaire about the ways in which hospitals not currently receiving Medical Safety Information by fax make use of this information. We received responses from 1,021 of the 3,385 hospitals that were asked to complete the survey (a response rate of 30.2%). As a result of this survey, we received new requests for Medical Safety Information faxes from 579 hospitals.

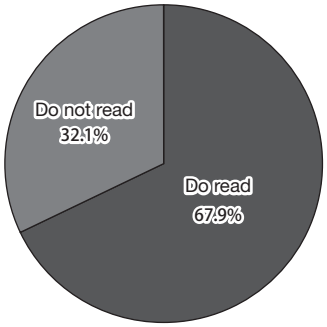
Table 6 Year of Survey on the Expansion of the Number of Hospitals to which Medical Safety Information is Provided and Resultant Increase in Recipients

	1st	2nd	3rd	4th	5th
	2006	2007	2008	2011	2015
Number of Hospitals newly Requesting the Provision of Information	1,924	1,039	623	697	579
Total Number of Medical Institutions Receiving Information	3,332	4,232	4,838	5,307	5,932
First Medical Safety Information Provided	From No.6	From No.15	From No.27	From No.63	From No.111

Even among hospitals not currently receiving Medical Safety Information by fax, 67.9% of hospitals stated that they "do read Medical Safety Information," while 92.6% of hospitals stated that they "use" or "sometimes use" Medical Safety Information. (Figure 4) This showed that even hospitals not currently receiving it by fax are aware of and use Medical Safety Information to some extent. Until now, we have used the number of hospitals receiving Medical Safety Information by fax and their share as a proportion of all hospitals nationwide as an indicator of the spread of Medical Safety Information, but it appears that this information has achieved even wider dissemination than these figures would suggest. Furthermore, when we asked hospitals that stated that they "rarely use" Medical Safety Information why this was the case, the majority (65.3%) responded that "the content is not relevant to our facility," while the next most common responses were "other" (14.3%) and "our facility has no way of making staff aware of it" (10.2%). Comments in the free text box for those selecting "other" included "this is a psychiatric hospital, so much of the content is not relevant, but the need for management of physical issues even in the psychiatric department is growing, so we would like to make use of it in future;" "this hospital carries out few medical procedures, so we use the content relevant to convalescence, medical procedures, and examinations;" and "this hospital has no adverse events, although there are many minor incidents." Thus, it appears that one task that we need to address in enhancing the content of Medical Safety Information going forward is our approach to providing information that will be useful in specific departments and environments involving few clinical procedures. Of the hospitals that stated that they "do not read Medical Safety Information," 86.9% replied "yes" when asked whether or not they wished to receive Medical Safety Information in the future, with 74.0% stating that they "wish to receive it by fax." As such, it would appear that there is still considerable latent demand for receiving Medical Safety Information by fax.

Figure 4 Results of Survey on the Expansion of the Number of Hospitals to which Medical Safety Information is Provided (Excerpt)

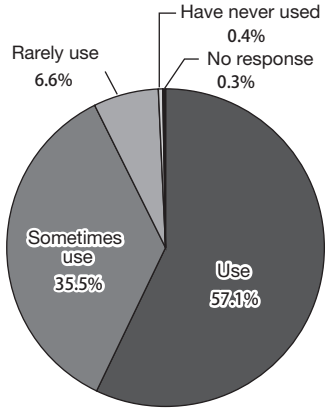
(1) Regular perusal of the latest Medical Safety Information



Item	Number of hospitals
Do read	693
Do not read	328
Total	1,021

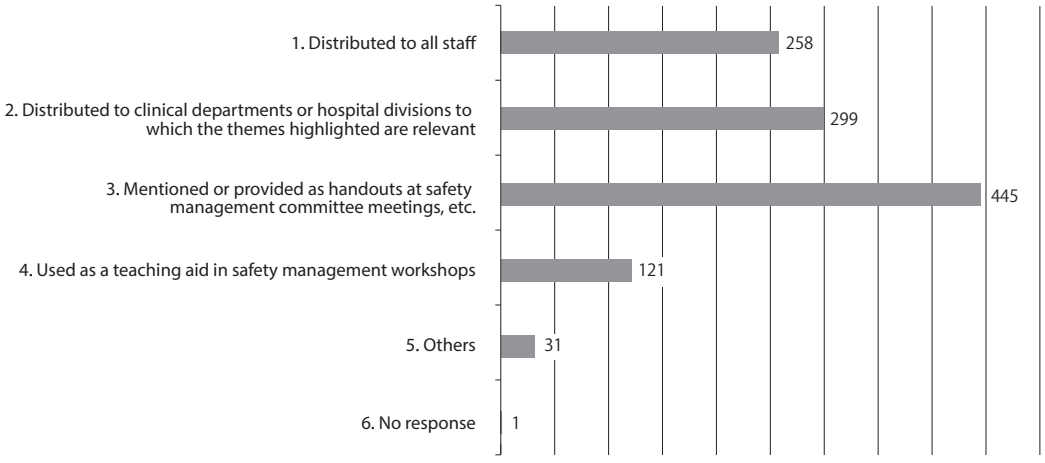
(Question for hospitals that replied “do read” to question (1))

(2) Use of Medical Safety Information within the hospital



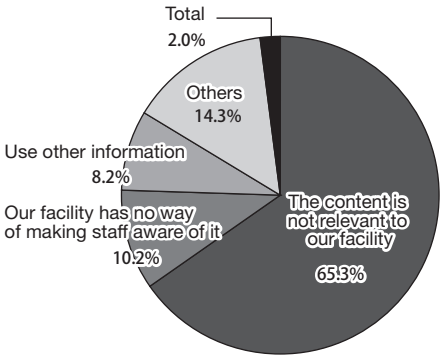
Item	Number of hospitals
Use	396
Sometimes use	246
Rarely use	46
Have never used	3
No response	2
Total	693

● Method of use at hospitals that responded that they “use” or “sometimes use” the information



(Question for hospitals that responded that they “rarely use” or “have never used” the information in question (2))

(3) Reasons for not using Medical Safety Information



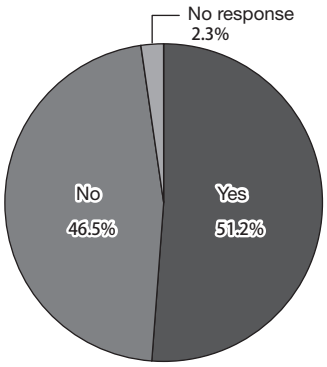
Item	Number of hospitals
The content is not relevant to our facility	32
Our facility has no way of making staff aware of it	5
Use other information	4
Others	7
Multiple responses	1
Total	49

□ Other responses

- We had not thought of a way of making staff aware of it, but we plan to use it in the future
- Efforts to build awareness among staff are inadequate
- This is a psychiatric hospital, so much of the content is not relevant, but the need for management of physical issues even in the psychiatric department is growing, so we would like to make use of it in future
- This hospital carries out few medical procedures, so we use the content relevant to convalescence, medical procedures, and examinations
- This hospital has no adverse events, although there are many minor incidents
- We only pass on relevant information to the departments that need it, based on this hospital’s current situation
- We use the information that we can, but we would like to make greater use of it in future
- We do not gather the information, other than cases in which individuals obtain the information from the website as and when needed

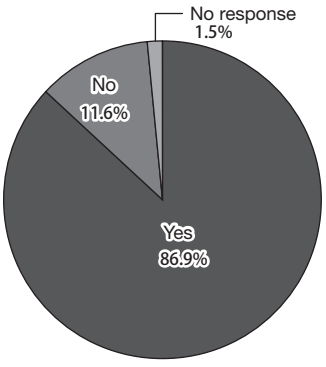
(4) Desire to receive Medical Safety Information in the future

● Hospitals that replied “do read” to question (1)



Item	Number of hospitals
Yes	355
No	322
No response	16
Total	693

● Hospitals that replied “do not read” to question (1)



Item	Number of hospitals
Yes	285
No	38
No response	5
Total	328

3) Compilation and Publication of the Anthology of Medical Safety Information

Medical Safety Information – one of the outcomes of this project – has been published since December 2006 and March 2015 saw the publication of Medical Safety Information No.100. In December 2011, this project compiled and published the Anthology of Medical Safety Information No.1-No.50, which contains Medical Safety Information issues No.1 to No.50. After we published the Anthology of Medical Safety Information No.1-No.50, many medical institutions contacted us to tell us that they found it a helpful summary and would like to make use of it within their institution, that they would like additional copies if we had any spare, that they would print it out and distribute it to their staff, and that they were particularly keen to use it in the education of new staff. We are deeply grateful for the interest that everyone has shown in this publication. Accordingly, in September 2015, this project compiled and published the Anthology of Medical Safety Information No.51-No.100, which contains Medical Safety Information issues No.51 to No.100, and sent this to medical institutions participating in the project, as well as publishing it on the website. It is available for everyone to download and use (http://www.med-safe.jp/pdf/med-safe-collection_051-100.pdf).

This anthology featured contributions by Dr. Yoji Nagai, Director of Hitachi, Ltd. Hitachinaka General Hospital and Chairman of the Management Committee for this project, and Dr. Tomonori Hasegawa, Professor and Chair of the Division of Health Policy and Health Service Research in Toho University School of Medicine's Department of Social Medicine and Chairman of the Comprehensive Evaluation Panel. Respectively entitled "The Significance of Medical Safety Information and Related Issues" and "On the Publication of Medical Safety Information," these brief articles explained the authors' thoughts on the nature and use of Medical Safety Information (Anthology of Medical Safety Information No.51-No.100). As stated therein, the fact that we succeeded in reaching the 100th issue is entirely thanks to the registered medical institutions participating in the project and the people associated with those institutions, so we would like to express our profound gratitude to them. Moreover, in an article entitled "The Progress and Future Prospects of Medical Safety Information," we have explained such matters as 1) the background to the compilation of Medical Safety Information; 2) the provision of Medical Safety Information; 3) the composition of Medical Safety Information; 4) approaches to the themes of Medical Safety Information; 5) the five basic patterns used for Medical Safety Information; 6) the impact of Medical Safety Information; and 7) the dissemination of information about Medical Safety Information overseas. In particular, the section entitled "6) The Impact of Medical Safety Information" introduces cases in which Medical Safety Information led to drug manufacturers issuing warnings about the mix-up of drugs with similar names and presents specific outcomes resulting from the provision of information.

In addition, the Anthology of Medical Safety Information No.51-No.100 featured a section entitled "Usage of Medical Safety Information by Medical Institutions," which highlighted real-life examples of the use of Medical Safety Information by medical institutions. These real-life examples gathered with the cooperation of registered medical institutions participating in the project were classified into four basic patterns: (1) examples in which the illustrations from Medical Safety Information were used; (2) examples in which events at that particular institution were added to the Medical Safety Information; (3) examples in which Medical Safety Information was incorporated into in-house newsletters; and (4) examples in which Medical Safety Information was used in materials for in-house training. We hope that the positive impact achieved by other institutions making concrete use of events that have actually occurred at Japanese medical institutions, thereby helping to prevent the occurrence of medical adverse events, will become even more widespread. Accordingly, the project intends to continue highlighting such examples of the use of Medical Safety Information.

Figure 5 Medical Safety Information No.54 “Accidental Removal of the Endotracheal/Tracheostomy Tube when Changing Positions”

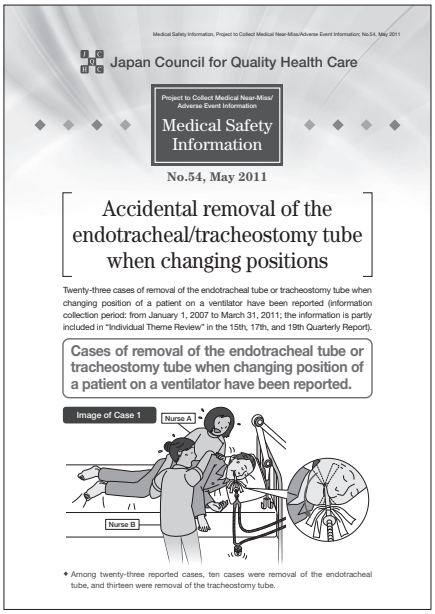


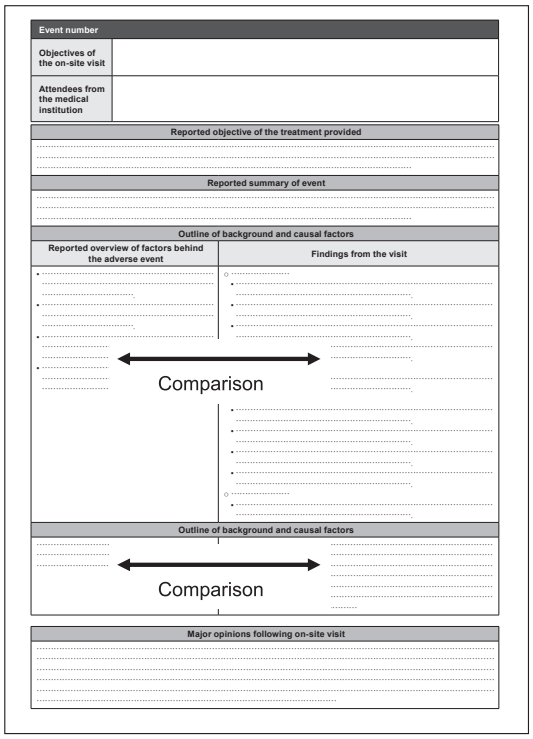
Figure 6 Example of the Use of Medical Safety Information at Medical Institutions (Published in the Anthology of Medical Safety Information No.51-No.100)

5. Provision of Follow-up Information and On-site Surveys

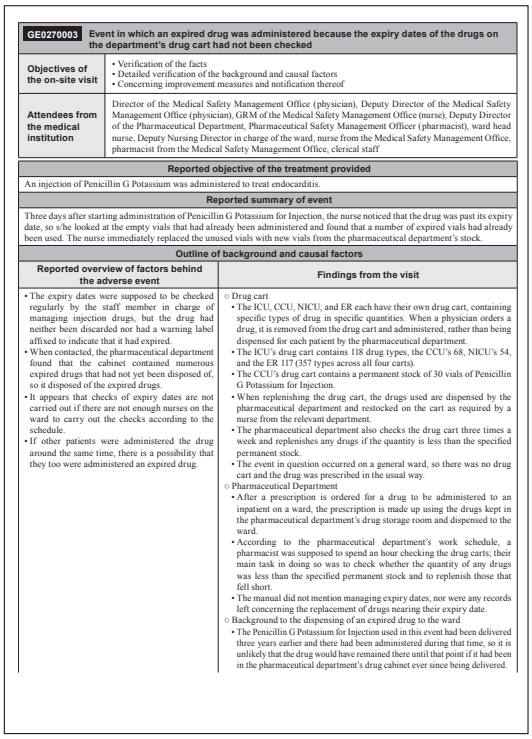
This project focuses on the collection of information by means of documents or on-site surveys, in the event that the secretariat or Expert Analysis Group deems it necessary to gather information concerning reported events. In 2015, we made 126 requests to medical institutions, asking them to provide documentation and other follow-up information concerning medical adverse events, and received 121 responses. Moreover, we asked 5 medical institutions to permit us to carry out on-site surveys regarding 9 cases, and all of these institutions offered us their cooperation.

In particular, we believe that the on-site surveys 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. Moreover, the content of the discussions at the time of the on-site survey has also been useful within the medical care facilities that have been visited. A summary of the events regarding which on-site survey visits have been conducted is published for reference purposes on p.83-91, 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 case, but from the 2012 Annual Report, we compared the outline of the reported event against the main findings from the visit, as shown in Figure 7. We have adopted this approach again for this Annual Report and hope that you will find it useful. The summaries of events that were the focus of on-site surveys are shown below.

Figure 7 Page Composition of the Overview of On-site Surveys



(Page Composition of the Overview of On-site Surveys)



GE0270003	Event in which an expired drug was administered because the expiry dates of the drugs on the department's drug cart had not been checked
Objectives of the on-site visit	• Verification of the facts • Detailed verification of the background and causal factors • Concerning improvement measures and notification thereof
Attendees from the medical institution	Director of the Medical Safety Management Office (physician), Deputy Director of the Medical Safety Management Office (physician), GRM of the Medical Safety Management Office (nurse), Deputy Director of the Pharmaceutical Department, Pharmaceutical Safety Management Officer (pharmacist), ward head nurse, Deputy Nursing Director in charge of the ward, nurse from the Medical Safety Management Office, pharmacist from the Medical Safety Management Office, clerical staff

Reported objective of the treatment provided

An injection of Penicillin G Potassium was administered to treat endocarditis.

Reported summary of event

Three days after starting administration of Penicillin G Potassium for Injection, the nurse noticed that the drug was past its expiry date, so s/he looked at the empty vials that had already been administered and found that a number of expired vials had already been used. The nurse immediately replaced the unused vials with new vials from the pharmaceutical department's stock.

Outline of background and causal factors

Reported overview of factors behind the adverse event	Findings from the visit
• The expiry dates were supposed to be checked regularly by the staff member in charge of managing injection drugs, but the drug had neither been discarded nor had a warning label affixed to indicate that it had expired. • When contacted, the pharmaceutical department found that the cabinet contained numerous expired drugs that had not yet been disposed of, so it disposed of the expired drugs. • It appears that checks of expiry dates are not carried out if there are not enough nurses on the ward to carry out the checks according to the schedule. • If other patients were administered the drug around the same time, there is a possibility that they too were administered an expired drug.	○ Drug cart • The ICU, CCU, NICU, and ER each have their own drug cart, containing specific types of drug in specific quantities. When a physician orders a drug, it is removed from the drug cart and administered, rather than being dispensed for each patient by the pharmaceutical department. • The ICU's drug cart contains 118 drug types, the CCU's 68, NICU's 54, and the ER 117 (357 types across all four carts). • The CCU's drug cart contains a permanent stock of 30 vials of Penicillin G Potassium for Injection. • When replenishing the drug cart, the drugs used are dispensed by the pharmaceutical department and restocked on the cart as required by a nurse from the relevant department. • The pharmaceutical department also checks the drug cart three times a week and replenishes any drugs if the quantity is less than the specified permanent stock. • The event in question occurred on a general ward, so there was no drug cart and the drug was prescribed in the usual way. ○ Pharmaceutical Department • After a prescription is ordered for a drug to be administered to an inpatient on a ward, the prescription is made up using the drugs kept in the pharmaceutical department's drug storage room and dispensed to the ward. • According to the pharmaceutical department's work schedule, a pharmacist was supposed to spend an hour checking the drug carts; their main task in doing so was to check whether the quantity of any drugs was less than the specified permanent stock and to replenish those that fell short. • The manual did not mention managing expiry dates, nor were any records left concerning the replacement of drugs nearing their expiry date. ○ Background to the dispensing of an expired drug to the ward • The Penicillin G Potassium for Injection used in this event had been delivered three years earlier and there had been administered during that time, so it is unlikely that the drug would have remained there until that point if it had been in the pharmaceutical department's drug cabinet ever since being delivered.

Table 7 Summary of Events on Which On-site Surveys Focused

Type of Event	Event number	Summary of event
Drug	GE0270001	Event in which an error was made in the method used to dilute Epoprostenol for I.V. Injection and the error was not rectified during the double-check
	GE0270002	Event in which there was not enough of the liquid medicine that was being administered, so another patient's liquid medicine, which had a different concentration, was added to it and administered
	GE0270003	Event in which an expired drug was administered because the expiry dates of the drugs on the department's drug cart had not been checked
	GE0270004	Event in which a drug was administered from a syringe on which the drug name was not written, resulting in a sedative being wrongly administered instead of contrast medium for an MRI examination
Blood transfusion	GE0270005	Event in which the name of a different patient with the same family name and similar given name was displayed on the screen when the order for the blood product was received, resulting in a blood product for the wrong patient being dispensed
Treatment/ procedure	GE0270006	Event in which right knee surgery was due to be performed, but the operating theater was erroneously set up for left knee surgery and the error was not noticed during the time out, resulting in surgery being performed on the wrong knee
Medical device, etc.	GE0270007	Event in which an MRI examination was carried out because the information that the patient had a pacemaker could not be shared
Drainage tube or other tube	GE0270008	Event in which there was a possibility that air entered a blood vessel, because the wrong connector was removed while the patient was in a sitting position when a heparin lock of a central venous catheter was carried out
Others	GE0270009	Event in which laboratory data for a different patient was transmitted, resulting in the insertion of the wrong intraocular lens

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

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.

6. Website Functions

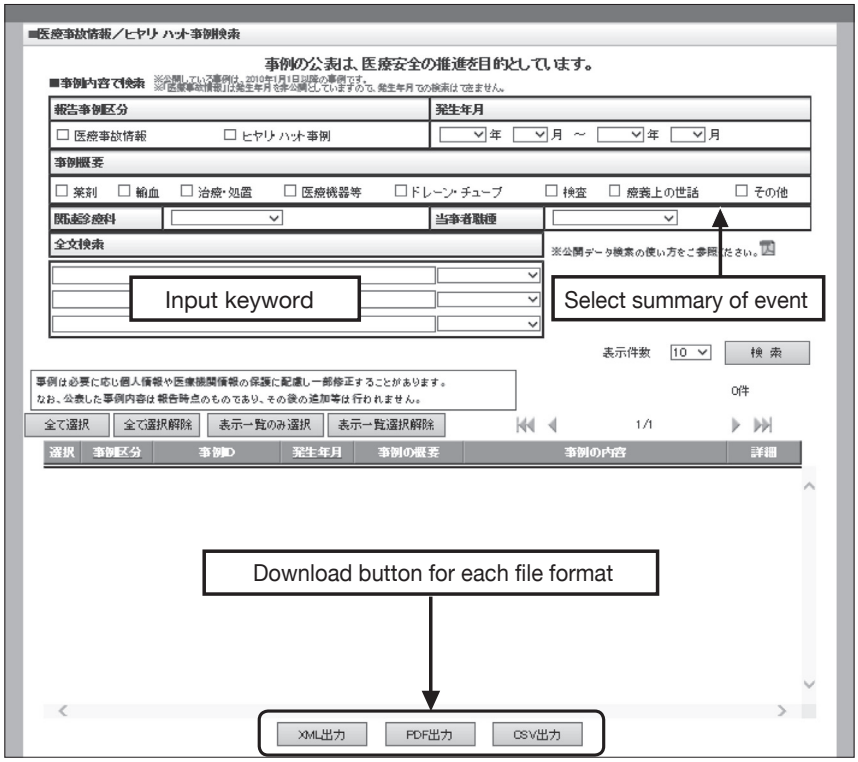
1) Published Data Search of Events / Search Function (available in Japanese only)

Clicking on the "Published Data Search" button on the website for this project brings up the following screen (Figure 8). Medical adverse event information and medical near-miss event information can be perused on this page. Moreover, as shown at the bottom of the illustration, there are buttons that enable the user to download the selected events in any of three file formats: XML, PDF, or CSV. In response to requests from users who wished to be able to download a large number of events at once, we have also provided a "Select all" button and enabled users to download more than 100 events at a time. This function is being used in medical and technological research 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."

This 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. As of the time of writing, this search page enables the user to search details of 19,231 medical adverse events and 43,967 medical near-miss events.

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 Page for Perusing Medical Adverse Events/Near-miss Events



2) Disclosure of Medical Adverse Events by Medical Institutions via This Project

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 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. Thus, we believe that this project's output and its Open Data Search function in particular play an important role in increasing the transparency of medical safety and improving the disclosure of medical adverse events at medical institutions.

3) Pharmaceutical Companies' Use of the Project to Collect Medical Near-miss/Adverse Event Information Database to Prevent Drug Mix-up

–Warning about Mix-ups Due to the Similarity in Brand Names Between Duphaston and Fareston, and Between Nolvadex and Norvasc–

Previous annual and quarterly reports have highlighted the fact that pharmaceutical companies have used the database of events reported as part of this project when issuing warnings about mix-up 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) (Abbott Japan Co., Ltd.) and Fareston® Tab. (generic name: toremifene citrate) (Nippon Kayaku Co., Ltd.), which is used to treat breast cancer, issued a warning about the similarities between the two brand names, as shown in Figure 9 (https://www.pmda.go.jp/files/000206336.pdf). 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.

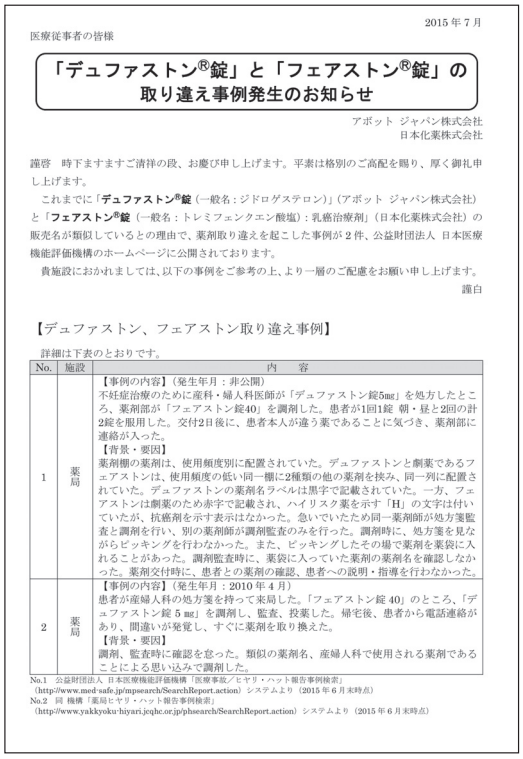
In addition, pharmaceutical companies have cited the outcomes of this project in repeated warnings concerning the mix-up of two drugs that are renowned for having similar names: Norvasc (generic name: amlodipine besylate), a drug to treat hypertension and angina that is also used as a long-acting calcium channel blocker, and Nolvadex (generic name: tamoxifen citrate), an anticancer drug used to treat breast cancer. Another warning was issued in November 2013 and the information in the warning was updated in July 2014 and March 2016 (Figure 10).

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 achieve improvements that will lead to 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 Notice Regarding Events Involving Mix-ups Between Duphaston® and Fareston® Tab.



2015 年 7 月

医療従事者の皆様

「デュファストン®錠」と「フェアストン®錠」の取り違え事例発生のお知らせ

アボット ジャパン株式会社
日本化薬株式会社

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

これまでに「**デュファストン®錠**（一般名：ジドロゲステロン）」（アボット ジャパン株式会社）と「**フェアストン®錠**（一般名：トレミフェンクエン酸塩）：乳癌治療剤」（日本化薬株式会社）の販売名が類似しているとの理由で、薬剤取り違えを起こした事例が 2 件、公益財団法人 日本医療機能評価機構のホームページに公開されております。

貴施設におかれましては、以下の事例をご参考の上、より一層のご配慮をお願い申し上げます。

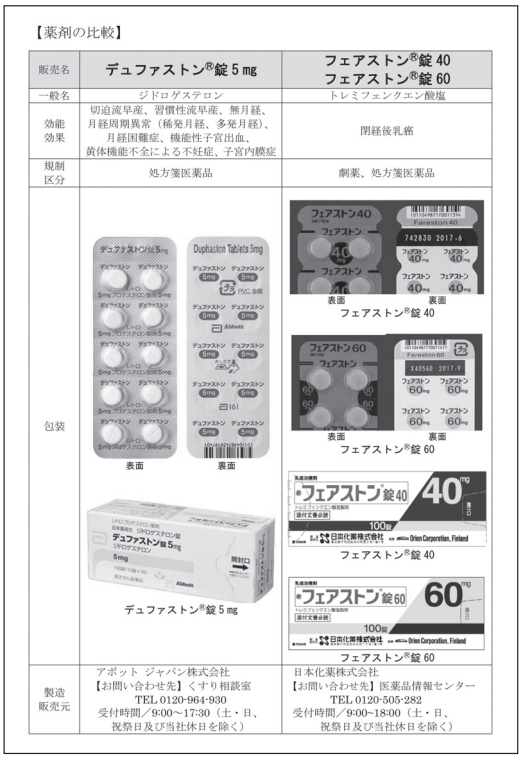
謹白

【デュファストン、フェアストン取り違え事例】

詳細は下表のとおりです。

No.	施設	内　容
1	薬局	【事例の内容】（発生年月：非公開） 不妊症治療のために産科・婦人科医師が「デュファストン錠5mg」を処方したところ、薬剤部が「フェアストン錠40」を調剤した。患者が1回1錠 朝・昼と2回の計2錠を服用した。交付2日後に、患者本人が違う薬であることに気づき、薬剤部に連絡が入った。 【背景・要因】 薬剤棚の薬剤は、使用頻度別に配置されていた。デュファストンと劇薬であるフェアストンは、使用頻度の低い同一棚に2種類の他の薬剤を挟み、同一列に配置されていた。デュファストンの薬剤名ラベルは黒字で記載されていた。一方、フェアストンは劇薬のため赤字で記載され、ハイリスク薬を示す「H」の文字は付いていたが、抗癌剤を示す表示はなかった。急いでいたため同一薬剤師が処方箋監査と調剤を行い、別の薬剤師が調剤監査のみを行った。調剤時に、処方箋を見ながらピッキングを行わなかった。また、ピッキングしたその場で薬剤を薬袋に入れることがあった。調剤監査時に、薬袋に入っていた薬剤の薬剤名を確認しなかった。薬剤交付時に、患者との薬剤の確認、患者への説明・指導を行わなかった。
2	薬局	【事例の内容】（発生年月：2010 年 4 月） 患者が産婦人科の処方箋を持って来局した。「フェアストン錠 40」のところ、「デュファストン錠 5 mg」を調剤し、監査、投薬した。帰宅後、患者から電話連絡があり、間違いが発覚し、すぐに薬剤を取り換えた。 【背景・要因】 調剤、監査時に確認を怠った。類似の薬剤名、産婦人科で使用される薬剤であることによる思い込みで調剤した。

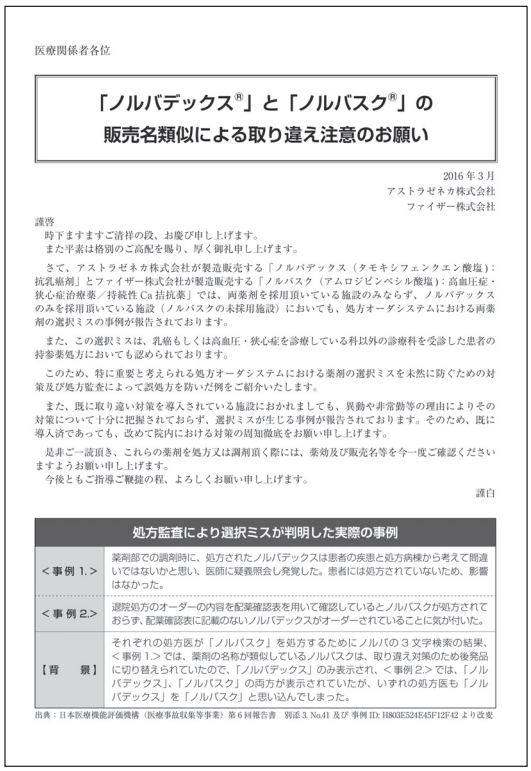
No.1　公益財団法人 日本医療機能評価機構「医療事故／ヒヤリ・ハット報告事例検索」
（http://www.med-safe.jp/mpsearch/SearchReport.action）システムより（2015 年 6 月末時点）
No.2　同 機構「薬局ヒヤリ・ハット報告事例検索」
（http://www.yakkyoku-hiyari.jcqhc.or.jp/phsearch/SearchReport.action）システムより（2015 年 6 月末時点）



【薬剤の比較】

販売名	デュファストン®錠 5 mg	フェアストン®錠 40 フェアストン®錠 60
一般名	ジドロゲステロン	トレミフェンクエン酸塩
効能効果	切迫流早産、習慣性流早産、無月経、月経周期異常（稀発月経、多発月経）、月経困難症、機能性子宮出血、黄体機能不全による不妊症、子宮内膜症	閉経後乳癌
規制区分	処方箋医薬品	劇薬、処方箋医薬品
包装	デュファストン®錠 5 mg 表面　裏面	フェアストン®錠 40 表面　裏面 フェアストン®錠 60 表面　裏面 フェアストン®錠 40 フェアストン®錠 60
製造販売元	アボット ジャパン株式会社 【お問い合わせ先】くすり相談室 TEL 0120-964-930 受付時間／9:00～17:30（土・日、祝祭日及び当社休日を除く）	日本化薬株式会社 【お問い合わせ先】医薬品情報センター TEL 0120-505-282 受付時間／9:00~18:00（土・日、祝祭日及び当社休日を除く）

Figure 10 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

2016年3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、アストラゼネカ株式会社が製造販売する「ノルバデックス（タモキシフェンクエン酸塩）：抗乳癌剤」とファイザー株式会社が製造販売する「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」では、両薬剤を採用頂いている施設のみならず、ノルバデックスのみを採用頂いている施設（ノルバスクの未採用施設）においても、処方オーダシステムにおける両薬剤の選択ミスの事例が報告されております。

また、この選択ミスは、乳癌もしくは高血圧・狭心症を診療している科以外の診療科を受診した患者の持参薬処方においても認められております。

このため、特に重要と考えられる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の対策及び処方監査によって誤処方を防いだ例をご紹介いたします。

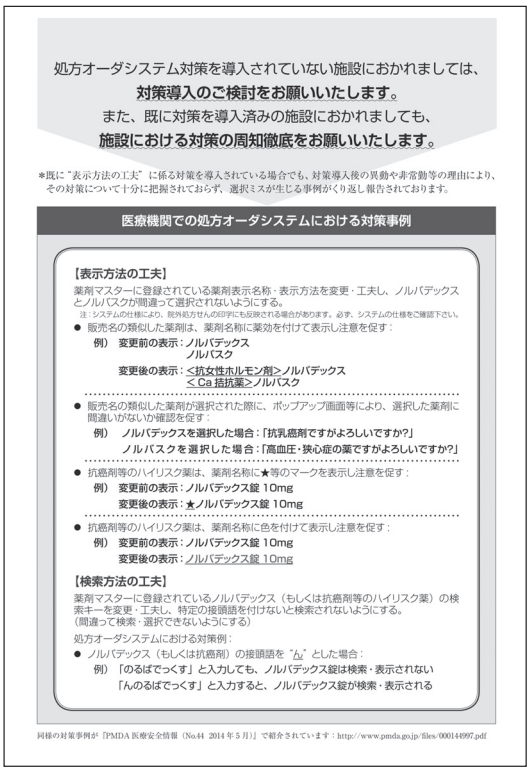
また、既に取り違い対策を導入されている施設におかれましても、異動や非常勤等の理由によりその対策について十分に把握されておらず、選択ミスが生じる事例が報告されております。そのため、既に導入済であっても、改めて院内における対策の周知徹底をお願い申し上げます。

是非ご一読頂き、これらの薬剤を処方又は調剤頂く際には、薬効及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

処方監査により選択ミスが判明した実際の事例	
＜事例1.＞	薬剤部での調剤時に、処方されたノルバデックスは患者の疾患と処方病棟から考えて間違いではないかと思い、医師に疑義照会し発覚した。患者には処方されていないため、影響はなかった。
＜事例2.＞	退院処方のオーダーの内容を配薬確認表を用いて確認しているとノルバスクが処方されておらず、配薬確認表に記載のないノルバデックスがオーダーされていることに気が付いた。
【背　景】	それぞれの処方医が「ノルバスク」を処方するためにノルバの3文字検索の結果、＜事例1.＞では、薬剤の名称が類似しているノルバスクは、取り違え対策のため後発品に切り替えられていたので、「ノルバデックス」のみ表示され、＜事例2.＞では、「ノルバデックス」、「ノルバスク」の両方が表示されていたが、いずれの処方医も「ノルバデックス」を「ノルバスク」と思い込んでしまった。

出典：日本医療機能評価機構（医療事故収集等事業）第6回報告書　別添3 No.41 及び 事例ID: H803E524E45F12F42 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、既に対策を導入済み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、院外処方せんの印字にも反映される場合があります。必ず、システムの仕様をご確認下さい。

- 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）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/000144997.pdf

<Reference> Warning Using Output from this Project

Events reported to this project have been the subject of warnings by pharmaceutical companies not only in respect of drug mix-up, but also in regard to proper usage. In August 2015, a warning was published concerning the preparation of PEGINTRON® Powder for Injection. The document explains that the information in the warning is based on events reported to this project, stating, “The Japan Council for Quality Health Care’s Project to Collect Medical Near-miss/Adverse Event Information has received multiple reports of events involving PEGINTRON® Powder for Injection 50μg/0.5mL, PEGINTRON® Powder for Injection 100μg/0.5mL, and PEGINTRON® Powder for Injection 150μg/0.5mL (hereinafter “this product”), in which, during preparation, the drug was dissolved in the accompanying 0.7mL of water for injection and the full quantity (0.7mL) was administered as it was, or was dissolved in 0.5mL of water for injection and an overdose was administered.” Although no similar events were reported after the issue of this warning document, a similar document was issued in April 2016, to ensure that medical staff remained alert to the risks.

Figure 11 Request for Caution When Preparing PEGINTRON® Powder for Injection

ペグイントロン®皮下注用
調製時の注意に関するお願い

ペグインターフェロン α-2b 製剤
ペグイントロン皮下注用50μg/0.5mL用
ペグイントロン皮下注用100μg/0.5mL用
ペグイントロン皮下注用150μg/0.5mL用
注射用ペグインターフェロン アルファ-2b（遺伝子組換え）

医療関係者の皆様

2015 年 8 月
MSD 株式会社

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弊社製品のペグイントロン®皮下注用 50μg/0.5mL 用、ペグイントロン®皮下注用 100μg/0.5mL 用、ペグイントロン®皮下注用 150μg/0.5mL 用（以下、本剤）につきまして、公益財団法人日本医療機能評価機構の医療事故情報収集等事業において、調製時に添付の注射用水 0.7mL で溶解し、そのまま全量（0.7mL）を投与した事例や、注射用水 0.5mL で溶解し、過量に投与した事例が複数報告されています。

これらの誤調製に基づく過量投与により特定の副作用は報告されていませんが、患者さんの安全性確保のため、本剤の適正使用にご協力ください。

調製時の注意点
本剤を添付の注射用水（0.7mL 全量）で溶解したときの
溶解液 0.5mL 中の含有量は
各表示量（50μg、100μg、150μg）となります

医療関係者の皆様におかれましては、本剤添付文書の**＜用法・用量に関連する使用上の注意＞**及び**「適用上の注意」**をご一読いただき、本剤の調製方法を再度ご確認いただきますようお願い申し上げます。

謹白

〔お問い合わせ先〕
MSD 株式会社 MSD カスタマーサポートセンター
電話番号：0120-024-961
受付時間：月～金 9：00～17：30（祝日・当社休日を除く）

ペグイントロン®皮下注用
調製時の注意に関するお願い

ペグインターフェロン α-2b 製剤
ペグイントロン皮下注用50μg/0.5mL用
ペグイントロン皮下注用100μg/0.5mL用
ペグイントロン皮下注用150μg/0.5mL用
注射用ペグインターフェロン アルファ-2b（遺伝子組換え）

医療関係者の皆様

2016 年 4 月
MSD 株式会社

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調製時の注意点
本剤を添付の注射用水（0.7mL 全量）で溶解したときの
溶解液 0.5mL 中の含有量は
各表示量（50μg、100μg、150μg）となります

医療関係者の皆様におかれましては、本剤添付文書の**＜用法・用量に関連する使用上の注意＞**及び**「適用上の注意」**をご一読いただき、本剤の調製方法を再度ご確認いただきますようお願い申し上げます。

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MSD 株式会社 MSD カスタマーサポートセンター
電話番号：0120-024-961
受付時間：9：00～17：30（土日祝日・当社休日を除く）

In August 2015, this project issued Medical Safety Information No.105 “Forgetting to Open/Close a T-shaped Stopcock” (Figure 12). On a similar theme, in January 2016, the Pharmaceuticals and Medical Devices Agency (PMDA) published PMDA Medical Safety Information No. 48 “Precautions in handling of Three-way Stopcocks” (Figure 13). The PMDA’s Medical Safety Information highlights issues identified from events reported to this project and side-effects/defects reported under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, providing information aimed at promoting the safe use of pharmaceuticals and medical devices based on expert opinions. Thus, the publication of events reported to this project and details of its analyses is helping to promote more widespread use of project output.

Figure 12 Medical Safety Information No.105 “Forgetting to Open/Close a T-shaped Stopcock”

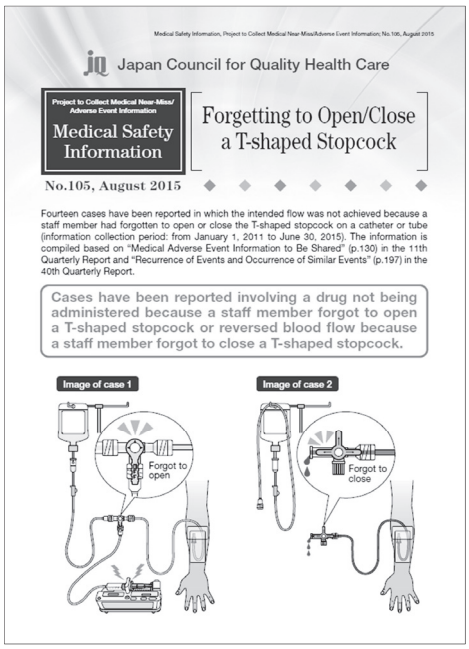
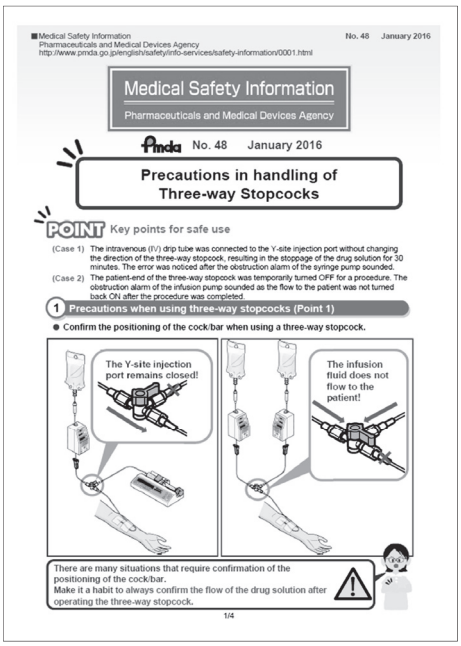


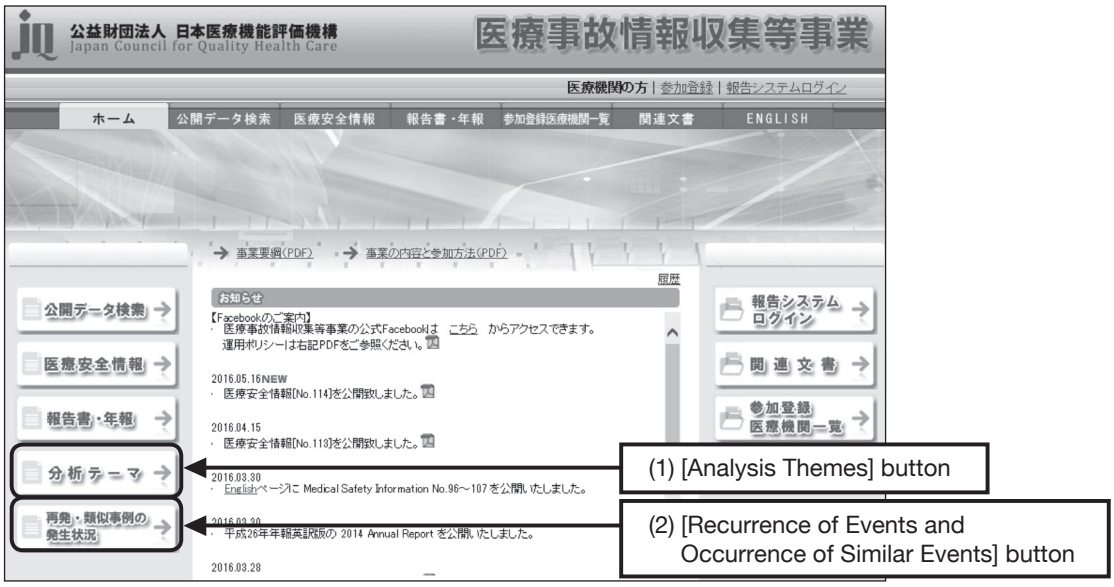
Figure 13 PMDA Medical Safety Information No.48 “Precautions in handling of Three-way Stopcocks”



4) Browse Function for “Analysis Themes” and “Recurrence of Events and Occurrence of Similar Events” (available in Japanese only)

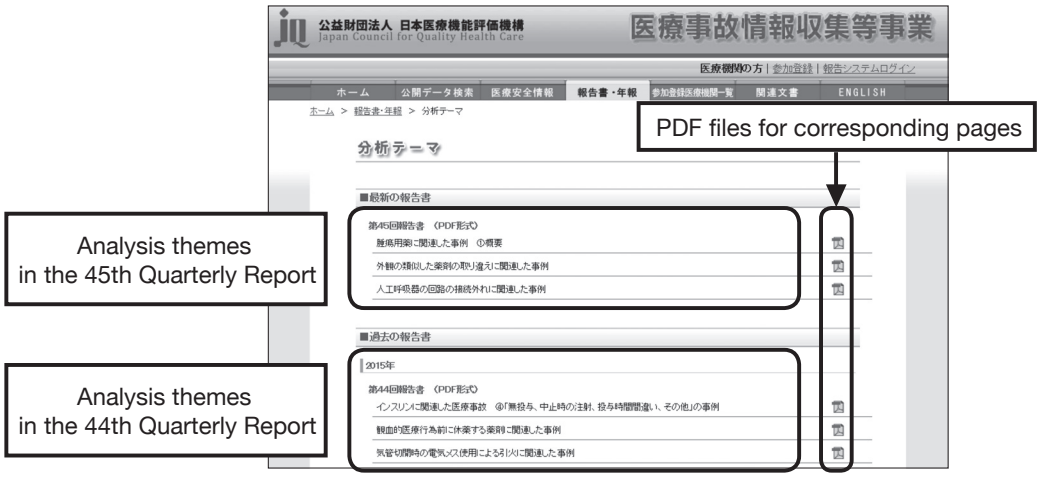
In 2013, buttons for (1) [Analysis Themes] and (2) [Recurrence of Events and Occurrence of Similar Events] were added to the project website (Figure 14).

Figure 14 Project Website



Clicking on button (1) enables the user to browse PDF files of pages that correspond to the titles of themes highlighted in the “Analysis Themes” section of the 1st-45th Quarterly Reports (Figure 15).

Figure 15 Analysis Themes Page



The following table lists the themes that have been featured in the last two years, up to the 45th Quarterly Report.

Table 8 Analysis Themes Featured in Quarterly Reports (Last Two Years)

Year	Quarterly Report	Cumulative Number	Title
2016	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

Year	Quarterly Report	Cumulative Number	Title
2014	40th	165	Medical Adverse Events Related to Nurses and Assistant Nurses with Less Than a Year's Professional Experience (iv) Events related to nursing care
		164	Events Related to the Use of Potassium Preparations as an Intravenous Bolus
		163	Events Related to Irradiation of the Wrong Site in Radiotherapy
		162	Events Related to Misinterpretation of Verbal Information
	39th	161	Medical Adverse Events Related to Nurses and Assistant Nurses with Less Than a Year's Professional Experience (iii) Events involving treatment and procedures, medical devices, etc., drains and tubes, and examinations
		160	Events Related to Reagents Used in Allergy Skin Testing
		159	Events Related to the Washing and Disinfection of Endoscopes
	38th	158	Medical Adverse Events Related to Nurses and Assistant Nurses with Less Than a Year's Professional Experience (ii) Events involving drugs and blood transfusions
		157	Events Involving the Failure to Provide Appropriate Drug Therapy Due to the Misidentification of Generic Drugs
		156	Events Related to the Transceivers of Wireless Electrocardiogram Monitors
		155	Events Related to the Management of Milk Formula and Breastfeeding
	37th	154	Medical Adverse Events Related to Nurses and Assistant Nurses with Less Than a Year's Professional Experience (i) Overview
		153	Events Involving the Subcutaneous or Mediastinal Migration of the Patient's Tracheostomy Tube
		152	Events Related to Medical Safety or Information Management Arising in the Course of the Duties of Administrative Staff

Clicking on button (2) in Figure 14 enables the user to browse PDF files of pages that correspond to the titles of themes previously highlighted in the "Recurrence of Events and Occurrence of Similar Events" section. The table below lists the matters featured over the last two years in the "Recurrence of Events and Occurrence of Similar Events" section, up to the 45th Quarterly Report.

Table 9 List of Matters Highlighted in the “Recurrence of Events and Occurrence of Similar Events” Section (Last 2 Years)

Year	Quarterly Report	Cumulative Number	Title
2016	45	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	44	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)
	43	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: Events involving Gauze left within the body (14th Quarterly Report)
	42	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)
2014	40th	72	Inadequate Checks Concerning Diagnostic Imaging Reports (Medical Safety Information No.63)
		71	Medical Adverse Event Information to Be Shared: Events related to the obstruction or disconnection of a T-shaped stopcock while in use (11th Quarterly Report)
	39th	70	Use of unsterile medical supplies (Medical Safety Information No.19)
		69	Burn caused by a bed-bath towel (Medical Safety Information No.46)
	38th	68	Extravascular leakage of gabexate mesilate (Medical Safety Information No.33), Vasculitis due to administration of gabexate mesilate (1st Follow-up Report) (Medical Safety Information No.77)
		67	Medical Adverse Event Information to Be Shared: Medical adverse events related to wrong-site treatment in dental consultations (15th Quarterly Report)
	37th	66	Extravascular leakage in pediatric patients (Medical Safety Information No.7)
		65	Surgical fire due to ignition of a flammable drug by an electrosurgical pencil (Medical Safety Information No.34)

In 2014, the Published Data Search page has pull-down menus that enable the user to select the clinical department involved and job title of the person involved. Leading academic societies in a range of clinical fields have invited representatives of this project to give lectures and it appears that the medical safety committees of some academic societies are considering embarking on projects to gather data about adverse events. However, systematically gathering information about events is not easy, so some academic societies have been considering making use of this project Published Data 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 hope that the addition of these functions will help to make the Published Data Search function even more useful in promoting medical safety.

7. Status of Access to Information Provided on the WebsiteTable

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 includes such sections as the List of Registered Medical Institutions, the Published Data Search function, Medical Safety Information, Quarterly and Annual Reports, Analysis Themes, Recurrence of Events and Occurrence of Similar Events, and Relevant Documents. 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 10 Survey Items Relating to the Number of Times Information Has Been Accessed

	Item	Content of Information Provided
1)	Published Data Search	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.

1) Changes in Access Frequency by Year

The following shows the number of times information has been accessed, by year. The figures indicate the number of times that the buttons [Published Data Search], [Medical Safety Information], and [Quarterly and Annual Reports] have been clicked on the homepage. In 2013, the number of times information was accessed inevitably declined, because the reporting and viewing systems were unavailable for about two months. It should also be noted that the figures for 2009 only include six months' worth of data, while figures for the number of published data searches are only available from mid-July 2010.

Accordingly, access figures for Published Data Search were higher in 2015 than in 2014. The information available in this database consists of information about reported medical adverse events and near-miss events that has been masked by deleting any details that could identify an individual or a particular medical institution. We provide this information in order to contribute to routine medical safety and efforts to address medical adverse events, as well as research concerning medical safety, and R&D, manufacture, and sale by companies of safe products. This would appear to suggest that its use is growing. There was also an 11% increase in access figures for Medical Safety Information, but the 2015 figure was lower than the figures for the period 2010 to 2012. When we investigated the reasons for this, we discovered that, as stated above, the access figures only count the number of times that the button [Medical Safety Information] on the homepage is clicked. We discovered that, in fact, people also frequently access the latest Medical Safety Information via direct links to the PDFs in the Latest Information column, or via a bookmark in the Favorites section of their web browser linked directly to the Medical Safety Information page, without using the homepage. Thus, figures for access from the homepage do not tell the whole story. Accordingly, from the 2014 Annual Report, to take such access methods into account, we began to compile figures for the number of times that each Medical Safety Information PDF was opened, counting the number of times that the Medical Safety Information button on the homepage was clicked, the number of times that each Medical Safety Information PDF was opened from the News list on the homepage, and the number of times that each PDF was accessed directly from a search engine. The access figures show an increase from 286,552 in 2014 to 349,337 in 2015.

Access figures for Quarterly and Annual Reports in 2015 remained more or less the same as in 2014. The Quarterly and Annual Reports contain a large volume of information, so we are increasing awareness of this introductory section in particular, as well as distributing it as reference material when we give lectures.

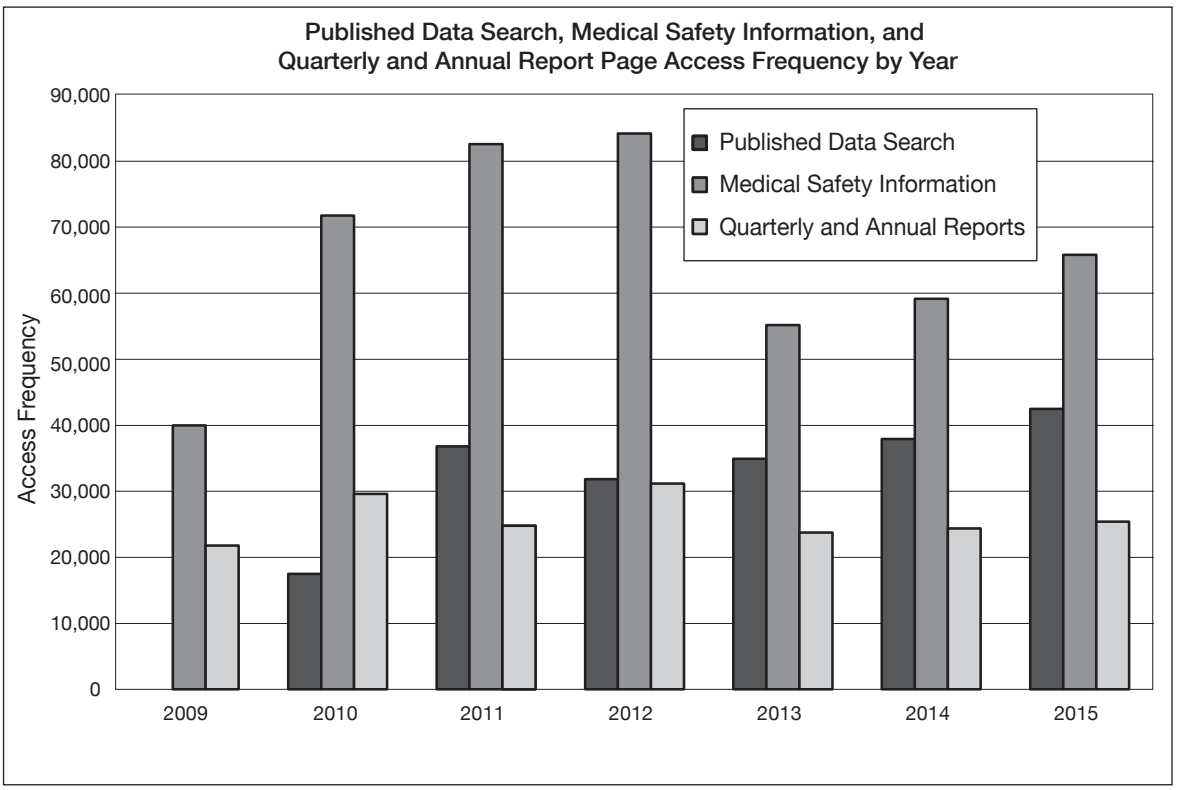
We imagine that medical institutions give priority to addressing day-to-day medical near-miss and medical adverse events, as well as areas for improvement. Accordingly, we believe that treating the fruits of this project undertaken with the participation of medical institutions as important external information and making effective use of it is a vital task for all facilities.

Table 11 Published Data Search, Medical Safety Information, and Quarterly and Annual Report Page Access Frequency by Year

	2009	2010	2011	2012	2013 Note 3	2014	2015
Published Data Search	-	17,501Note 2	36,826	31,846	34,930	37,906	42,495
Medical Safety Information	39,973Note 1	71,746	82,579	84,163	55,180	59,156	65,834
Quarterly and Annual Reports	21,769Note 1	29,626	24,766	31,179	23,743	24,400	25,420

Note 1) The collection period for Medical Safety Information and Quarterly and Annual Reports in 2009 is June 1 – December 31.
Note 2) The collection period for the published data search in 2010 is July 14 – December 31.
Note 3) The Published Data Search, Medical Safety Information, and Quarterly and Annual Reports sections of the website were unavailable between July 22 and September 16, 2013, due to a system stoppage.

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



(Note) The method used for compiling data changed in 2014, so figures for this year onward are not comparable with those for previous years.

2) Medical Safety Information Access Frequency

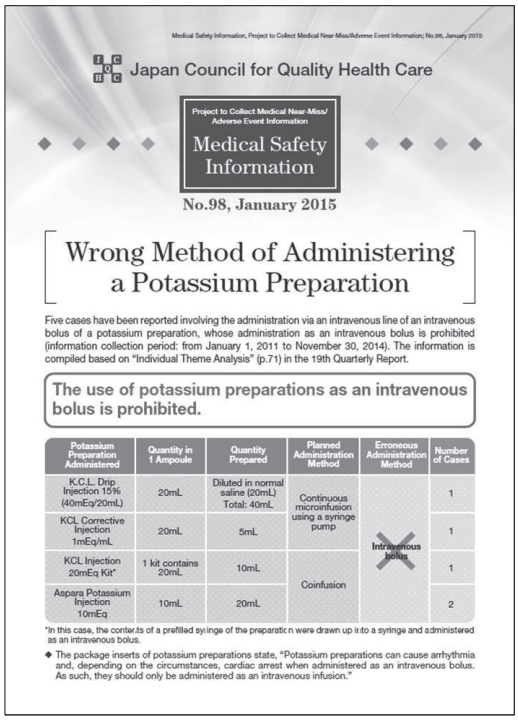
We investigated how many times each of the issues of Medical Safety Information (from No.1 to No.108) was accessed between January and December 2015; Table 12 shows which issues of Medical Safety Information were accessed the most during that period. Usually, access frequency increases over the course 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 the fact that the collection period for some is longer than that for others, depending on the month and year in which the Medical Safety Information was originally published; and the fact that, as shown in Figure 16, there is a possibility that the overall upward trend in the number of times that Medical Safety Information is accessed is 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 viewed 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 was Medical Safety Information No.98 "Wrong Method of Administering a Potassium Preparation" (Figure 17), which was issued in January 2015.

As pointed out in previous Annual Reports, it was not necessarily the case that the issues accessed the most were the ones which were available for the longest, due to their having been published at the beginning of the survey period, and it would appear that some issues of Medical Safety Information have been accessed many times, while others have received few views. Looking at the access figures for each year, the issues of Medical Safety Information that appeared to have been accessed comparatively often were those published in June each year, featuring recurrent and similar events to those highlighted in previous issues of Medical Safety Information, entitled "Medical Safety Information released from 2011 to 2013" (★), and those termed "1st Follow-up Report" (☆), which repeat the information published previously.

Table 12 Medical Safety Information Accessed the Most (2015)

		2015	Number of events
	1	No.98: Wrong Method of Administering a Potassium Preparation	21,032
	2	No.101: Wrong Drug Administration Route	16,902
	3	No.102: Misinterpretation of a Verbal Order	15,892
	4	No.104: Wrong Weight When Prescribing an Antineoplastic Agent	13,928
	5	No.100: Medical Safety Information released in 2014	12,382
★	6	No.103: Medical Safety Information released from 2011 to 2013	12,137
	7	No.105: Forgetting to Open/Close a T-shaped Stopcock	12,065
	8	No.106: Wrongly Prepared Drug for a Pediatric Patient	11,118
	9	No.99: Left-Right Mix-Up When Inserting a Thoracostomy Tube	10,662
☆	10	No.107: Surgical Fire Due to Ignition of a Flammable Drug by an Electrosurgical Pencil (1st Follow-up Report)	10,229

Figure 17 Medical Safety Information Accessed the Most in 2015: 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

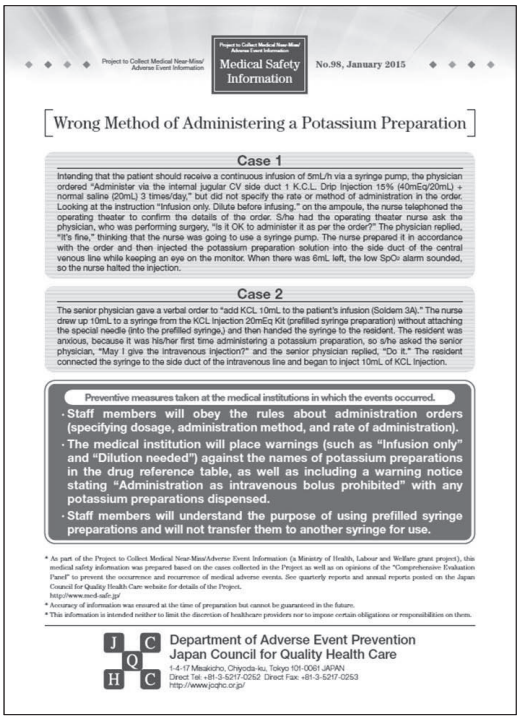
Five cases have been reported involving the administration via an intravenous line of an intravenous bolus of a potassium preparation, whose administration as an intravenous bolus is prohibited (information collection period: from January 1, 2011 to November 30, 2014). The information is compiled based 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 into 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 SpO₂ 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/

8. 7th Workshop on Process Flows and the Project to Collect Medical Near-miss/ Adverse Event Information

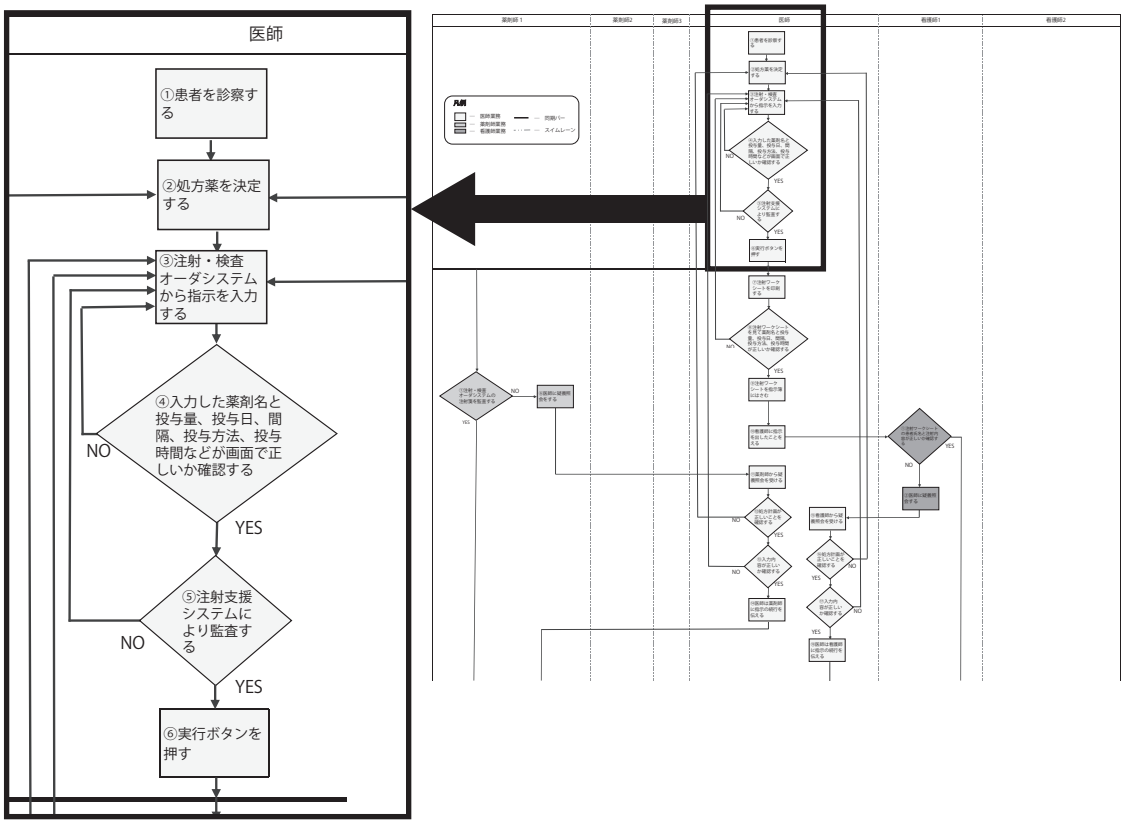
Duties are usually carried out via various operational processes in such areas as medical care, nursing care, and drug dispensing at medical institutions. However, in reality, one cannot really say that optimal, standardized operational processes have been created. Accordingly, it seems that operational processes differ between medical personnel and that they vary considerably from one medical institution to another, even for the same medical procedure. For example, can you call to mind the processes that are followed at your own medical institution when carrying out the procedures “preparing and injecting an injection drug from stock drugs, following an order sheet” and “injecting a drug based on a verbal order”? Do you think that these processes were designed with consideration for eliminating waste and unreasonable practices, 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 44 people from 15 medical institutions, including 11 physicians, 1 dentist, 19 nurses, 9 pharmacists, and 4 clerical staff members. Representing the JQ, Shin Ushiro opened proceedings in the morning by explaining the current status of this project. After that, Dr. Yoji Nagai, Director of Hitachi, Ltd. Hitachinaka General Hospital, spoke on the subject “What is a Process Flow?” Next, the JQ’s Misa Sakaguchi gave a talk entitled “Drawing up Process Flows and their Importance in Medical Safety.” Following on from this, 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 Event Information 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, 95.4% of respondents replied “I understood the content of the exercise (well).”

Feedback about the workshop from participants included such comments as “The problems became clear as a result of drawing up the process flow,” “I became keenly aware that the challenge facing me now is how to handle the solutions to problems,” and “As a result of drawing up the process flow, I realized that we had no double-checks in routine operations and actions, so I want to make use of this knowledge in operational improvements from now on.” One can see how motivated the participants were, from these questionnaire responses alone. We also received requests about future workshops, such as “I hope that workshops like this will continue to be held.” We will take these requests into account in planning further workshops.

Figure 18 Example of a Process Flow (Extract) (Japanese version)



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

1) Project to Collect and Analyze Pharmaceutical Near-miss Event Information: 13th and 14th Aggregate Reports and 2015 Annual Report

(1) The Current 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 2014 Annual Report was published in October 2015, while the 13th and 14th Aggregate Reports were published in October 2015 and March 2016, respectively. At present, work on the 2015 Annual Report is being undertaken.

The number of pharmacies participating is continuing to increase, even now, and has reached 8,541 at the present time of writing. The number of events reported is currently around 340 – 450 a 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. 47,094 such events have already been published on the website for this project. Moreover, if you click on the "Published Data Search" button on the website, you can search the data by inputting keywords (http://www.yakkyoku-hiyari.jcqhc.or.jp/phsearch/SearchReport.action).

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) 2015 Annual Report

Through the Project to Collect and Analyze Pharmaceutical Near-miss Event Information, 4,779 events have been tabulated and analyzed between January and December 2015, and we are aiming to publish the 2015 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 sixth 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.

The themes due to be taken up in the 2015 Annual Report are shown Table 13 and we hope that, once published, this information will be of use to hospital pharmaceutical departments as well.

Table 13 Theme Analysis in the 2015 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 immunosuppressants —
5	Events related to inquiries about prescriptions
6	Recurrence of Events to Be Shared or similar events — Events related to drugs in which the quantity prescribed or dosage form for pediatric patients differs according to the patient's age —
7	Events related to patients with impaired renal function

Moreover, there are plans to create one-page color PDFs of diagrams of particular importance from the analysis of themes, adjusting the design to make them easy to read, and to publish them on the website as Pharmaceutical Near-miss Event Information Analysis Tables (http://www.yakkyoku-hiyari.jcqhc.or.jp/contents/analysis_table/index.html).

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

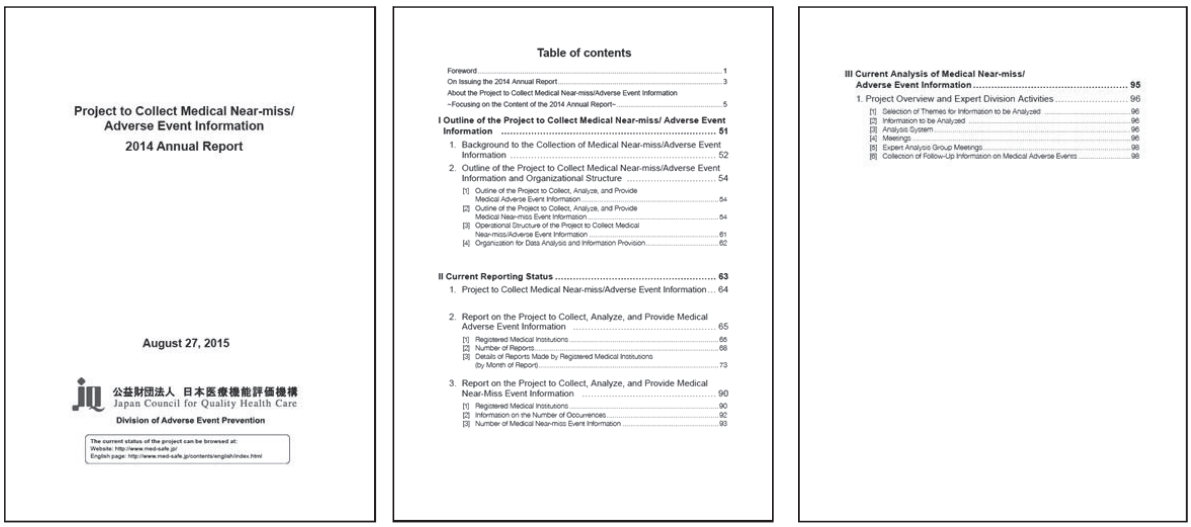
Approximately 80% of the pharmaceutical near-miss events reported in the Project to Collect and Analyze Pharmaceutical Near-miss Event Information are events relating to dispensing, most of which are events that also arise in the pharmaceutical departments of medical institutions, such as wrong quantity 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 relevant to pharmacies (http://www.yakkyoku-hiyari.jcqhc.or.jp/contents/medicine/index.html).

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.10. Publication of the English-language Editions of the Project to Collect Medical Near-miss/Adverse Event Information 2014 Annual Report and Medical Safety Information No.96-107 and Dissemination of Information via the Global Patient Safety Alerts Project of the Canadian Patient Safety Institute (cpsi-icsp)

10. Publication of the English-language Editions of the Project to Collect Medical Near-miss/Adverse Event Information 2014 Annual Report and Medical Safety Information No.96-107 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. In the end of March 2016, we published the English translation of this project's 2014 Annual Report, entitled "Project to Collect Medical Near-miss/Adverse Event Information 2014 Annual Report". As well as being available for perusal and download on our website, the content can also be searched in English via the search page (Full Text Search of Annual and/or Quarterly Reports: http://www.med-safe.jp/reportsearch/SearchReportInit).

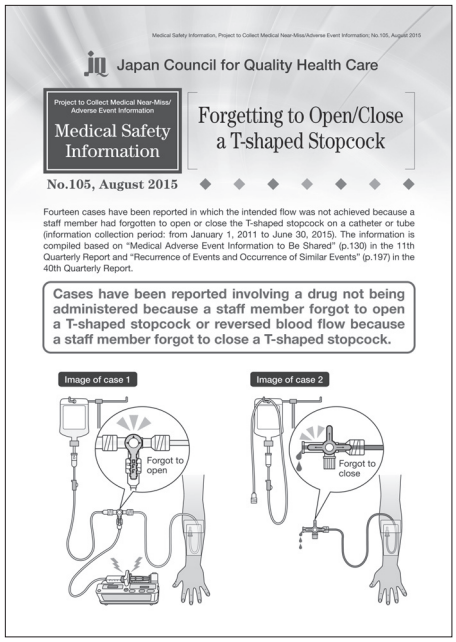
Figure 19 Project to Collect Medical Near-miss/Adverse Event Information 2014 Annual Report (English Edition) and Table of Contents

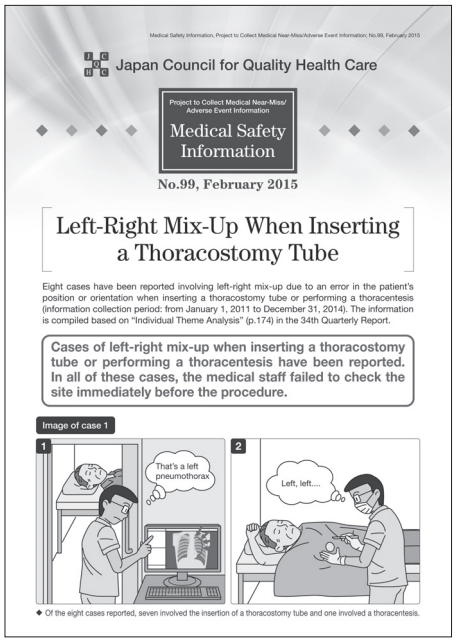


We publish English-language versions of the Medical Safety Information, which we provide to various organizations overseas. The latest English editions of Medical Safety Information, No.96-No.107, were published at the end of March 2016. The latest English editions of Medical Safety Information, No.84-No.95, were published at the end of March this year. They are published on the English-language page of this project's website (http://www.med-safe.jp/contents/english/index.html); we hope that you will make use of them if you have the opportunity to do so (Figure 20).

In addition, the Canadian Patient Safety Institute (cpsi-icsp) again requested permission to share the English-language editions of our Medical Safety Information globally through its Global Patient Safety Alerts project, which it is implementing jointly with the WHO, so we are continuing to disseminate information via this project. The JQ's name is listed on the website for the Global Patient Safety Alerts project as a contributing organization, and the site has a link to the English versions of the Medical Safety Information. A Global Patient Safety Alerts app is also available, enabling users to view the material on their mobile device. 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 20 Example of Medical Safety Information (English Version)





11. Development and Operation of the WHO Minimal Information Model for Patient Safety Incident Reporting and Learning (MIM PS)

As part of the ongoing medical safety program that it founded in October 2004, 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.

The WHO then compiled and published the Conceptual Framework for the International Classification for Patient Safety (ver.1.1), 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. In addition, a systematic set of concepts required for gaining an understanding of an incident was prepared by using natural language processing to analyze specific events. Following comprehensive consideration of these proposals, the Minimal Information Model for Patient Safety Incident Reporting and Learning System (MIM PS) is now being developed to serve as a system for learning and sharing information at the global level, transcending the boundaries between individual facilities. MIM PS has been voluntarily trialed in the EU and the feedback is to be used to refine the model further. It is hoped that these initiatives will result in such outcomes as the development of a common, internationally comparable template, the formulation of guidelines for the use of reporting systems, the potential for evaluation of reporting systems developed on the basis of MIM PS, the establishment of appropriate terminology, and publications that will support research presentations and reporting systems. Challenges to be addressed going forward include the assembly of information sources that reinforce reporting and learning systems, the fostering of a non-punitive, non-retaliatory safety culture, legal protection of information, and the development of learning systems.

12. 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.

The 32nd ISQua International Conference was held at the National Convention Center in Doha, Qatar, on October 4-7, 2015. JQ Executive Board member Yuichi Imanaka was elected to the ISQua Board at a board meeting held during the conference.

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 2013, the JQ underwent evaluation under ISQua's International Accreditation Programme. The JQ's Ver.4.0 and Ver.5.0 evaluation criteria had already been accredited, so the JQ underwent evaluation for accreditation of its 3rdG: ver.1.0 evaluation criteria based on function classification, which began operating in FY2014, as well as for accreditation of the JQ as an organization, which focuses on its management. Over the course of a year or so, as part of the process of preparing for the evaluation, we sought to understand the IAP evaluation criteria and conducted a self-appraisal, as well as compiling the materials that would form the basis for the evaluation, while discussing matters as part of the Evaluation Program Team. This was a good opportunity for us to review the JQ's approach to organizational systems and duties as the secretariat of a body providing third-party appraisal based on international evaluation criteria. Thus, we have used ISQua's programs to improve the JQ.

The JQ wishes to contribute to improving the quality of health care in Japan from an even broader international perspective. Accordingly, taking the opportunity offered by the JQ's 20th anniversary in 2015, we applied for Japan to be considered as a candidate for hosting ISQua's International Conference. As a result, we were permitted to host the conference in 2016. The 2016 International Conference is due to be held in Tokyo, at the Tokyo International Forum, on October 16 (Sunday) – 19 (Wednesday), 2016 (http://jcqhc.or.jp/banaimg/ISQua.pdf).

Recently, the JQ has been redoubling its efforts to disseminate information, running Japanese webinars (online seminars in Japanese) on the ISQua website. The same content is also being made available in English language webinars.

The JQ is taking advantage of opportunities and initiatives such as these to deepen its partnership with ISQua to ensure that it does not merely put into practice initiatives that accord with international trends, but also actually participates in shaping those trends.

Figure 21 Article about ISQua's 2016 International Conference in Tokyo (ISQua website)

13. Dissemination of Information Overseas Through Participation in International Conferences and Academic Society Meetings

The Project to Collect Medical Near-miss/Adverse Event Information publishes English-language versions of the Annual Report and Medical Safety Information on the English-language page of the project 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.

This project was the subject of five lectures between September and November 2015 (including the ISQua conference) and another two lectures in 2016, at the time of writing. An overview of these is provided below.

1) 2015 Joint Conference on Promoting Patient Safety (Taiwan Patient Safety Culture Club)

On September 12, 2015, Shin Ushiro gave a lecture at the 2015 Joint Conference on Promoting Patient Safety held in the Taiwanese city of Taichung. Entitled "A new peer-review system on clinically accidental death case in Japan 'How does it relate to JQ' s projects on patient safety?'," the lecture provided an overview of the medical adverse event investigation system that was launched in October 2015, this project, and the Japan Obstetric Compensation System for Cerebral Palsy, as well as outlining the relationship between them.

Specifically, Ushiro used the law, ministerial ordinances, and appendices to notices to explain matters concerning the medical adverse event investigation system, including the reporting of medical adverse events, internal investigation of medical adverse events by institutions and the role of support organizations, the explanations provided to bereaved families, reporting to the medical accident investigation/support center which is legally assigned to the Japan Medical Safety Research Organization, the collation and analysis of information and dissemination of measures to prevent recurrence by centers, and the investigation of medical adverse events by centers. Regarding internal investigation of medical adverse events by institutions, Ushiro explained the preparation method and content of the Cause Analysis Reports used in the Japan Obstetric Compensation System for Cerebral Palsy run by the JQ, as well as outlining the compensation provided before

and after the Japan Obstetric Compensation System for Cerebral Palsy began operating and changes in the number of lawsuits. In respect of the collation and analysis of information and dissemination of measures to prevent recurrence by centers, he also explained the outcomes and usage of theme analysis, Quarterly and Annual Reports, Medical Safety Information, and Published Data Search in the context of this project.

2) Policy Round Table on Quality in Health Services (WPRO: WHO West Pacific Region)

On September 28, 2015, the WHO Regional Office for the Western Pacific held a meeting at the Hong Kong Convention and Exhibition Center in the Hong Kong Special Administrative Region. One of the topics on the agenda was the use of adverse event reporting and learning systems in improving the quality of health care. At the start of the session, Shin Ushiro explained Japan's experience, providing an overview of this project and its results.

The session also featured presentations about adverse event reporting systems in Malaysia and Australia.

3) International Forum on Quality and Safety in Healthcare: Asia (IHI/BMJ)

The Institute for Healthcare Improvement (IHI) and the British Medical Journal (BMJ) held a new Asia-based academic society meeting on September 28-30, 2015 at the Hong Kong Convention and Exhibition Center in the Hong Kong Special Administrative Region, at which the JQ was asked to give a lecture about this project. The meeting was held in conjunction with the policy round table organized by the WHO Regional Office for the Western Pacific described in 2) above. A session entitled "Adverse Event Management – From Culture, Response, Reporting to Open disclosure" took place on September 30, at which Shin Ushiro gave a lecture about this project, with the inclusion of some information about the Japan Obstetric Compensation System for Cerebral Palsy, the Project to Collect and Analyze Pharmaceutical Near-miss Event Information, and the medical adverse event investigation system. Speakers from Hong Kong and Malaysia also gave lectures during this session. These were followed by a panel discussion. Key points discussed included the specific methods used within medical institutions to protect individuals involved in medical adverse events, the specific methods used within nationwide adverse event reporting systems to protect reporting medical institutions, the relationships maintained with news media to ensure transparency, and ways of presenting improvement measures as system outcomes (the point being that proposals for improvement measures should acknowledge the discretion of medical institutions, rather than setting out uniform improvement measures). In particular, during the discussion of what relationships are maintained with news media to ensure transparency, Ushiro explained that this project had issued around 50 press releases over a decade or so. In response, other participants expressed the view that Japan appeared to have a great deal of experience in this area.

4) ISQua (International Society for Quality in Healthcare)

The 32nd ISQua International Conference was held at the National Convention Center in Doha, Qatar, on October 4-7, 2015 (http://www.isqua.org/Events/previous-conferences/doha-2015). This international academic conference featured lectures and presentations on eight themes, including patient-centered care, patient safety, and education and research in quality and safety.

Representatives of the JQ gave eight presentations, including oral and poster presentations about the Project to Collect Medical Near-miss/Adverse Event Information and the Project to Collect and Analyze Pharmaceutical Near-miss Event Information.

In an oral presentation about this project, entitled "Application of knowledge gained through Adverse Event Reporting System and No-Fault Compensation/Peer-Review System to new Peer-Review System on Clinical Death Case in Japan," Shin Ushiro explained the potential for applying knowledge gained from the Project to Collect Medical Near-miss/Adverse Event Information and the Japan Obstetric Compensation System for Cerebral Palsy to the medical adverse event investigation system that began operating in October 2015. The

poster presentation, entitled "Preventing Medication Errors Based on Nationwide Pharmaceutical Near-miss Event Reporting System and Medical Near-miss/Adverse Event Reporting System in Japan," outlined the Project to Collect and Analyze Pharmaceutical Near-miss Event Information and the Project to Collect Medical Near-miss/Adverse Event Information, as well as explaining the importance of working in partnership with pharmacies and medical institutions.

5) WHO Strategic Expert Working Group Meeting — Developing Vision and Strategic Directions for Improving Patient Safety and Quality of Care

On November 16-17, 2015, a meeting was held at WHO headquarters in Geneva, Switzerland, to discuss specific issues to be tackled by the WHO in improving global patient safety and quality of care. Shin Ushiro attended this meeting as a WHO temporary advisor. Participants in the meeting, who included staff from the WHO's headquarters and regional offices, as well as WHO advisors, engaged in a lively and enthusiastic discussion. Getting proceedings underway on the first day, the UK's Sir Liam Donaldson, WHO Envoy for Patient Safety, explained the current state of initiatives for improving patient safety and quality of care and challenges to be addressed going forward. This was followed by discussion of the importance of undertaking initiatives focused specifically on safety and quality (the vertical approach), as well as the need to support various existing projects that include safety and quality elements (the horizontal approach). The fact that Universal Health Coverage (UHC) was to be a key issue on the agenda at the Ise-Shima Summit in May 2016 was also mentioned and some participants expressed the hope that this would provide additional impetus for the vertical approach. Ushiro outlined this project and its achievements at appropriate points in the discussion. Discussions on the second day resulted in the identification of five priority tasks (Priority 1: Political requirements for action; Priority 2: The importance of metrics for providing accurate data; Priority 3: Fostering a culture of safety through reporting and learning; Priority 4: Educational issues: developing the ability to implement sustainable initiatives at the national level; and Priority 5: Raising public awareness: awakening the public to the importance of medical safety). "Priority 3: Fostering a culture of safety through reporting and learning" is particularly relevant to this project. A representative of the WHO department in charge of patient safety asked Ushiro to give a presentation about Japan's initiatives, including the experiences and achievements of this project, at an inter-regional WHO meeting, as an example of best practice worldwide. Accordingly, we took this opportunity to disseminate information about this project to an even wider audience across the globe.

6) "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.

7) 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.

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. The JQ is a support organization under the medical adverse event investigation system that began operating in October 2015, so we have recently been receiving a growing number of requests for lectures focused on that system. As described below, this is the JQ’s role as a support organization under the medical adverse event investigation system. Figure 22 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 14 shows the content explained in lectures, including the relationship between the various projects. We respond to as many requests as possible, so if there are any medical institutions participating in this project that would like us to give a lecture, please do contact us.

Figure 22 Nationwide Systems/Projects for Adverse Event (Medical Near-miss/Adverse Events) Investigation, Collection, Analysis, and Learning

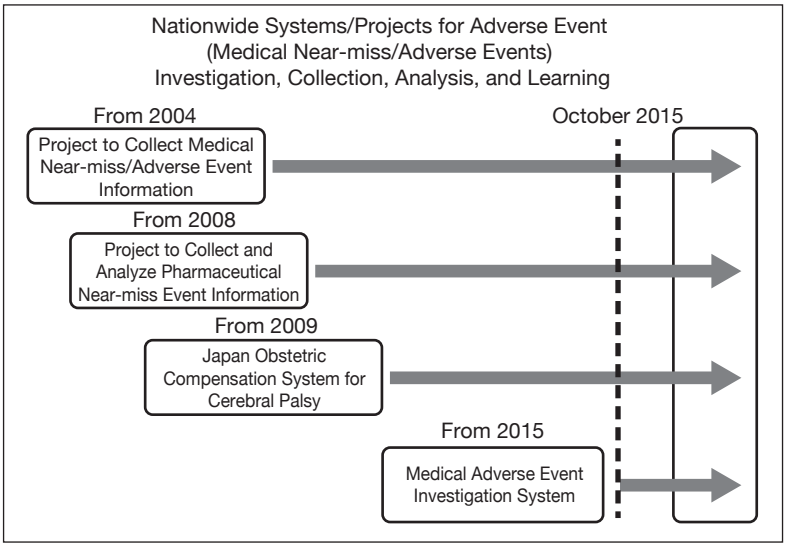


Table 14 Examples of the Content of Lectures

1. Project to Collect 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 - Utilization of the Website - Causal analysis significance and methods - Dissemination of information overseas
2. Project to Collect and Analyze Pharmaceutical Near-miss Event Information
- Purpose and overview of the project - Content of Aggregate Reports and Annual Reports (content of aggregate results and theme analysis) - Pharmaceutical Near-miss Event Information Analysis Tables - Utilization of the Events to Be Shared - Utilization of the Website
3. Japan Obstetric Compensation System for Cerebral Palsy
- Purpose and overview of the system - Current status of screening - Current status of the analysis of causes - Approaches to the analysis of causes - Current status of the prevention of recurrence
4. Medical Adverse Event Investigation System
- Overview of the system and its relationship to the Project to Collect Medical Near-miss/Adverse Event Information and the Japan Obstetric Compensation System for Cerebral Palsy - Current status of the system (current reporting status, etc.)

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. The JQ has been officially announced to be a “medical accident investigation support organization” under this law. Specifically, this support takes the form of explaining the system in response to requests from medical institutions.

16. Dissemination of Information via Facebook

On April 8, 2014, the Department of Adverse Event Prevention began disseminating information via the project’s official Facebook page. Using Facebook has the advantages that (1) we can distribute the latest information about this project in a timely manner, enabling users who have “Liked” our page to access it promptly; and (2) via users who have “Liked” our page, we can distribute information on Facebook to people who are unfamiliar with this project. We mainly plan to distribute (1) information about the Quarterly and Annual Reports; (2) information about Medical Safety Information; (3) information about system maintenance; and (4) other information about developments involving this project (such as media coverage, etc.). We aim to update the page about once a week. As of the time of writing, this project’s Facebook page had been “Liked” by 1,657 Facebook users.

The following shows our Facebook page and an example of its content (Figure 23).

Figure 23 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. As such, we greatly appreciate your understanding and cooperation.

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 of 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.
(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." Moreover, 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 2015 is "Medical Near-miss Events Related to Insulin."

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

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, 2015), 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 12 experts (as of December 31, 2015) 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, 2015), 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 status confirmation surveys.

[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 status confirmation surveys 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, 2015 are shown below.

Fig. II-1-1 (YI-01) Registration Status of Medical Institutions Participating in Each Project

<table>
<tr><th colspan="3" rowspan="3">Registration status</th><th colspan="4">Project for medical near-misses</th><th colspan="2" rowspan="3">Total</th></tr>
<tr><th colspan="4">Participating</th><th colspan="2" rowspan="2">Not participating</th></tr>
<tr><th colspan="2">Number of occurrences and medical near-miss event information</th><th colspan="2">Only number of occurrences</th></tr>
<tr><td rowspan="3">Project for medical adverse events</td><td>Required</td><td>Participating</td><td>125</td><td rowspan="2">477</td><td>81</td><td rowspan="2">293</td><td>69</td><td rowspan="2">248</td><td>275</td><td rowspan="2">1,018</td></tr>
<tr><td rowspan="2">Voluntary</td><td>Participating</td><td>352</td><td>212</td><td>179</td><td>743</td></tr>
<tr><td>Not participating</td><td colspan="2">166</td><td colspan="2">242</td><td></td><td>408</td></tr>
<tr><td colspan="3" rowspan="2">Total</td><td colspan="2">643</td><td colspan="2">535</td><td rowspan="2">248</td><td rowspan="2">1,426</td></tr>
<tr><td colspan="4">1,178</td></tr>
</table>

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, 2015 are shown below.

[1] Registered Medical Institutions

(1) Number of Medical Institutions Subject to Reporting Requirement and Voluntarily Participating Medical Institutions

The number of medical institutions participating in the Project to Collect, Analyze, and Provide Medical Adverse Event Information as of December 31, 2015 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 Labour Health and Welfare Organization	0	31
	Japan Community Health care Organization	0	40
	Other national organizations	0	0
Municipality	Prefecture	2	18
	City/village	0	81
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	9	2
	Local independent administrative institutions	1	22
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	10
	National Health Insurance Society	0	0
Corporation	School juridical organization	53	13
	Healthcare corporation	0	302
	Charitable organization	1	45
	Company	0	12
	Other corporation	0	28
Individual practitioner		0	42
Total		275	743

(Note 1) Details of the medical institutions subject to reporting requirement (275 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) 107 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) Changes in Number of Voluntarily Participating Medical Institutions

The changes in the number of voluntarily participating medical institutions between January 1 and December 31, 2015 are shown below.

Fig. II-2-2 (YA-02) Changes in Number of Voluntarily Participating Medical Institutions

	2015											
	January	February	March	April	May	June	July	August	September	October	November	December
Number of new registrations	4	3	4	4	2	3	1	2	2	0	3	1
Number of rejected registrations	0	0	0	0	0	1	1	0	0	1	0	1
Accumulated total	722	725	729	733	735	737	737	739	741	740	743	743

[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, 2015 is shown below.

Fig. II-2-3 (YA-03) Number of Monthly Reports Made by Medical Institutions Subject to Reporting Requirement and Voluntarily Participating Medical Institutions

	2015												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of reports made by medical institutions subject to reporting requirement	277	303	352	257	223	291	290	303	253	288	242	295	3,374
Number of reports made by voluntarily participating medical institutions	43	23	22	37	11	17	35	28	14	5	23	22	280
Number of medical institutions subject to reporting requirement	275	275	275	275	275	275	275	275	275	275	275	275	-
Number of voluntarily participating medical institutions	722	725	729	733	735	737	737	739	741	740	743	743	-

(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, 2015 are shown in Fig. II-2-4, tabulated numbers of reports made since the launch of the project by the parent organization are shown in Fig. II-2-5, those by the number of beds are shown in Fig. II-2-6, and those by region are shown in Fig. II-2-7. In addition, tabulated numbers of reporting medical institutions in the same period by number of reports are shown in Fig. II-2-8. 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, 2015, the number of medical institutions subject to reporting requirement was 275, and the total number of beds at those institutions was 141,373.

Fig. II-2-4 (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, 2015)	Number of reporting medical institutions	Number of reports
			January to December, 2015	January to December, 2015
Government	National University Corporation, etc.	45	45	934
	National Hospital Organization	143	131	1,374
	National Research and Development Agencies	8	7	116
	National Hansen's Disease Sanatorium	13	9	61
Municipality	Prefecture	12	11	304
	City/village			
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities			
	Local independent administrative institutions			
Corporation	School juridical organization	53	39	576
	Charitable organization	1	1	9
Total		275	243	3,374

Fig. II-2-5 (QA-05) Number of Reports Made by Medical Institutions Subject to Reporting Requirement (Accumulated Total)

Parent organization		Number of reports
		October 2004 to December 2015
Government	National University Corporation, etc.	5,451
	National Hospital Organization	9,913
	National Research and Development Agencies	948
	National Hansen's Disease Sanatorium	269
Municipality	Prefecture	1,509
	City/village	
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	
	Local independent administrative institutions	
Corporation	School juridical organization	5,301
	Charitable organization	36
Total		23,427

Fig. II-2-6 (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, 2015)	Number of reporting medical institutions	Number of reports
		January to December, 2015	January to December, 2015
0-19 beds	0	0	0
20-49 beds	14	5	8
50-99 beds	5	3	8
100-149 beds	8	4	27
150-199 beds	7	4	15
200-249 beds	16	13	76
250-299 beds	16	13	90
300-349 beds	27	26	173
350-399 beds	17	16	219
400-449 beds	27	26	281
450-499 beds	19	18	291
500-549 beds	9	9	71
550-599 beds	9	9	175
600-649 beds	26	24	439
650-699 beds	8	8	177
700-749 beds	11	11	260
750-799 beds	3	3	16
800-849 beds	12	12	359
850-899 beds	4	3	85
900-999 beds	11	11	172
1000 beds or more	26	25	432
Total	275	243	3,374

Fig. II-2-7 (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, 2015)	Number of reporting medical institutions	Number of reports
		January to December, 2015	January to December, 2015
Hokkaido	10	8	62
Tohoku	25	22	149
Kanto/Koshinetsu	86	75	1,054
Tokai/Hokuriku	38	35	576
Kinki	35	28	366
Chugoku/Shikoku	35	35	613
Kyushu/Okinawa	46	40	554
Total	275	243	3,374

Fig. II-2-8 (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, 2015
0	32
1	17
2	20
3	12
4	17
5	16
6	13
7	14
8	11
9	12
10	10
11-20	52
21-30	17
31-40	13
41-50	12
51-100	6
101-150	1
151-200	0
200 or above	0
Total	275

B. Reporting status of voluntarily participating medical institutions

The number of voluntarily participating medical institutions as of December 31, 2015 and reports made by those institutions between January 1 and December 31, 2015 are shown in Fig. II-2-9 and tabulated number of reports made since the launch of the project by parent organization is shown in Fig. II-2-10.

Fig. II-2-9 (YA-08) Number of Reporting Voluntarily Participating Medical Institutions and Number of Reports

Parent organization	Number of medical institutions (As of December 31, 2015)	Number of reporting medical institutions	Number of reports
		January to December, 2015	January to December, 2015
Government	72	12	48
Municipality	123	27	90
Public medical institution	106	12	30
Corporation	400	45	112
Individual practitioner	42	0	0
Total	743	96	280

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

Parent organization	Number of reports
	October 2004 to December 2015
Government	121
Municipality	652
Public medical institution	752
Corporation	1,350
Individual practitioner	6
Total	2,881

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

The website for this project contains three types of tabulated information.
http://www.med-safe.jp/contents/report/html/StatisticsMenu.html

A. Details of Reports Made by Medical Institutions Subject to Reporting Requirement (by Month of Report) Same tabulation as that published quarterly reports
B. Details of Reports Made by Medical Institutions Subject to Reporting Requirement (by Month of Occurrence)
C. Details of Reports Made by Registered Medical Institutions (by Month of Report)

The medical adverse event information reported by registered medical institutions (medical institutions subject to reporting requirement and voluntarily participating medical institutions) between January 1 and December 31, 2015 is shown below. Each table is compiled on the basis of the Medical Adverse Event Information Report Input Items (Note).

Fig. II-2-11 (YA-28-C) Job Title of the Person Involved

Job title of the person involved	Number of event
Doctor	2,169
Dentist	63
Nurse	2,268
Assistant nurse	25
Pharmacist	24
Clinical engineer	21
Midwife	13
Nursing assistant	21
Radiological technologist	35
Clinical technologist	22
Registered dietitian	0
Dietitian	1
Cook/kitchen staff	0
Physical therapist (PT)	24
Occupational therapist (OT)	11
Speech -language -hearing therapist (ST)	2
Medical technologist	0
Dental hygienist	0
Dental technologist	0
Others	52
Total	4,751

* 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-2-12 (YA-29-C) Years of Experience of the Person Involved

Years of experience of the person involved	Doctor	Dentist	Nurse	Assistant nurse	Pharmacist	Clinical engineer	Midwife	Nursing assistant	Radiological technologist	Clinical technologist
Less than 1 year	23	2	146	0	4	0	1	1	4	3
1 year	40	7	205	0	3	2	3	2	1	2
2 years	111	5	181	0	3	2	0	2	4	0
3 years	100	1	166	1	0	0	2	0	0	1
4 years	97	6	125	0	0	0	1	1	1	0
5 years	123	1	106	0	0	1	0	2	2	0
6 years	95	1	99	0	1	1	1	1	1	1
7 years	105	4	94	0	2	1	0	1	0	0
8 years	87	3	83	0	1	1	0	0	2	1
9 years	95	4	86	0	1	0	2	0	0	0
10 years	106	3	106	1	2	5	0	3	6	0
11 years	88	1	55	0	0	2	0	0	2	0
12 years	105	4	46	0	0	0	0	3	0	1
13 years	100	1	51	0	2	1	0	1	0	2
14 years	91	0	49	1	0	0	0	0	1	0
15 years	87	3	55	0	2	0	0	0	2	0
16 years	59	4	34	0	1	1	0	1	1	0
17 years	77	3	36	0	0	0	0	0	2	2
18 years	49	0	34	0	0	0	1	0	0	0
19 years	50	1	30	1	1	0	0	0	0	0
20 years	85	1	65	2	0	0	0	1	0	0
21 years	49	1	36	2	0	0	0	0	0	2
22 years	51	1	25	0	0	1	0	0	1	0
23 years	37	0	31	0	0	0	0	0	2	0
24 years	30	1	31	0	0	0	0	0	0	1
25 years	41	0	46	2	0	1	0	0	1	0
26 years	25	1	33	2	0	0	0	0	1	0
27 years	29	1	31	3	0	0	1	1	0	1
28 years	12	0	25	1	1	0	0	1	0	0
29 years	16	1	28	1	0	0	0	0	0	1
30 years	25	0	48	3	0	0	0	0	0	0
31 years	14	0	7	1	0	1	0	0	0	0
32 years	15	0	10	0	0	0	0	0	0	0
33 years	15	0	15	0	0	1	1	0	0	2
34 years	16	0	12	0	0	0	0	0	0	1
35 years	5	0	12	1	0	0	0	0	1	0
36 years	3	0	11	0	0	0	0	0	0	0
37 years	2	0	2	1	0	0	0	0	0	0
38 years	5	1	7	0	0	0	0	0	0	1
39 years	0	0	1	1	0	0	0	0	0	0
40 years or longer	6	1	5	1	0	0	0	0	0	0
Total	2,169	63	2,268	25	24	21	13	21	35	22

* 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.

Registered dietitian	Dietitian	Cook/ kitchen staff	Physical therapist (PT)	Occupational therapist (OT)	Speech -language -hearing therapist (ST)	Medical technologist	Dental hygienist	Dental technologist	Others	Total
0	0	0	1	1	0	0	0	0	5	191
0	0	0	3	0	0	0	0	0	2	270
0	1	0	4	0	1	0	0	0	8	322
0	0	0	3	1	0	0	0	0	5	280
0	0	0	1	3	0	0	0	0	2	237
0	0	0	1	0	0	0	0	0	2	238
0	0	0	0	0	0	0	0	0	5	206
0	0	0	0	2	0	0	0	0	3	212
0	0	0	1	0	0	0	0	0	0	179
0	0	0	1	0	0	0	0	0	1	190
0	0	0	0	1	0	0	0	0	2	235
0	0	0	1	0	0	0	0	0	1	150
0	0	0	0	1	1	0	0	0	2	163
0	0	0	0	0	0	0	0	0	1	159
0	0	0	1	0	0	0	0	0	1	144
0	0	0	0	1	0	0	0	0	4	154
0	0	0	1	0	0	0	0	0	1	103
0	0	0	1	0	0	0	0	0	1	122
0	0	0	0	0	0	0	0	0	0	84
0	0	0	0	0	0	0	0	0	1	84
0	0	0	1	0	0	0	0	0	1	156
0	0	0	0	0	0	0	0	0	0	90
0	0	0	0	1	0	0	0	0	0	80
0	0	0	0	0	0	0	0	0	1	71
0	0	0	0	0	0	0	0	0	0	63
0	0	0	0	0	0	0	0	0	0	91
0	0	0	0	0	0	0	0	0	0	62
0	0	0	0	0	0	0	0	0	0	67
0	0	0	2	0	0	0	0	0	0	42
0	0	0	1	0	0	0	0	0	0	48
0	0	0	0	0	0	0	0	0	1	77
0	0	0	0	0	0	0	0	0	1	24
0	0	0	0	0	0	0	0	0	0	25
0	0	0	0	0	0	0	0	0	0	34
0	0	0	0	0	0	0	0	0	0	29
0	0	0	0	0	0	0	0	0	0	19
0	0	0	0	0	0	0	0	0	1	15
0	0	0	0	0	0	0	0	0	0	5
0	0	0	0	0	0	0	0	0	0	14
0	0	0	0	0	0	0	0	0	0	2
0	0	0	1	0	0	0	0	0	0	14
0	1	0	24	11	2	0	0	0	52	4,751

Fig. II-2-13 (YA-30-C) Number of Years Person Involved Has Been Working at the Current Department

Number of years person involved has been working at the current department	Doctor	Dentist	Nurse	Assistant nurse	Pharmacist	Clinical engineer	Midwife	Nursing assistant	Radiological technologist	Clinical technologist
Less than 1 year	496	12	554	3	9	1	2	4	8	6
1 year	287	14	469	2	2	4	3	4	1	2
2 years	220	4	371	2	3	2	0	7	6	1
3 years	199	9	267	3	2	1	2	2	2	1
4 years	127	1	166	4	1	1	1	1	0	0
5 years	129	2	130	2	0	2	0	1	3	0
6 years	97	2	93	2	1	3	1	0	1	1
7 years	79	2	58	3	1	2	0	1	2	0
8 years	92	3	41	0	1	1	0	0	1	0
9 years	54	2	29	0	0	1	2	0	1	0
10 years	98	3	32	0	0	0	0	0	3	1
11 years	48	0	12	0	0	0	0	1	0	1
12 years	27	1	8	1	0	0	0	0	0	1
13 years	33	0	3	1	1	0	0	0	0	1
14 years	29	1	5	0	0	0	0	0	0	0
15 years	26	1	2	0	2	0	0	0	1	0
16 years	20	1	5	0	1	0	1	0	0	0
17 years	23	2	3	0	0	0	0	0	1	1
18 years	16	0	3	1	0	0	1	0	0	0
19 years	6	0	2	0	0	0	0	0	0	0
20 years	14	0	4	0	0	0	0	0	0	0
21 years	4	0	1	0	0	1	0	0	0	2
22 years	7	0	1	0	0	0	0	0	1	0
23 years	6	0	0	0	0	0	0	0	1	0
24 years	4	0	2	0	0	0	0	0	0	0
25 years	5	1	2	0	0	0	0	0	1	0
26 years	3	1	0	0	0	0	0	0	1	0
27 years	3	0	0	0	0	0	0	0	0	1
28 years	1	0	1	0	0	0	0	0	0	0
29 years	2	1	1	0	0	0	0	0	0	1
30 years	6	0	1	0	0	0	0	0	0	0
31 years	3	0	0	0	0	1	0	0	0	0
32 years	0	0	1	0	0	0	0	0	0	0
33 years	1	0	0	0	0	1	0	0	0	1
34 years	0	0	1	0	0	0	0	0	0	0
35 years	2	0	0	0	0	0	0	0	1	1
36 years	0	0	0	0	0	0	0	0	0	0
37 years	0	0	0	0	0	0	0	0	0	0
38 years	0	0	0	0	0	0	0	0	0	0
39 years	0	0	0	1	0	0	0	0	0	0
40 years or longer	2	0	0	0	0	0	0	0	0	0
Total	2,169	63	2,268	25	24	21	13	21	35	22

* 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.

Registered dietitian	Dietitian	Cook/ kitchen staff	Physical therapist (PT)	Occupational therapist (OT)	Speech -language -hearing therapist (ST)	Medical technologist	Dental hygienist	Dental technologist	Others	Total
0	0	0	3	3	0	0	0	0	11	1,112
0	0	0	6	1	0	0	0	0	7	802
0	1	0	3	1	1	0	0	0	9	631
0	0	0	2	2	0	0	0	0	6	498
0	0	0	1	1	1	0	0	0	5	310
0	0	0	1	0	0	0	0	0	2	272
0	0	0	0	0	0	0	0	0	4	205
0	0	0	0	2	0	0	0	0	1	151
0	0	0	2	0	0	0	0	0	0	141
0	0	0	1	0	0	0	0	0	1	91
0	0	0	1	0	0	0	0	0	1	139
0	0	0	0	0	0	0	0	0	0	62
0	0	0	0	0	0	0	0	0	1	39
0	0	0	0	0	0	0	0	0	1	40
0	0	0	0	0	0	0	0	0	1	36
0	0	0	0	0	0	0	0	0	0	32
0	0	0	0	0	0	0	0	0	0	28
0	0	0	1	0	0	0	0	0	1	32
0	0	0	0	0	0	0	0	0	0	21
0	0	0	0	0	0	0	0	0	0	8
0	0	0	1	0	0	0	0	0	0	19
0	0	0	0	0	0	0	0	0	0	8
0	0	0	0	1	0	0	0	0	0	10
0	0	0	0	0	0	0	0	0	1	8
0	0	0	0	0	0	0	0	0	0	6
0	0	0	0	0	0	0	0	0	0	9
0	0	0	1	0	0	0	0	0	0	6
0	0	0	1	0	0	0	0	0	0	5
0	0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	0	0	0	5
0	0	0	0	0	0	0	0	0	0	7
0	0	0	0	0	0	0	0	0	0	4
0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	3
0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	4
0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	1
0	0	0	0	0	0	0	0	0	0	2
0	1	0	24	11	2	0	0	0	52	4,751

Fig. II-2-14 (YA-35-C) Summary of Event

Summary of event	Number of event	%
Drug	260	7.1
Blood transfusion	10	0.3
Treatment/procedure	1,109	30.4
Medical device, etc.	66	1.8
Drainage tube or other tube	260	7.1
Examination	168	4.6
Nursing care	1,301	35.6
Others	480	13.1
Total	3,654	100.0

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

Fig. II-2-15 (YA-37-C) Severity of Event

Severity of event	Number of event	%
Death	352	9.6
High potential of residual disability	362	9.9
Low potential of residual disability	1,030	28.2
No potential of residual disability	985	27.0
No disability	769	21.0
Unknown	156	4.3
Total	3,654	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-2-16 (YA-40-C) Clinical Department

Clinical department	Number of event	%
Internal medicine	265	5.8
Anesthesiology	132	2.9
Cardiovascular medicine	249	5.5
Neurology	115	2.5
Respiratory medicine	246	5.4
Gastrointestinal medicine	301	6.6
Hematology	65	1.4
Circulatory surgery	38	0.8
Allergy	5	0.1
Rheumatism	20	0.4
Pediatrics	222	4.9
General surgery	352	7.8
Orthopedics	566	12.5
Plastic surgery	41	0.9
Cosmetic surgery	0	0
Neurosurgery	220	4.8
Respiratory surgery	69	1.5
Cardiovascular surgery	165	3.6
Pediatric surgery	39	0.9
Pain clinic	1	0
Dermatology	55	1.2
Urology	136	3.0
Venereology	0	0
Proctology	1	0
Gynecology/Obstetrics	81	1.8
Obstetrics	19	0.4
Gynecology	47	1.0
Ophthalmology	60	1.3
Otolaryngology	87	1.9
Psychosomatic medicine	3	0.1
Psychiatry	250	5.5
Rehabilitation	37	0.8
Radiology	75	1.7
Dentistry	15	0.3
Orthodontics	1	0
Pediatric dentistry	0	0
Dental/oral surgery	59	1.3
Unknown	6	0.1
Others	494	10.9
Total	4,537	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-2-17 (YA-41-C) Cause of Event

Cause of event	Number of event	%
Action of the person involved	4,412	45.6
Neglect to check	1,163	12.0
Neglect to observe	1,003	10.4
Delayed (neglected) reporting	109	1.1
Inadequate documentation	100	1.0
Inadequate coordination	553	5.7
Inadequate (neglected) explanation to patient	520	5.4
Misjudgment	964	10.0
Human factors	1,808	18.7
Lack of knowledge	478	4.9
Deficiency of technique/skill	530	5.5
Busy working condition	370	3.8
Under unusual physical condition	63	0.7
Under unusual psychological condition	116	1.2
Others	251	2.6
Environment/facilities and devices	1,754	18.0
Computerized system	59	0.6
Drug	101	1.0
Medical device	139	1.4
Facility	157	1.6
Other items	109	1.1
Patient side	1,069	11.1
Others	120	1.2
Others	1,698	17.5
Education/training	682	7.1
System	166	1.7
Inadequate rules	246	2.5
Others	604	6.2
Total	9,672	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-2-18 (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	10	0.3
Death or disability due to nosocomial infection	1	0
Suicide or suicide attempt of patient	81	2.2
Disappearance of inpatient	8	0.2
Burn of patient	37	1.0
Electric shock of patient	0	0
Death or disability of patient due to facility fire	0	0
Handling over of infant to wrong parent	0	0
No applicable option	3,517	96.3
Total	3,654	100.0

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

Fig. II-2-19 (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	30	1	52	2	14	16	118	32	265
Anesthesiology	11	1	74	4	18	2	1	21	132
Cardiovascular medicine	20	0	102	7	15	16	58	31	249
Neurology	3	0	11	2	11	4	51	33	115
Respiratory medicine	11	0	26	4	18	14	143	30	246
Gastrointestinal medicine	23	0	139	3	20	27	50	39	301
Hematology	10	1	9	2	6	7	26	4	65
Circulatory surgery	3	0	18	2	3	2	3	7	38
Allergy	0	0	2	0	0	0	3	0	5
Rheumatism	2	0	2	0	0	1	11	4	20
Pediatrics	36	2	30	1	30	5	100	18	222
General surgery	24	2	139	3	33	19	87	45	352
Orthopedics	15	1	90	4	12	9	361	74	566
Plastic surgery	2	0	19	4	3	2	9	2	41
Cosmetic surgery	0	0	0	0	0	0	0	0	0
Neurosurgery	12	0	80	5	19	6	66	32	220
Respiratory surgery	1	0	29	4	8	3	20	4	69
Cardiovascular surgery	9	0	87	12	20	3	18	16	165
Pediatric surgery	2	0	13	1	8	2	9	4	39
Pain clinic	0	0	0	0	0	0	0	1	1
Dermatology	9	0	9	0	1	3	29	4	55
Urology	10	0	58	3	10	9	34	12	136
Venereology	0	0	0	0	0	0	0	0	0
Proctology	0	0	0	0	0	0	1	0	1
Gynecology/Obstetrics	4	1	34	2	3	4	16	17	81
Obstetrics	1	1	10	0	2	1	3	1	19
Gynecology	4	0	29	1	3	2	6	2	47
Ophthalmology	4	0	28	0	1	0	17	10	60
Otolaryngology	4	0	40	0	8	6	20	9	87
Psychosomatic medicine	0	0	0	0	0	0	1	2	3
Psychiatry	5	0	4	0	1	0	178	62	250
Rehabilitation	0	0	6	1	0	0	24	6	37
Radiology	5	1	39	2	0	19	5	4	75
Dentistry	0	0	7	0	0	1	4	3	15
Orthodontics	0	0	1	0	0	0	0	0	1
Pediatric dentistry	0	0	0	0	0	0	0	0	0
Dental/oral surgery	2	0	38	0	1	2	13	3	59
Unknown	1	0	1	0	0	0	2	2	6
Others	45	2	140	15	45	44	145	58	494
Total	308	13	1,366	84	313	229	1,632	592	4,537

* Clinical department may be more than one.

Fig. II-2-20 (YA-71-C) Cause of Event and Summary of Event

Cause of event × Summary of event	Drug	Blood transfusion	Treatment/ procedure	Medical device, etc.	Drainage tube or other tube	Examination	Nursing care	Others	Aggregate total
Action of the person involved									4,412
Neglect to check	199	7	310	41	117	65	310	114	1,163
Neglect to observe	43	3	179	21	82	21	525	129	1,003
Delayed (neglected) reporting	9	0	27	5	7	5	35	21	109
Inadequate documentation	16	0	37	1	5	6	21	14	100
Inadequate coordination	82	4	120	20	43	36	187	61	553
Inadequate (neglected) explanation to patient	29	1	75	0	16	16	319	64	520
Misjudgment	62	1	299	16	95	37	370	84	964
Human factors									1,808
Lack of knowledge	93	3	91	25	55	16	157	38	478
Deficiency of technique/skill	20	1	248	12	61	16	127	45	530
Busy working condition	47	0	58	5	26	18	169	47	370
Under unusual physical condition	7	1	25	2	2	2	17	7	63
Under unusual psychological condition	31	0	35	3	7	5	18	17	116
Others	25	1	78	4	14	14	74	41	251
Environment/facilities and devices									1,754
Computerized system	24	2	8	1	2	11	0	11	59
Drug	65	0	17	0	2	7	8	2	101
Medical device	2	0	58	30	20	11	8	10	139
Facility	2	1	10	2	2	8	107	25	157
Other items	4	1	29	0	23	2	40	10	109
Patient side	19	1	176	0	43	26	650	154	1,069
Others	7	0	40	3	5	2	43	20	120
Others									1,698
Education/training	56	3	170	21	53	27	291	61	682
System	31	1	34	7	12	15	33	33	166
Inadequate rules	44	2	68	11	26	19	58	18	246
Others	27	2	291	6	25	41	112	100	604
Total	944	35	2,483	236	743	426	3,679	1,126	9,672

* Cause of event may have been 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, 2015 is reported herein.

[1] Registered Medical Institutions

(1) Number of Medical Institutions Participating in the Project to Collect, Analyze, and Provide Medical Near-Miss Event Information

The number of medical institutions participating in the Project to Collect, Analyze, and Provide Medical Near-Miss Event Information as of December 31, 2015 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	70
	National Research and Development Agencies	5	3
	National Hansen's Disease Sanatorium	11	4
	Japan Labour Health and Welfare Organization	30	25
	Japan Community Health care Organization	44	24
	Other national organizations	0	0
Municipality	Prefecture	26	16
	City/village	129	75
	Japan Association of Municipal and Prefectural Municipality Colleges and Universities	9	5
	Local independent administrative institutions	25	11
Parent organization of public medical institution other than municipality	Japan Red Cross	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	405	203
	Charitable organization	52	23
	Company	12	3
	Other corporation	41	21
Individual practitioner		51	33
Total		1,178	643

[2] Information on the Number of Occurrences

(1) Reporting Status of Information on the Number of Occurrences

The reports of the information on the number of occurrences between January 1 and December 31, 2015 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	855	4,522	74,747	177,769	257,893
(2) Blood transfusion	132	194	1,690	2,855	4,871
(3) Treatment/procedure	318	2,015	10,815	31,744	44,892
(4) Medical device, etc.	200	799	8,757	14,921	24,677
(5) Drainage tube or other tube	168	1,559	23,185	95,507	120,419
(6) Examination	270	1,570	23,982	43,964	69,786
(7) Nursing care	446	2,624	46,698	124,923	174,691
(8) Others	480	2,523	37,181	46,777	86,961
Total	2,869	15,806	227,055	538,460	784,190
Re-posted					
[1] Events involving name or dosage form of drug	143	449	4,143	11,765	16,500
[2] Events caused by drug	539	2,454	25,747	70,459	99,199
[3] Events caused by medical device, etc.	167	497	3,900	9,879	14,443
[4] Current theme	70	245	2,581	12,158	15,054

Number of reporting medical institutions	586
Total number of beds	231,981

[3] Number of Medical Near-miss Event Information

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

The number of monthly reports for medical near-miss event information between January 1 and December 31, 2015 is shown below.

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

	2015												Total
	January	February	March	April	May	June	July	August	September	October	November	December	
Number of medical near-miss event information	4,430	964	1,953	3,773	1,915	1,509	5,528	1,593	1,721	3,643	1,199	2,043	30,271
Number of participating medical institutions for medical near-miss event information reporting	629	632	636	637	640	641	641	641	642	641	642	643	-

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 gathered 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 gathered 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. Theme-specific Expert Analysis Group meetings are generally held once or twice a month, depending on the timing of the publication of the quarterly reports and the number of events about which information has been gathered. 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] Meetings

A list of Management Committee (a subcommittee specified in the JQ Act of Endowment) meetings and Comprehensive Evaluation Panel meetings for this project held between January 1 and December 31, 2015 is shown below.

(1) Management Committee

Two meetings of the Management Committee were held between January 1, 2015 and December 31, 2015.

Fig. III-1-1 Status of Meetings of the Management Committee

	Year, Month, Date	Agenda
24th	February 13, 2015	• Project to Collect Medical Near-miss/Adverse Event Information: Concerning the Renewal of Registration as a Registered Analysis Center • Concerning the Results of the Questionnaire Concerning the Project to Collect Medical Near-miss/Adverse Event Information • Project to Collect and Analyze Pharmaceutical Near-Miss Event Information: Concerning the Project Guide • Project to Collect Medical Near-miss/Adverse Event Information: Concerning the FY2015 Activity Plan (Proposal) and 2015 Budget (Proposal)
25th	May 21, 2015	• Project to Collect Medical Near-miss/Adverse Event Information: Concerning the Publication of the English edition of the 2013 Annual Report and Medical Safety Information. • Project to Collect Medical Near-miss/Adverse Event Information: Concerning the Number of Times Information was Accessed on the Website • Concerning the Dissemination of Information via Facebook • Concerning the Achievements of the Project to Collect Medical Near-miss/Adverse Event Information in FY2014

(2) Comprehensive Evaluation Panel

Five meetings of the Comprehensive Evaluation Panel were held between January 1, 2015 and December 31, 2015.

Fig. III-1-2 Status of Meetings of the Comprehensive Evaluation Panel

	Year, Month, Date	Agenda
53rd	February 19, 2015	• Concerning the Outline and Results of the FY2014 Process Flow Training Course • Concerning Medical Safety Information No.102, 103 and 104 (Draft) • Project to Collect Medical Near-miss/Adverse Event Information: Concerning the 40th Quarterly Report (Draft)
54th	May 13, 2015	• Project to Collect Medical Near-miss/Adverse Event Information: Concerning the FY2015 Activity Plan • Concerning the Dissemination of Information via Facebook • Concerning Workshops Hosted by the Department of Adverse Event Prevention in FY2015 • Concerning Medical Safety Information No.105 and 106 (Draft) • Project to Collect Medical Near-miss/Adverse Event Information: Concerning the 41st Quarterly Report (Draft) • Concerning the Publication of the English edition of the 2013 Annual Report and Medical Safety Information.
55th	July 30, 2015	• Concerning the Event Search Function and Examples of Use on the New Website • Concerning Medical Safety Information No.106, 107 and 108 (Draft) • Project to Collect Medical Near-miss/Adverse Event Information: Concerning the 2014 Annual Report (Draft)
56th	August 13, 2015	• Concerning the Anthology of Medical Safety Information No.51-No.100 (draft) • Concerning Medical Safety Information No.109 and 110 (Draft) • Project to Collect Medical Near-miss/Adverse Event Information: Concerning the 42th Quarterly Report (Draft)
57th	November 16, 2015	• Concerning the Results of the Follow-up Survey of FY2014 Process Flow Training Course Participants • Concerning Medical Safety Information No.111, 112 and 113 (Draft) • Project to Collect Medical Near-miss/Adverse Event Information: Concerning the 43rd Quarterly Report (Draft) • Concerning the “Current theme” for Medical Near-miss Event Information

[4] Expert Analysis Group Meetings

Expert Analysis Groups composed of experts in medical safety meet once or twice a month to gain an overall understanding of adverse events in general and analyze events in respect of individual themes. If necessary, they gather the information required to conduct analysis, and conduct on-site status confirmation surveys.

[5] 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) 7th 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 21, 2016

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 : The Current Status of the Project to Collect Medical Near-miss/Adverse Event Information and its Challenges

What is a Process Flow?

Drawing up Process Flows and their Importance in Medical Safety

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: 44 people (15 medical institutions)

[6] Questionnaire Survey Results

In 2015, the project conducted a questionnaire-based survey on “Usage of Medical Safety Information” among hospitals that were not receiving Medical Safety Information by fax.

(1) Outline of the Questionnaire Survey

As of December 2015, more than 5,400 medical institutions were receiving the Medical Safety Information bulletins issued by the project by fax. This equates to around 60% of Japan's approximately 8,500 hospitals. However, there has been no major increase in the number of hospitals wishing to have Medical Safety Information sent by fax since a letter was sent out in 2011 to ask about their preferences in this regard.

Accordingly, a questionnaire was sent out to hospitals not currently receiving information by fax, with the aim of soliciting new requests for the provision of Medical Safety Information by fax, while also ascertaining how the project's Medical Safety Information bulletins are used.

(2) Questionnaire Survey Subjects

Hospitals not receiving Medical Safety Information from the project by fax were selected from the hospital data held by the project. The questionnaire was to be completed by the person in charge of medical safety at the hospital.

(3) Questionnaire Survey Method

The questionnaires were distributed and returned by post (an envelope for the response was enclosed).

(4) Questionnaire Survey Period

December 11, 2015 – January 15, 2016 (responses received before the end of January were accepted).

(5) Questionnaire Survey Results

The project received responses from 1,022 of the 3,385 institutions to which the survey was distributed (1,021 valid responses, giving a valid response rate of 30.2%).

Details of the responses are provided on p.13.

[7] 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 by Means of Documentation

In 2015, 126 requests were made to medical institutions, asking them to provide follow-up information about medical adverse events, such as documentation; 121 responses were received. The breakdown of these is shown in Fig. III-1-3.

Fig. III-1-3 Breakdown of Requests for Follow-up Information by Means of Documentation

Overview of the event	Number of events
Drugs	59
Blood transfusions	1
Treatment/procedure	20
Medical device, etc.	8
Drainage tubes or other tubes	10
Examination	5
Nursing care	11
Others	12
Total	126

Requests for follow-up information in the form of documentation mainly consist of requests 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, requests are also made to medical institutions in cases in which 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 nine medical adverse events occurred were requested to cooperate in conducting on-site visits, and they all did so. A list of on-site visits conducted in 2015 is provided in Fig. III-1-4, while details of a few of these visits are provided in Fig. III-1-5.

Fig. III-1-4 List of On-site Visits

Overview of the Event	Case Number	Details of Events
Drugs	GE0270001	Event in which an error was made in the method used to dilute Epoprostenol for I.V. Injection and the error was not rectified during the double-check
	GE0270002	Event in which there was not enough of the liquid medicine that was being administered, so another patient's liquid medicine, which had a different concentration, was added to it and administered
	GE0270003	Event in which an expired drug was administered because the expiry dates of the drugs on the department's drug cart had not been checked
	GE0270004	Event in which a drug was administered from a syringe on which the drug name was not written, resulting in a sedative being wrongly administered instead of contrast medium for an MRI examination
Blood transfusions	GE0270005	Event in which the name of a different patient with the same family name and similar given name was displayed on the screen when the order for the blood product was received, resulting in a blood product for the wrong patient being dispensed
Treatment/ procedure	GE0270006	Event in which right knee surgery was due to be performed, but the operating theater was erroneously set up for left knee surgery and the error was not noticed during the time out, resulting in surgery being performed on the wrong knee
Medical device, etc.	GE0270007	Event in which an MRI examination was carried out because the information that the patient had a pacemaker could not be shared
Drainage tube or other tube	GE0270008	Event in which there was a possibility that air entered a blood vessel, because the wrong connector was removed while the patient was in a sitting position when a heparin lock of a central venous catheter was carried out
Others	GE0270009	Event in which examination data for a different patient was transmitted, resulting in the insertion of the wrong intraocular lens

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

Fig. III-1-5 Overview of On-site Surveys

GE0270003	**Event in which an expired drug was administered because the expiry dates of the drugs on the department's drug cart had not been checked**
Objectives of the on-site visit	• Verification of the facts • Detailed verification of the background and causal factors • Concerning improvement measures and notification thereof
Attendees from the medical institution	Director of the Medical Safety Management Office (physician), Deputy Director of the Medical Safety Management Office (physician), GRM of the Medical Safety Management Office (nurse), Deputy Director of the Pharmaceutical Department, Pharmaceutical Safety Management Officer (pharmacist), ward head nurse, Deputy Nursing Director in charge of the ward, nurse from the Medical Safety Management Office, pharmacist from the Medical Safety Management Office, clerical staff

Reported objective of the treatment provided
An injection of Penicillin G Potassium was administered to treat endocarditis.
Reported summary of event
Three days after starting administration of Penicillin G Potassium for Injection, the nurse noticed that the drug was past its expiry date, so s/he looked at the empty vials that had already been administered and found that a number of expired vials had already been used. The nurse immediately replaced the unused vials with new vials from the pharmaceutical department's stock.

Outline of background and causal factors

Reported overview of factors behind the adverse event	**Findings from the visit**
• The expiry dates were supposed to be checked regularly by the staff member in charge of managing injection drugs, but the drug had neither been discarded nor had a warning label affixed to indicate that it had expired. • When contacted, the pharmaceutical department found that the cabinet contained numerous expired drugs that had not yet been disposed of, so it disposed of the expired drugs. • It appears that checks of expiry dates are not carried out if there are not enough nurses on the ward to carry out the checks according to the schedule. • If other patients were administered the drug around the same time, there is a possibility that they too were administered an expired drug.	○ Drug cart • The ICU, CCU, NICU, and ER each have their own drug cart, containing specific types of drug in specific quantities. When a physician orders a drug, it is removed from the drug cart and administered, rather than being dispensed for each patient by the pharmaceutical department. • The ICU's drug cart contains 118 drug types, the CCU's 68, NICU's 54, and the ER 117 (357 types across all four carts). • The CCU's drug cart contains a permanent stock of 30 vials of Penicillin G Potassium for Injection. • When replenishing the drug cart, the drugs used are dispensed by the pharmaceutical department and restocked on the cart as required by a nurse from the relevant department. • The pharmaceutical department also checks the drug cart three times a week and replenishes any drugs if the quantity is less than the specified permanent stock. • The event in question occurred on a general ward, so there was no drug cart and the drug was prescribed in the usual way. ○ Pharmaceutical Department • After a prescription is ordered for a drug to be administered to an inpatient on a ward, the prescription is made up using the drugs kept in the pharmaceutical department's drug storage room and dispensed to the ward. • According to the pharmaceutical department's work schedule, a pharmacist was supposed to spend an hour checking the drug carts; their main task in doing so was to check whether the quantity of any drugs was less than the specified permanent stock and to replenish those that fell short. • The manual did not mention managing expiry dates, nor were any records left concerning the replacement of drugs nearing their expiry date. ○ Background to the dispensing of an expired drug to the ward • The Penicillin G Potassium for Injection used in this event had been delivered three years earlier and there had been administered during that time, so it is unlikely that the drug would have remained there until that point if it had been in the pharmaceutical department's drug cabinet ever since being delivered.

	• There is a strong possibility that the expiry date of the Penicillin G Potassium for Injection on the CCU drug cart was not checked for some time, and when it was found to be near its expiry date, the Penicillin G Potassium for Injection removed from the CCU drug cart was erroneously returned to the pharmaceutical department's drug cabinet. It was thought that it was subsequently dispensed in response to this particular order, without a check of its expiry date. ○ Nurses • The administration of Penicillin G Potassium to the patient involved in this event took the form of "Penicillin G Potassium for Injection 1,000,000 Units 5V + normal saline 100mL administered at 20mL/h," which needed to be refreshed five times/day. • In the nursing procedure for "Preparing an Intravenous Injection," the mixing section states, "Check the drug" and "Check the expiry date and that the drug does not appear abnormal." Thus, the expiry date is supposed to be checked each time mixing is carried out. • The link nurse group has decided on a specific method for carrying out double-checks when mixing drugs and the procedure has been posted in all wards, etc. (1) Two people to conduct a simultaneous double-check before mixing (One of the two should hold the rank of leader) a. The person preparing the drug looks only at the physician's order and reads it aloud. b. The checker looks only at the drug that has been prepared and checks it. (2) Content of double-checks (11 items) a. Physician's order: Name, date, drug name, dosage, administration method, rate of administration, time of administration, order number, comments (9 items) b. Drug: Drug name, expiry date (2 items) • The expiry was noticed on the third day after commencing administration of Penicillin G Potassium, which means that the expiry date check specified in the procedure was not carried out. ○ Checks of the stability of Penicillin G Potassium for Injection • Penicillin G Potassium for Injection (if stored at room temperature in its final packaging) had a residual percentage of 98.7% after 3.5 years.
Improvement measures	
Reported improvement measures following adverse event	**Findings from the visit**
Unknown	• Drugs on the drug cart will be divided up by drawer and pharmacists will spend two months checking their expiry dates. • The pharmaceutical department's procedure for dealing with expired drugs has been clarified and a procedure manual for the management of expiry dates has been prepared. • If a drug's expiry date falls within the next three months, the expiry date on the drug itself will be underlined with a red marker, and the drug will be placed inside a plastic bag at the front of the drawer. The drug name, quantity, and expiry date will be noted on the Drug Expiry Date Checklist. • At the end of the month, two pharmacists will review the drugs on the Drug Expiry Date Checklist and check and dispose of any with expiry dates during the month in question. • The hospital will notify nursing staff once more about the double-check to be carried out when mixing drugs.

Major opinions following on-site visit
○ Given the size of the hospital, it is unlikely that Penicillin G Potassium had remained unused for three years. It would be advisable to revise the procedure, with a focus on the fact that expired drugs that should have been removed from the drug cart re-entered the pharmaceutical department in the opposite direction to the usual dispensing route. ○ The chart indicating the quantity of each drug to be kept as a permanent stock on the ICU, CCU, NICU, and ER drug carts shows that many different types of drug are kept in large quantities. This makes checks burdensome, so it might be advisable to consider revising the quantities kept in stock or dispensing drugs for each patient. ○ The administration of expired drugs could conceivably entail problems from the perspective of the stability of the preparation and the manufacturer's warranty. In the case of the Penicillin G Potassium involved in this event, it was confirmed that there were virtually no problems with its stability, even after 3.5 years. However, in terms of the warranty aspect, use of a drug after its expiry date might not be accepted as being "proper use," so in the event of any side-effects or other problems, there is a risk that redress might not be forthcoming under the Relief System for Sufferers from Adverse Drug Reactions, etc. ○ A nurse on the ward discovered that the drug had expired when preparing it, but administration had commenced three days earlier, which meant that the expiry date checks had not been carried out prior to that point. Busy times are the precisely the time when there is the greatest need to carry out point-and-call checks of the designated items on the designated procedure. With 11 items to check, the double-check procedure is too cumbersome, so it would be advisable to narrow the items down to those which are truly essential.

GE0270004	Event in which a drug was administered from a syringe on which the drug name was not written, resulting in a sedative being wrongly administered instead of contrast medium for an MRI examination
Objectives of the on-site visit	• Verification of the facts • Detailed verification of the background and causal factors • Concerning improvement measures and notification thereof
Attendees from the medical institution	Director of the Medical Safety Management Office (physician), Deputy Directors of the Medical Safety Management Office (physician and nurse), 2 nurses working full-time in the Medical Safety Management Office, pharmacist working full-time in the Medical Safety Management Office, clerical staff working full-time in the Medical Safety Management Office, 2 radiological technologists, head nurse from the radiology department, pediatrician (in charge of safety), pediatric ward head nurse

Reported objective of the treatment provided

Administration of contrast medium for an MRI examination

Reported summary of event

Usually, sedatives for pediatric inpatient examinations are mixed on the ward and taken to the examination room with the patient. The physician mixed the drug on the ward, but did not affix an injection label to the syringe. S/he involved placed it on the table in the examination room along with his/her laboratory coat, so that s/he would know which it was. Prefilled syringes of contrast medium are used at the hospital, but in the case of pediatric patients, the radiological technologist draws the necessary amount up into a syringe. When it was time to administer the contrast medium, the radiological technologist picked up the syringe that had been placed on the table and, assuming it to be the contrast medium prepared by the other radiological technologist (in fact, the contrast medium had not been prepared), passed it to the physician. The physician had doubts, because s/he thought that there was a bit too much in the syringe to be contrast medium, but s/he did not check it. The physician administered the whole quantity to the patient, while observing his/her condition. Immediately after administration, the patient's breathing slowed, so the physician checked the syringe again and realized that it was Citosol. The physician checked the patient's respiratory condition and confirmed that there were no abnormalities in his/her vital signs. The physician then provided respiratory care and remained near the patient while the examination continued. The amount of Citosol administered in error was 81.25mg.

Outline of background and causal factors

Reported overview of factors behind the adverse event	Findings from the visit
• When mixing the drug, the physician failed to comply with the rule that either a label must be affixed to the syringe or the name of the drug and the name of the patient must be written on it. • The prepared sedative was placed in a different location from usual. • The radiological technologist did not comply with the rule about carrying out a double-check with another radiological technologist when preparing contrast medium, nor the rule about writing the drug name and patient name on the syringe. • The radiological technologist assumed that the syringe, on which neither the drug name nor the patient's name had been written, was the contrast medium for the patient and did not check it. • Staff members failed to comply with the rule that a single tray must be used for a single procedure for a single patient when preparing drugs. • Staff members failed to comply with the rule that a double-check of the drug name, the patient's name, and the dosage must be carried out when administering drugs.	○ Internal rules • Within the medical institution, there was a rule in all departments, including the ward and the radiology department, that a single tray must be used for a single procedure for a single patient when preparing drugs. All of the trays in the medical institution are identical in appearance (pink). • For prescribed injection drugs, only one patient authentication label is issued; this bears the patient's name and the dosage, and barcode authentication is possible. It is not possible to issue multiple labels. • When used for imaging examinations, 0.5g of Citosol is dissolved with 20mL of liquid and a label is affixed to the syringe for patient authentication purposes. Only a small amount is used for pediatric patients, so part of the solution is drawn up into a 5mL or 10mL syringe and the name of the drug is written on that syringe using a permanent marker pen. • The hospital's Shared Manual stated, "Write the drug name on the syringe," but did not state that the patient's name or dosage must be written on it. As this is a basic procedure, there was not thought to be a need to specify it again in the manual. • Contrast medium is supposed to be prepared in the imaging examination room by a nurse. However, the nurses' working conditions were such that they dealt solely with examinations up to 16:00, with a radiological technologist preparing the contrast medium for examinations after 16:00. • If the patient is an adult, a physician administers the contrast medium, but in the case of pediatric patients, the physician administers a sedative and monitors the patient, so the contrast medium is often administered by the nurse who received the order. However, a pediatrician may administer the contrast medium, depending on the nurses' working conditions.

	• A sticker with the name of the contrast medium is attached to each vial, so that sticker was supposed to be affixed to the prepared syringe. However, there was no rule about writing the patient's name, etc. on it. ○ Preparation of the sedative (physician) • The Citosol Injection 0.5g that was prepared as a sedative had been prescribed for the patient. • In the pediatric department, physicians prepare the drug used for sedation on the ward and bring it with them. • After dissolving the Citosol in 20mL of liquid, the pediatrician drew up 5mL into a 5mL syringe and brought it with him/her to the examination room. The pediatrician intended to use 2mL for the patient. • When preparing the drug on the ward, there was nobody to carry out a double-check, so there was nobody to point out that the name of the drug was not written on the syringe. • The pediatrician who prepared the drug did not know about the rule stating that the drug must be prepared and brought to the examination room on a tray. There was no rule about bringing the prescription along with the drug. ○ Radiology Department • Prefilled syringes of contrast medium are used for adults, but in the case of pediatric patients, the requisite quantity is prepared in a syringe from a vial of ProHance 5mL. • Contrast medium (ProHance 5mL) is calculated using the formula weight × 0.2mL, so 3mL was due to be administered to the patient. • In this event, the examination was to take place around 16:30, so there was no nurse to prepare the contrast medium. Accordingly, the contrast medium had not been prepared when the patient arrived. • The radiological technologist in charge of the examination was concentrating on imaging, so did not notice that the contrast medium had not been prepared. Accordingly, s/he assumed that the syringe (Citosol) on the table, which did not have a drug name written on it, was contrast medium and handed it to the physician. • There was 5mL of the drug in the syringe that the radiological technologist handed over under the misapprehension that it was contrast medium, which the physician felt was a bit more than there should have been, based on his/her experience, but s/he nonetheless administered 3.25mL without checking it. • The lighting had been dimmed in the MRI examination room, so it was difficult to spot the difference in color between the transparent, colorless contrast medium and the pale yellow Citosol. • After the physician had administered the drug in the syringe, the radiological technologist recalled that there had been no contrast medium sticker on the syringe and realized that s/he had handed a drug that was not contrast medium to the physician.

[Improvement measures]	
Reported improvement measures following adverse event	**Findings from the visit**
• Injection labels will be affixed to syringes, without fail. • The hospital has reiterated to staff members the rule that the drug name and patient's name must be written on syringes that do not bear an injection label. • The hospital has reiterated to staff members the rule that a double-check must be carried out without fail when administering a drug. • The hospital has reiterated to staff members the rule that a single tray must be used for a single procedure for a single patient when preparing drugs.	• An instruction to write the 6Rs (including right patient name, right drug name, right administration method, and right dosage et al) on syringes has been added to the hospital's Shared Manual. • The hospital has imposed a rule that sedatives must be prepared after being checked by two ward nurses (one may be a physician), in the same way as other drugs, and that sedatives must not be prepared by the physician accompanying the patient to the examination. • The physician will be responsible for managing sedatives in the imaging examination room. • In the imaging examination room, the pediatrician and the nurse or radiological technologist will check the name of the drug and the patient's name shown on the syringe before administering the sedative and before administering the contrast medium.

Major opinions following on-site visit
○ In many cases, preparing an injection drug for a pediatric patient does not simply involve dissolving the drug, but also requires the drug to be diluted or divided into a smaller portion. Accordingly, there are multiple syringes involved and it can be difficult to affix a label to a syringe with a small capacity. ○ We heard that staff members would devise a way to deal with this by folding down a corner of the sticker's mounting sheet and affixing part of it to the syringe or placing the label and syringe on the tray when preparing the drug. However, allowing staff members to devise ways of dealing with a situation actually leads to multiple procedures emerging, such as local rules and personal rules. It would be preferable to decide upon a single common rule for the whole hospital. It might be advisable to allow multiple labels to be issued by departments that need to do so. ○ If a permanent marker pen is used to write on a syringe, it overlaps with the scale markings, making them hard to see or making it hard to read the name of the drug. Another approach might be to write the details on a piece of tape and affix that. ○ Based on the assumption that information will be written on the syringes, it might be advisable to use colored syringes for contrast medium.

GE0270006	Event in which right knee surgery was due to be performed, but the operating theater was erroneously set up for left knee surgery and the error was not noticed during the time out, resulting in surgery being performed on the wrong knee
Objectives of the on-site visit	• Verification of the facts • Verification of the background and causal factors • Concerning improvement measures
Attendees from the medical institution	Hospital Director, Deputy Hospital Director & Director of the Medical Safety Management Division (physician), 2 orthopedists, Deputy Nursing Department Director (in charge of medical safety), Nursing Division Director (Medical Safety Manager), theater head nurse, chief nurse on the ward in question

Reported objective of the treatment provided

Surgery for partial resection of the right meniscus to alleviate pain

Reported summary of event

Scrub Nurse A, who was to prepare the operating theater, looked at the surgical procedure column on the anesthesia request form that had been placed on the anesthesia machine, and checked whether it was the left or right side that was to be operated on. S/he then set up the theater for surgery on the left knee. In the operating theater anteroom, the patient, Ward Nurse B, and Circulating Nurse C checked whether it was the left or right side that was to be operated on and checked the marking, and then went into the operating theater expecting surgery to be performed on the right knee. After entering the operating theater, the anesthesiologist introduced him/herself and checked the patient's name and the surgical procedure to be performed before putting the patient under anesthesia. Subsequently, without checking the marking, the assisting physician, Scrub Nurse A, Circulating Nurse C, and Freelance Nurse D applied the tourniquet used for left side surgery to the patient and fitted the foot pump in accordance with the way in which the theater had been prepared, then disinfected and draped the left side. Before commencing surgery, the assisting physician, Scrub Nurse A, Circulating Nurse C, and Freelance Nurse D observed a time out, during which they read out the patient's name, disease name, and planned surgical procedure, but nobody noticed the mix-up between left and right. The surgeon, who arrived after preparations had been completed, performed arthroscopic surgery on the left knee, without noticing the mix-up between left and right that had occurred during the preparations for surgery. There were similar findings in the left knee to those in the right, so the operation was completed without the error being noticed during surgery. The left-right mix-up was discovered by the patient, who woke up immediately after returning to his/her room and noticed that a dressing had been applied to his/her left knee.

Outline of background and causal factors

Reported overview of factors behind the adverse event	Findings from the visit
• This patient's operation was scheduled for the second slot in Theater 2, but it was hastily changed to the third slot in Theater 3, due to the progress status of other operations. Accordingly, the circulating primary nurse was also changed. • Circulating Nurse C had been serving as the scrub nurse for another operation, so the operating theater ended up being prepared by Scrub Nurse A, who had only just been assigned to the operating theater. • The form that s/he looked at while preparing the theater was one placed in each operating theater by the anesthesiologist, showing the operations that were due to be carried out that day; the form had been left there after the previous operation. • Scrub Nurse A thought that it was the form for the patient and did not check any of the information other than whether surgery was to be carried out on the left or right side. • Marking was carried out on the day of surgery by the ward nurse, who used a black permanent marker pen to circle the upper part of the right patella after the site was confirmed by the patient him/herself. However, this was not visible during the time out because a drape had been placed over the right knee.	<Details of the event> • Marking of the surgical site on the patient was carried out on the day of surgery; the ward nurse obtained the information from the record and checked it with the patient, then used a permanent marker pen to circle the upper part of the right patella. • The tasks were divided up such that Scrub Nurse A prepared the operating theater, while Circulating Nurse C received the patient on arrival. • When Nurse A was preparing the theater, s/he set up the sheets to keep the floor clean, the foot pump, and the tourniquet for surgery on the left side, in accordance with the "left knee arthroscopy" procedure specified on the Anesthesia Request Form affixed to the anesthesia machine, which was actually for another patient, whose operation had been carried out during the slot before last. • The anesthesiologist was supposed to remove the Anesthesia Request Form after the operation, but in this event, it had been left in the operating theater. • After the patient was brought into the operating theater, the anesthesiologist introduced him/herself, then checked the patient's name and the fact that s/he was for "right" surgery, but did not notice that the theater had been set up for surgery on the left side. • The assisting physician, Scrub Nurse A, Circulating Nurse C, and Freelance Nurse D adjusted the patient's operative position according to the prepared layout and then observed a time out, during which they read out the surgical procedure to be performed, including the side that would be operated on, but they did not check the marking and nobody noticed the error.

- There was no marking on the left knee, but nobody questioned this.
- The anesthesiologist checked the patient's name and the surgical procedure to be performed before putting the patient under anesthesia, but was not aware of whether it was to be performed on the left or right.
- The anesthesiologist was absent during the time out, because s/he was checking the condition of a patient in another operating theater.
- At the time of the handover from the theater nurses to the ward nurses on leaving the operating theater, the schema diagram showing the operative site bore a symbol indicating the left side, but the handover was conducted on the basis of the progress note, which did not specify left or right, and the nurses did not lift up the blanket to check the surgical site, so the patient was returned to his/her room without the left-right mix-up being noticed.
- Both the surgeon and the anesthesiologist were absent during the time out.
- The post-operative handover from the theater nurses to the ward nurses was carried out using images from the electronic medical record. When doing so, they did not notice the left-right mix-up on the schema and conducted the handover on the basis that the surgical procedure was carried out according to plan.

<Background and causal factors>

○ Marking
- The ward nurses carry out marking. Decisions about such matters as the position of the marking were left to the discretion of the individual nurse and there were no set rules; in some cases, there was no marking, while in others, the position of the marking was not aligned with the site.
- The marking on the right knee was covered by an absorbent sheet, so it was not visible. Nobody thought it strange that they could not see any markings.

○ Time out
- The process to be followed in observing a time out before skin incision was unclear, so the time out was just a meaningless formality, without a clear purpose.

○ Operating theater staffing
- Around 13 operations are carried out per day, with 12 nurses assigned to four operating theaters.
- There are few cases of emergency surgery. Changes in the operating theater to be used are often determined by the finishing time of the previous operation.
- The surgery schedule included no allowance for the time required to prepare the operating theater.
- The lead nurse is the central repository of information about such matters as the order in which the operations would take place and changes in the operating theater to be used. Nurses in at least their fifth year as a theater nurse serve as lead nurses.
- Many operations were scheduled for the day in question. In addition, the anesthesiology department was short-handed because of an academic society meeting.
- A list of operations is posted in the operating theater and the list can also be viewed on the electronic medical record screen.
- The information required for preparing the operating theater is obtained from the Anesthesia Request Form or the Pre-operative Visit Form, which are paper-based forms, but no rule had been set for which should be used to check.

○ Preparation of the operating theater by the nurse
- The change in the planned operating theater and order of surgery meant that the nurse in charge also changed. Usually, the procedure is that the scrub nurse and the circulating nurse prepare the operating theater together, or the circulating nurse checks the preparations made by the scrub nurse. However, the circulating nurse was in another operation, so the tasks of preparing the operating theater and receiving the patient were divided up between them and the circulating nurse did not check the preparation of the operating theater.
- Rules had not been established for the procedure for preparing the operating theater or the method to be used for conducting checks.
- Preparations for surgery are supposed to be made and checked on the basis of the Pre-operative Visit Form, rather than the Anesthesia Request Form, but Scrub Nurse A did not know this, as s/he had only a month's experience of being assigned to the operating theater. Moreover, this had not been documented as a rule.
- The Pre-operative Visit Form is filed at the nurses' station for the operating theater and is prepared before the patient enters theater.

	○ Physicians • The anesthesiologist was providing anesthesia for both this case and another operation at the same time, and was absent during the time out because this coincided with the extubation of the other patient. • The surgeon entered the operating theater after the preparations were completed, so s/he did not check whether the operative field had been prepared on the correct side. ○ Other • The anesthesiologist is supposed to remove the Anesthesia Request Form once the relevant operation has been completed, but the form was left there on occasion. Rules had not been established for its handling. • If the patient has a drain, two nurses look at the insertion site during the post-operative handover from the theater nurses to the ward nurses, but no check of the wound is carried out if the patient does not have a drain. • Communication issues also appear to have contributed to this event. We would like to create an environment where staff members can speak up.
Improvement measures	
Reported improvement measures following adverse event	**Findings from the visit**
• The procedure for surgical safety checks and content thereof will be revised in accordance with the WHO standard (2009 edition) and implemented rigorously. • Time outs will be observed with all staff members – anesthesiologist and operating surgeon – present. • A standardized rule will be set regarding the document to which nurses should refer when checking information to prepare for surgery. • A standardized rule will be set for who is to carry out pre-operative marking, and when and how they should do it; staff members will be aware of this and conduct checks accordingly at each stage. • The theater lead nurse will coordinate arrangements to ensure that there is adequate time to prepare for surgery in the event of a sudden change to the surgery schedule.	• Internal checklists (Before induction of anesthesia (Sign In), Before skin incision (Time Out), and Before patient leaves operating room (Sign Out)) have been prepared with reference to the WHO Surgical Safety Checklist and introduced in all departments. • When observing a time out, the site will be checked using point and call. ○ Implementation status • The medical safety management division examines the checklists to ensure that they are completed. The checklists are used without fail. Some items on the checklists have a compliance rate of 80%-90%, which seems to require further consideration, including whether or not the items should be included. • Although the WHO checklist has been used as the basis for the hospital's checklists, it would appear advisable to revise the items on them. • When observing a time out, all staff will stop what they are doing, without fail.

Major opinions following on-site visit
○ Clarifying why preparations for surgery continued in the absence of any marking on the left knee might make it easier to see where problems lie. ○ Even if it is difficult to have the surgeon him/herself do the marking, it might be better to have it done by someone who knows which site to mark to ensure that the marking remains visible once drapes have been put in place. It might be advisable to have multiple physicians participate in the time out in the operating theater, so that the person who actually marked the site can check it. ○ If marking is established as a rule, it is vital to mark the surgical site using a predetermined method. ○ A growing number of medical institutions are introducing the WHO checklists. Other medical institutions are considering which items to check in the sign in and time out process, tailoring them to their specific circumstances. Items such as the surgical procedure and whether or not pre-operative antibiotics have been administered would seem to be important in the time out. ○ Observing a time out might seem burdensome, but errors such as the one involved in this event can occur, so it is important to continue to observe time outs, during which all members of the team thoroughly implement the check process immediately before starting the operation.

2 Individual Theme Review by the Expert Division

[1] Selection of Themes for Information to be Analyzed

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

Individual theme analysis in the quarterly reports for this project takes two forms: prospective analysis and retrospective analysis. Prospective analysis involves first establishing the theme and then continuing to collect details of relevant medical near-miss event information, while undertaking a comprehensive analysis of these in conjunction with medical adverse event information. The theme analyzed in 2015 was "Medical Adverse Events Related to Insulin." Retrospective analysis involves selecting a theme from medical adverse event information gathered during the period under analysis in the quarterly report and then compiling and analyzing details of similar events in the past.

Fig. III-2-1 Themes Highlighted in "Individual Theme Review" in the 41st to 44th Quarterly Reports

Quarterly Report	Theme
Prospective analysis	
41st	Medical Adverse Events Related to Insulin
	(1) Overview
42nd	(2) Events classed as drug mix-up or patient mix-up
43rd	(3) Events classed as wrong dosage of the drug or wrong rate of administration
44th	(4) Events classed as drug not administered, injected when drug had been stopped, wrong time of administration, or other
Retrospective analysis	
41st	Events Related to the Lithotomy Position during Surgery
	Events Involving Suicide or Attempted Suicide in Hospital
42nd	Events Related to Patient or Drug Mix-up at the Time of Administration
	Events Related to Urgent Contact Regarding Panic Values
43rd	Events Related to Central Venous Catheter Procedures on Patients in a Sitting Position
	Events Related to Wrongly Inserted Gastric Tube
44rd	Events Related to Drugs Subject to a Drug Holiday Before an Invasive Procedure
	Events Related to Fires Caused by Use of an Electrosurgical Pencil During a Tracheotomy

[2] Themes Highlighted in "Individual Theme Review"

(1) Prospective analysis

1) Medical Adverse Events Related to Insulin

Type 1 diabetes mellitus, diabetic coma, serious infectious diseases and surgery requiring whole-body management, and pregnancy in diabetes are absolute indications for insulin therapy. Moreover, insulin therapy may be used in cases of type 2 diabetes mellitus, where there is poor control of blood glucose by means of dietary therapy, exercise therapy, and oral hypoglycemic agents, or where there is marked hyperglycemia. Insulin is mostly administered by means of subcutaneous injection, generally using an insulin pen, but continuous subcutaneous insulin infusion (CSII) may be carried out in some cases. Other methods used include mixing insulin with the nutritional formula when administering parenteral nutrition, mixing a small quantity of insulin into an infusion administered via a peripheral vein, and, in the case of surgery or intensive care, using a syringe pump to provide a continuous intravenous infusion. Based on the duration and form of effect, insulin preparations are classified into such categories as rapid-acting, short-acting, intermediate-acting, pre-mixed, and long-acting. They can also be classified by type of preparation, as either cartridge preparations, kit preparations, or vial preparations. Insulin effects and preparations thus vary in type, so appropriate selection and use is crucial.

Insulin is regarded as a high-risk drug with a particular need for safety management, so this project has issued Medical Safety Information concerning insulin on four occasions, highlighting a number of events and providing warnings. The 28th Quarterly Report (published in March 2011) highlighted "Events Involving Mistakes in the Insulin Unit by a Resident When Preparing and Administering Insulin to Patients" as an analysis theme, analyzing the causes of such events. A great deal of medical adverse event information and many medical near-miss event information involving insulin have been reported to this project, with contributing factors including the fact that insulin dosages are expressed as units; the numerous different types of preparation; the diversity of administration methods, including self-injection by patients themselves; and the frequent changes in dosage. Accordingly, we have decided to take up medical adverse event information and near-miss event information related to insulin as an individual theme, so that they can be analyzed over the course of a year.

Fig. III-2-2 Medical Adverse Event Information: Occurrence

			Summary of event													
			Drug mix-up	Patient mix-up	Mistake in the quantity of medication			Wrong rate of administration	Wrong time of administration	Double dosing	Not administered	Injected when drug had been stopped	Coordination with meal, etc.	Needlestick	Other	Total
					Overdose	Underdose	Unknown									
Occurrence stage	Prescription		3	0	3	0	0	0	0	0	0	0	0	0	0	6
	Dispense		0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Order	Issue of order	2	0	8	0	0	1	0	0	0	3	2	0	1	17
		Acceptance of order	0	0	5	0	0	1	2	0	5	4	0	0	1	18
		Other	1	0	1	0	0	0	0	0	0	0	0	0	0	2
	Explanation/guidance to patient		0	0	1	0	0	0	0	0	1	0	0	0	0	2
	Drug preparation		3	0	14	0	0	0	0	0	0	0	0	0	0	17
	Administration of injection		11	5	3	0	0	2	0	4	6	0	1	2	2	36
	Checks/observation associated with injection		0	0	0	0	0	0	0	0	0	1	7	0	7	15
	Other		1	0	0	0	0	0	0	0	0	0	3	0	4	8
Total			21	5	35	0	0	4	2	4	12	8	13	2	15	121

(2) Retrospective analysis

1) Events Related to Wrongly Inserted Gastric Tube

Gastric tubes are tubes inserted through the nose or mouth into the stomach or intestine via the esophagus, in order to relieve pressure in the gastrointestinal tract, manage the patient during surgery, or facilitate nutrition management when the patient is incapable of oral ingestion. Insertion of a gastric tube is a routine procedure at most medical institutions, but the tube could potentially be inserted into the airway in error or perforate the esophagus or stomach. Moreover, there is a risk of serious complications such as pneumonia if a tube has been inserted into the airway in error and nutritional supplements are injected into it before anyone notices the error.

This project highlighted events in which a nasogastric feeding tube was wrongly inserted as part of the Individual Theme Analysis "Medical Adverse Events Related to Medical Procedures" in the 6th Quarterly Report (published in September 2006) and the 8th Quarterly Report (published in February 2007). Five events involving the insertion of a gastric tube into the trachea or bronchus in error were reported during the period under analysis in the 43rd Quarterly Report (July – September 2015). Accordingly, we searched for and analyzed past events involving a wrongly inserted gastric tube.

In this analysis, we compiled details of the circumstances of the occurrence, the effect on the patient, and the site into which the tube was wrongly inserted, presenting these details along with a summary of the timing when the insertion error was discovered, the reason why it was discovered, the background and causal factors of each event, and the main improvement measures reported by the medical institution concerned. In analyzing the background and causal factors, we broadly classified the method used to check the gastric tube after insertion into five categories: "Length of gastric tube inserted," "Listening for a bubbling sound (Whoosh test)," "Suction of contents," "pH check of aspirate," and "X-ray image." A bobbling sound was audible in 33 cases involving a gastric tube, despite the fact that the tube was not in the stomach, demonstrating that it is difficult to judge whether or not a gastric tube has been inserted into the stomach using the "Whoosh test" method alone. The analysis suggested that multiple methods need to be used to check whether the gastric tube actually has been inserted into the stomach, including "X-ray imaging," "Suction of contents," and "pH check of aspirate."

Fig. III-2-3 When and Why the Insertion Error was Discovered

When insertion error was discovered	Why insertion error was discovered	Number of cases	
After injection of the nutritional supplement	Diagnostic imaging after respiratory condition deteriorated (X-ray image, CT examination)	23	39
	Check of an X-ray image taken after insertion but not previously checked	6	
	CT examination conducted due to abdominal pain	2	
	X-ray image taken a day or two after insertion	2	
	Nutritional supplement spurted out of tracheotomy	2	
	Re-check of an X-ray image taken at the time of insertion	1	
	Aspiration of enteral nutrient during tracheal suction	1	
	Notification of insertion error received from radiologist who interpreted the CT	1	
	X-ray imaging / CT examination after death	1	
Before injection of the nutritional supplement	Check of the insertion site on an X-ray image	11	13
	Check of the insertion site on an X-ray image and CT examination	1	
	X-ray imaging and CT examination due to hemorrhage during insertion	1	
After injection of Gastrografin	Contrast radiography after injection of Gastrografin	2	2
During surgery	Discovery of foreign substance thought to be a gastric tube in the margin of a resected specimen following a right lower lobectomy	1	1
1 week after insertion (Unclear whether injection was done)	X-ray image taken 1 week after insertion	1	1
Total		**56**	

2) Events Related to Fires Caused by Use of an Electrosurgical Pencil During a Tracheotomy

Tracheotomies are performed when long-term tracheal intubation is required, when it is difficult to clear respiratory secretions, or when a tumor, etc. is obstructing the upper airway, among other situations. When a tracheotomy is performed, most patients are on a ventilator after undergoing orotracheal or nasotracheal intubation. Events in which a fire occurred near the trachea when using an electrosurgical pencil during a tracheotomy under high-concentration oxygen were reported during the period under analysis in the 44th Quarterly Report (October – December 2015). Accordingly, we searched for and analyzed events related to fires caused by use of an electrosurgical pencil during a tracheotomy, going all the way back to the beginning of this project.

Four reports of medical adverse event information related to fires caused by use of an electrosurgical pencil during a tracheotomy were submitted to the project between 2009 and the period under analysis in the 44th Quarterly Report (December 2015). The location of the event was the ICU in three cases and the HCU in one, with the fraction of inspired oxygen in the reported events ranging between 50% and 100%. We presented the reported summary of the event, the main background and causal factors, and improvement measures at the medical institutions concerned. Based on these events, the analysis suggested how important it is to conduct a team briefing before carrying out the procedure, in order to share information about the hazards, etc., according to the patient's condition. Moreover, for reference, the analysis carried warnings from the Management Subcommittee of the JQ's Patient Safety Promotion Committee, the Pharmaceuticals and Medical Devices Agency, the Japan Association of Medical Devices Industries, and the Japan Surgical Society.

Fig. III-2-4 Main Background and Causal Factors

Main background and causal factors
○ Communication • Inadequate briefing at the location concerned at the time of the tracheotomy • Lack of adequate sharing of information about events that had occurred at other medical institutions with the medical safety department and surgical department.
○ Condition of the patient • The patient had severely impaired left ventricular function (EF15%) and oxygen fraction of 40% or lower caused hypoxemia, so the tracheotomy was performed with the concentration set to 50%. • The patient had a low platelet count and was therefore at high risk of hemorrhaging, so an electrosurgical pencil was used. • The patient had severe pneumonia and tracheotomy imposes a burden on the patient, so the oxygen concentration was set to 100%.
○ Other • The endotracheal tube cuff was already leaking when the electrosurgical pencil was used. • While coagulating, the physician was aware that the electrosurgical pencil was not touching the endotracheal tube, but it was quite close to it.

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Project to Collect Medical Near-miss/Adverse Event Information

2015 Annual Report

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101-0061, Japan
Tel: +81-3-5217-0252

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