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original article

The current status of the safety management in practices of cardiopulmonary bypass : Focus to the report of JaSECT safety survey 2013

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Abstract

We carried out a questionnaire about the incidents, accidents and safety of cardiopulmonary bypass and PCPS (include ECMO) in 2013, and we describe considerations about the current state of the safety control of cardiopulmonary bypass based on its questionnaire results.

This questionnaire targeted the cardiopulmonary bypass use cases in both of 2011 and 2012 and its response rate was 76.6%. (423 of 552 establishments replied.)

The 70,015 cases (35,015 of them in 2011 and 37,000 in 2012) used cardiopulmonary bypass during the period subject to the questionnaire. On the 1,323 cases of them, some events were occurred despite the levels of affects to the patients and its incidence was 1.8%.

It is necessary to draw up checklists and double-check them for the risk management, and also it is important the proper method for using safety equipment.

We need to turn to not only the accidents but also the incidents or potentially dangerous incidents and develop the strategies for them.

We hope the questionnaire results will be taken advantage as the one of the consultations in order to prevent any incident and need to continue to take similar and further surveys in the future.

Keywords : cardiopulmonary bypass, incident, questionnaire, survey, safety management

Ⅰ. Introduction

In order to promote advances in extracorporeal technology and improve patient safety by enhancing awareness of the importance of extracorporeal circulation-related safety measures, the Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) conducted a Questionnaire Survey on Cardiopulmonary Bypass- and Assisted Circulation-related Incidents, Accidents, and Safety in 2013 (Cardiopulmonary Bypass Questionnaire Survey 2013).[1)]

The current status of safety management for cardiopulmonary bypass based on the results of this survey is described herein.

Ⅱ. Outline of the Cardiopulmonary Bypass Questionnaire Survey 2013

1. Subjects and methods

The Cardiopulmonary Bypass Questionnaire Survey

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3) Nagoya Daini Red Cross Hospital
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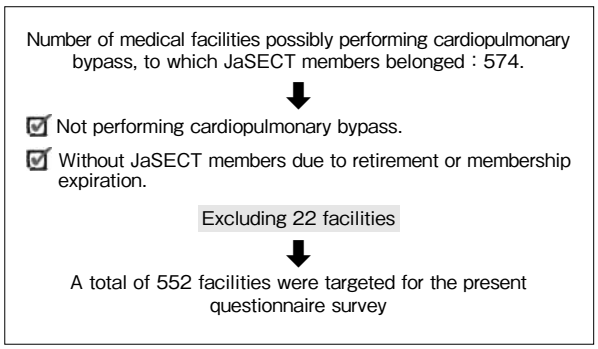


Fig.1 Facilities targeted for the questionnaire survey

2013 examined cases of cardiopulmonary bypass use in 552 medical institutions to which JaSECT members belonged between 2011 and 2012 (**Fig.1**).

After mailing a letter of request for cooperation to the head and a contact person selected for the questionnaire, namely, a JaSECT member, of each target facility, the questionnaire sheet created using Microsoft Excel® was downloaded from the membership page of the JaSECT website. As a security measure, responses were collected in data files attached to e-mails using the JaSECT membership webmail and encryption processing systems.

In response to the request for the provision of facility-related information when responding, the target facilities individually examined the appropriateness of this survey, and this led to the study period, which had originally been set between January 20 and February 28, being extended to March 14, 2014.

2. Level of influence on patients

Questions regarding the numbers of events were added based on the level of influence on patients. Since the classification of events varies among facilities, organizations, and groups to some extent,[2] that used by the Independent Administrative Agency National Hospital Organization and others was adopted in the present survey. In order to examine the preventability of incorrect practices, incidents were classified into levels 0 to 1-3a : 0 : near-miss events ; 1-3a : incidents ; and 3b-5 : accidents. Furthermore, their levels of influence on patients were presented to the respondents, with a view to ensuring the uniformity of responses (**Table 1**).

Ⅲ. Results

1. Response rate and number of valid responses

Among the 552 target facilities that participated, responses were obtained from 423, at a response rate of 76.6%. Excluding 19 facilities, which had not approved the request for cooperation with the study, and 1 from which the response file could not be opened, 403 facilities that returned valid responses were studied (**Fig.2**).

A calculation of the response rate based on the classification of JaSECT regional blocks (areas) revealed that the value was more than 70% in all blocks (**Table 2**).

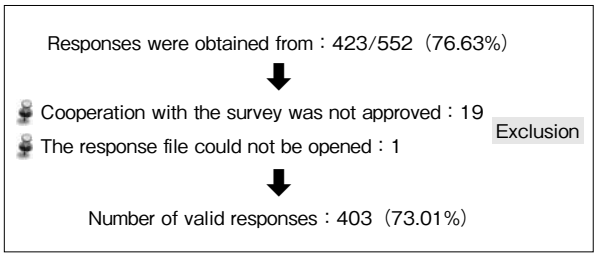


Fig.2 Response rate and number of valid responses

Table 1 Classification of the level of influence on patients

● Near-miss events	
Level 0	An incorrect medical practice was noted, but it has not been executed (it may have influenced patients to some extent if it had been executed).
● Incidents	
Level 1	The incident has not caused actual damage to patients, but it may have influenced them to some extent, indicating the necessity of intensive observations and physical and mental considerations.
Level 2	The incident has led to changes in patients' vital signs, indicating the necessity of intensive observations or examinations.
Level 3a	The incident has led to a condition requiring treatment (such as a change in the oxygen supply or gas flow level or medication dose).
● Accidents	
Level 3b	The accident has led to a condition requiring treatment (such as an unscheduled addition or change to treatment or surgical procedures ; change in the extracorporeal circulation method, hypothermic care ; addition of drugs ; and extension of the scheduled extracorporeal circulation or aortic blockage time or hospital stay).
Level 4	The accident has led to permanent disability or sequelae.
Level 5	The accident has led to death.

Table 2 Response rate in each area

	Targets	Respondents	Respons rate
Hokkaido	39	31	79.5%
Tohoku	41	30	73.2%
Kanto Koshinetsu	190	136	71.6%
Hokuriku	14	14	100.0%
Tokai	62	48	77.4%
Kinki	89	73	82.0%
Chugoku	35	28	80.0%
Shikoku	20	17	85.0%
Kyushu	62	46	74.2%
Total	552	423	

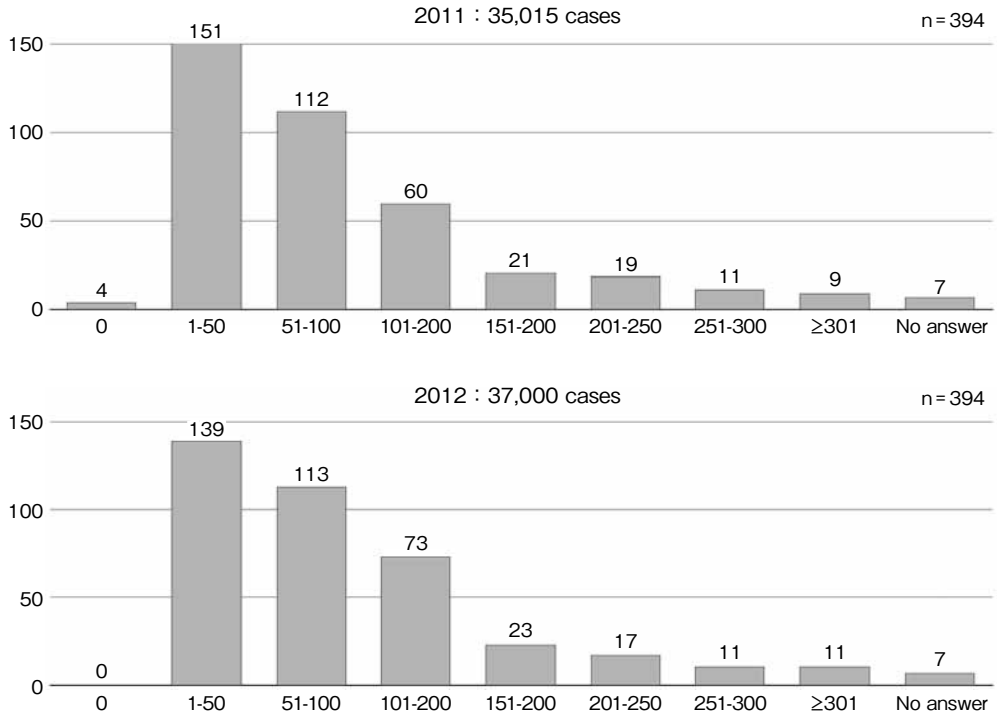


Fig.3 Case distribution

2. Backgrounds

Among the 403 facilities participating, 394 had experience of performing surgery using cardiopulmonary bypass. In these facilities, cardiopulmonary bypass had been used in 72,015 cases within a 2-year period (35,015 in 2011 and 37,000 in 2012), while those that had used it in 100 or less cases accounted for approximately two-thirds (66.8% in 2011 and 64.0% in 2012) (**Fig.3**).

Regarding patients, cardiopulmonary bypass had only been performed on adult patients in 302 (76.6%) facilities; the number of those using it only for pediatric patients was limited to 6 (1.5%). Only centrifugal pumps had been used as arterial pumps in 182 (46.2%) facilities, while the numbers of those using roller pumps only and those using either in consideration of each situation were 101 (25.6%) and 111 (28.2%), respectively. The venous reservoir had been open in 330 (83.7%), closed in 6 (1.5%), and combined in 57 (14.5%) facilities. The method of venous return was gravity drainage in 338 (87.1%) facilities, including those combining it with vacuum-assisted venous drainage (VAVD) (**Fig.4-7**).

3. Frequency of cardiopulmonary bypass-related incidents

The total number of cardiopulmonary bypass-related events (incidents) was 1,323, at a frequency of 1.8%, regardless of the level of influence on patients (**Table 3**). **Table 4** lists these incidents in detail.

Cardiopulmonary bypass device-related incidents

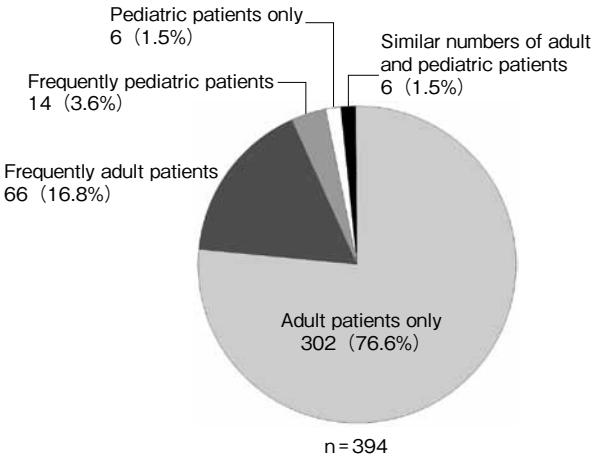


Fig.4 Classification of patients

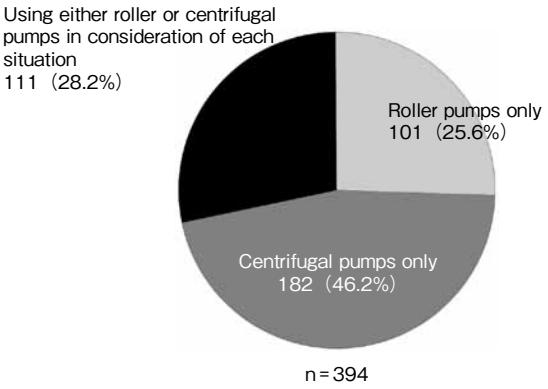


Fig.5 Blood Pumps

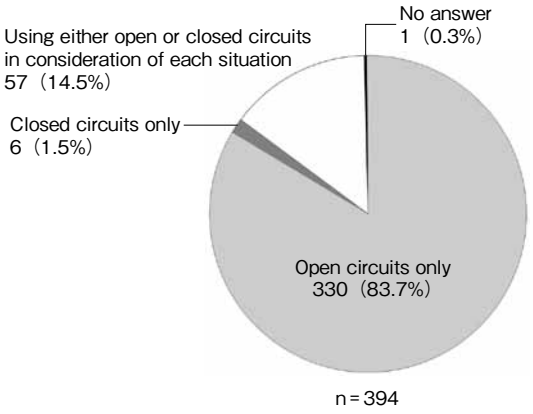
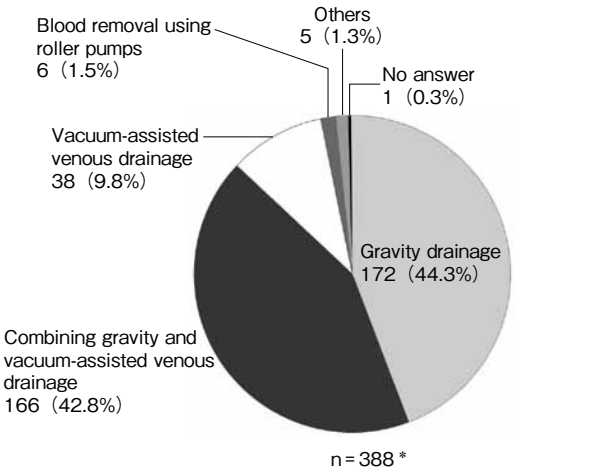


Fig.6 Cardiopulmonary bypass circuits



* Excluding 6 facilities selecting closed-type cardiopulmonary bypass circuits.

Fig.7 Methods of blood removal

Table 3 Frequency of incidents at each level

	2011	2012	Total
Number of cases using cardiopulmonary bypass	35,015	37,000	72,015
Level (0)	390 (1.11%)	411 (1.11%)	801 (1.11%)
Level (1-3a)	232 (0.66%)	241 (0.65%)	473 (0.66%)
Level (3b-5)	22 (0.06%)	27 (0.07%)	49 (0.07%)
Total	644 (1.84%)	679 (1.84%)	1,323 (1.84%)

had occurred in 156 (39.6%) facilities, at 300 (0.4%); the numbers of those related to the power supply and control systems were similar. Oxygenator-related incidents had occurred in 183 (46.4%) facilities, at 459 (0.6%) ; an increased internal (inlet) pressure was the most frequently observed, at 178 (38.8%), followed by insufficient oxygen addition, at 126 (27.5%). Venous reservoir-related incidents had occurred in 111 (28.2%) facilities, at 225 (0.3%), due to blood clotting in cardiotomy reservoirs and bubble removers in 108 (48.0%) and 91 (40.4%), respectively. Arterial line filter-related incidents had occurred in 31 (7.9%) facilities, at 59 (0.08%); oxygenators with filters incorporated were excluded from the study items.

Blood pumps were examined, with a focus on pump failure and inappropriate handling, and incidents related to the former and latter had occurred in 39 (9.9%) and 44 (11.2%) facilities, respectively; in both cases, the frequency was approximately 10%. The numbers of roller and centrifugal pump failures were

Table 4 Facilities experiencing incidents and the number of each type of incident

Cardiopulmonary bypass device-related incidents	156 facilities		(39.6%)
Power supply systems	83	cases	(27.7%)
Control systems	88	cases	(29.3%)
Communication systems	51	cases	(17.0%)
Others	78	cases	(26.0%)
Oxygenator-related incidents	183 facilities		(46.4%)
Increased internal (inlet blood) pressure levels	178	cases	(38.8%)
Inappropriate oxygen addition	126	cases	(27.5%)
Insufficient CO_2 removal	24	cases	(5.2%)
Blood clotting in the oxygenator	43	cases	(9.4%)
Damage	27	cases	(5.9%)
Blood or plasma leakage	19	cases	(4.1%)
Oxygenator air entry	18	cases	(3.9%)
Others	24	cases	(5.2%)
Venous reservoir-related incidents	111 facilities		(28.2%)
Blood clotting in the venous reservoir bubble remover	91	cases	(40.4%)
Blood clotting in the cardiotomy filter	108	cases	(48.0%)
Damage	6	cases	(2.7%)
Others	20	cases	(8.9%)
Arterial line filter-related incidents	31 facilities		(7.9%)
Blood clotting	4	cases	(6.8%)
Leakage	16	cases	(27.1%)
Damage	17	cases	(28.8%)
Increased internal (inlet blood) pressure levels	3	cases	(5.1%)
Others	19	cases	(32.2%)
Incidents related to blood supply interruptions due to blood pump failures	39 facilities		(9.9%)
Defective roller pump main bodies	15	cases	(31.9%)
Pump tube damage	2	cases	(4.3%)
Centrifugal pump drive motor failures	11	cases	(23.4%)
Centrifugal pump head damage and/or dysfunction	8	cases	(17.0%)
Inappropriate centrifugal pump attachment	3	cases	(6.4%)
Others	8	cases	(17.0%)
Inappropriate blood pump handling-related incidents	44 facilities		(11.2%)
Inappropriate setting of roller pump rotation directions	8	cases	(11.9%)
Inappropriate setting of roller pump tube sizes	16	cases	(23.9%)
Inappropriate roller pump occlusion	8	cases	(11.9%)
Accidental backflow when using centrifugal pumps	26	cases	(38.9%)
Others	9	cases	(13.4%)
Measurement and alarm device-related incidents	105 facilities		(26.7%)
Flowmeter abnormalities	15	cases	(6.9%)
Bubble detector abnormalities	42	cases	(19.4%)
Level sensor abnormalities	71	cases	(32.7%)
SvO_2 measurement device abnormalities	11	cases	(5.1%)
Pressure monitor abnormalities	11	cases	(5.1%)
Inappropriate measurement or alarm device attachment	18	cases	(8.3%)
Failure to attach measurement or alarm devices	32	cases	(14.7%)
Others	17	cases	(7.8%)
Cardiopulmonary bypass circuit-related incidents	169 facilities		(42.9%)
Insufficient cleanliness	39	cases	(10.4%)
Inappropriate connection	17	cases	(4.5%)
Bending or torsion	47	cases	(12.5%)
Inappropriate rotation directions	40	cases	(10.6%)
Tube damage	31	cases	(8.2%)
Inappropriate forceps placement and failure to place or remove them	103	cases	(27.5%)
Foreign body entry	21	cases	(5.6%)
Others	78	cases	(20.7%)

Cannula-related incidents	127 facilities		(32.3%)
Arterial cannula detachment	17	cases	(6.7%)
Venous cannula detachment	46	cases	(18.2%)
Inappropriate arterial cannula sizes	4	cases	(1.6%)
Inappropriate venous cannula sizes	18	cases	(7.1%)
Cannula damage	11	cases	(4.3%)
Inappropriate arterial cannula directions	9	cases	(3.6%)
Dissection	47	cases	(18.6%)
Increased circuit internal pressure levels due to bending or blockage at the end	75	cases	(29.6%)
Others	26	cases	(10.3%)
Failure to supply oxygen at the start of extracorporeal circulation	111 facilities		(28.2%)
Failure to discontinue oxygen supply at the end of extracorporeal circulation	134 facilities		(34.0%)
Accidental air entry-related incidents	39 facilities		(9.9%)
The reservoir became empty after leaving the cardiopulmonary bypass device unmonitored.	1	cases	(2.0%)
The reservoir became empty when the person in front of the device stopped continuously monitoring.	16	cases	(31.4%)
Oxygenator air entry when using cerebral perfusion or cardioplegic lines	8	cases	(15.7%)
Air entry into the levocardia due to excessive drainage on vent insertion	1	cases	(2.0%)
Inappropriate vent pump placement (reverse rotations)	2	cases	(3.9%)
Excessive negative pressure associated with the left ventricular vent (without one-way valves)	1	cases	(2.0%)
Others	22	cases	(43.0%)
Unexpected drainage through arterial or venous cannulas	109 facilities		(27.7%)
Tube forceps detachment (due to external factors)	8	cases	(4.9%)
Accidental arterial forceps or clamper detachment	38	cases	(23.3%)
Inappropriate tube forceps placement	10	cases	(6.1%)
Backflow due to an insufficient rotation speed of the centrifugal pump	14	cases	(8.6%)
Backflow when using roller pumps	1	cases	(0.6%)
Failure to close purge lines or sampling ports	73	cases	(44.8%)
Others	19	cases	(11.7%)
Overflow when using venous reservoirs	18 facilities		(4.6%)
Medication errors *excluding those related to myocardial protection	41 facilities		(10.4%)
Intraoperative dissection	125 facilities		(31.7%)
Myocardial protection device-related incidents	68 facilities		(17.3%)
Power supply systems	31	cases	(35.6%)
Control systems	36	cases	(41.4%)
Communication systems	8	cases	(9.2%)
Others	12	cases	(13.8%)
Myocardial protection-related incidents	126 facilities		(32.0%)
Inappropriate cardioplegic solution compositions	21	cases	(8.9%)
Failure to administer	13	cases	(5.5%)
Inappropriate injection rates	22	cases	(9.4%)
Inappropriate injection doses	29	cases	(12.3%)
Inappropriate injection temperatures	28	cases	(11.9%)
Inappropriate injection pressure levels	2	cases	(0.9%)
Line or heat exchanger damage	17	cases	(7.2%)
Inappropriate injection methods (antero- or retrograde)	5	cases	(2.1%)
Accidental air administration	21	cases	(8.9%)
Others	77	cases	(32.9%)
Power outage (such as breakdown) -related incidents	58 facilities		(14.7%)
(Unscheduled) extensive power supply interruptions in the area	13	cases	(16.7%)
Scheduled power supply interruptions in the area	2	cases	(2.6%)
Unscheduled facility-wide power supply interruptions	7	cases	(9.0%)
Scheduled facility-wide power supply interruptions	0	cases	(0.0%)
Fires or earthquakes	5	cases	(6.4%)
Automatic circuit breaker operation	31	cases	(39.7%)
Short-circuited sockets	0	cases	(0.0%)
Socket or electric power cable damage	4	cases	(5.1%)
Socket detachment (intended or accidental)	14	cases	(17.9%)
Others	2	cases	(2.6%)
Medical gas supply interruption-related incidents	2 facilities		(0.5%)

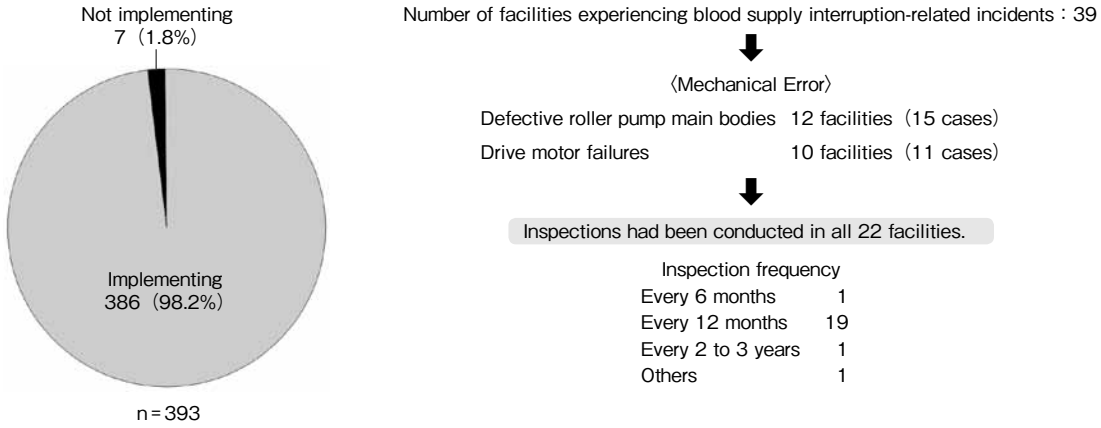


Fig.8 Implementation of periodic inspections in facilities experiencing incidents

15 (31.9%) and 11 (23.4%), respectively, while the most frequent inappropriate handling pattern was an accidental backflow when using centrifugal pumps, at 26 (38.9%).

Measurement or alarm device-related incidents had occurred in 105 (26.7%) facilities, at 217 (0.3%), due to : device failures : 150 (69.1%) and human errors : 50 (23.0%). Incidents related to the cardiopulmonary bypass circuit, excluding devices, such as oxygenators and arterial line filters, had occurred in 169 facilities (42.9%), at 376 (0.5%) ; inappropriate forceps placement and the failure to remove them were the most frequent causes, at 103 (27.5%). Cannula-related incidents had occurred in 127 (32.3%) facilities, at 253 (0.4%) ; an increased circuit internal pressure due to a broken or blocked cannula was the most frequent cause, at 75 (29.6%), while intraoperative dissection had occurred in 47 (29.6%) cases.

Oxygen had not been supplied at the start of extracorporeal circulation in 111 (28.2%) facilities, and the supply had not been discontinued at the end of the procedure in 134 (34.0%). Accidental air entry when using cardiopulmonary bypass had occurred in 39 (9.9%) facilities ; in 16 (31.4%) cases, the reservoir became empty when the person in front of the device was not monitoring it continuously. Unintended drainage from the arterial or venous cannula after the termination of extracorporeal circulation had occurred in 109 (27.7%) facilities due to : failure to close the purge line or sampling port : 73 (44.8%) and backflow due to an insufficient rotation speed (lifting height) of the centrifugal pump : 14 (8.6%).

Medication errors when using cardiopulmonary bypass had occurred in 41 (10.4%) facilities, and 125 (31.7%) had experienced dissection as an intraoperative complication.

Myocardial protection device-related incidents had occurred in 68 (17.3%) facilities ; those related to power supply (31 ; 35.6%) and control (36 ; 41.4%) systems accounted for the majority. Myocardial protection-related incidents had occurred in 126 (32.0%) facilities due to an inappropriate injection dose, temperature, rate, and composition in 29 (12.3%), 28 (11.9%), 22 (9.4%), and 21 (8.9%) cases, respectively ; the cause markedly varied among facilities. Accidental air injection had also occurred in 21 (8.9%) cases.

Ⅳ. Discussion

1. Blood pumps

Cardiopulmonary bypass and related devices had been periodically inspected in 386 (98.2%) facilities, regardless of the method. A more detailed analysis revealed that, among the blood supply interruptions due to blood pump failures, 15 and 11 had occurred as mechanical errors in 12 and 10 facilities, respectively, due to a defective roller pump main body and centrifugal pump drive motor failure, respectively. However, all 22 facilities had conducted periodic inspections ; every 6 months in 1 and annually or more frequently in 19 (**Fig.8**). This indicates that although periodic inspections are important, their implementation does not necessarily prevent device failures.

In the event of a blood supply interruption due to such failures, blood supply using a hand crank or handle had been required in 19 (48.7%) facilities. In a questionnaire survey conducted by the JaSECT in 2014 to clarify the status of safety measures for cardiopulmonary bypass (JaSECT Questionnaire Survey 2014),[3] the proportion of facilities in which hand cranks or handles had been continuously available

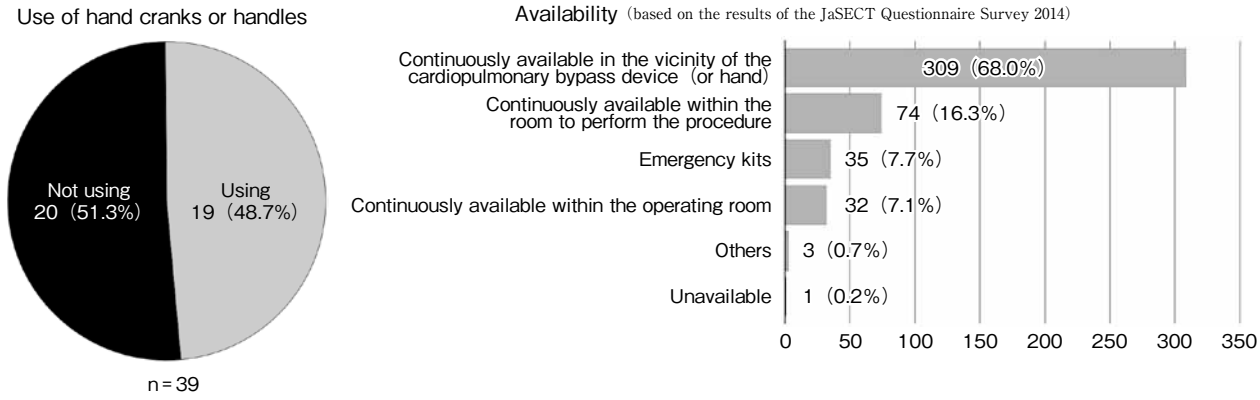


Fig.9 Use and availability of hand cranks and other instruments

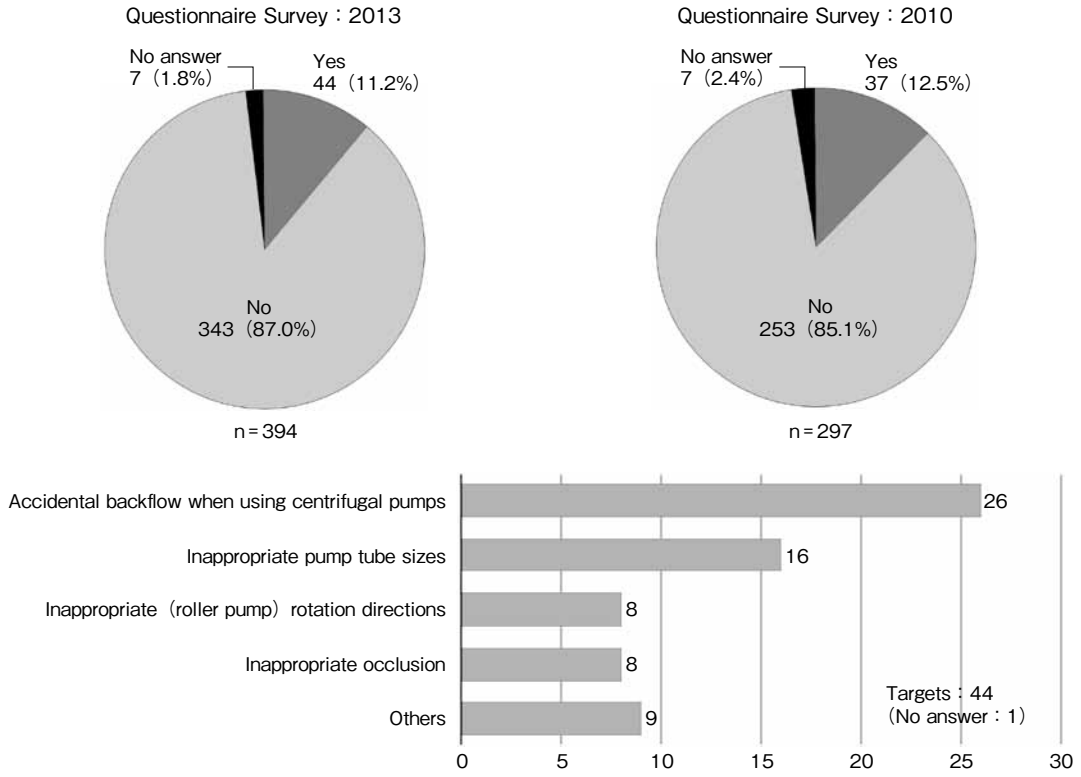
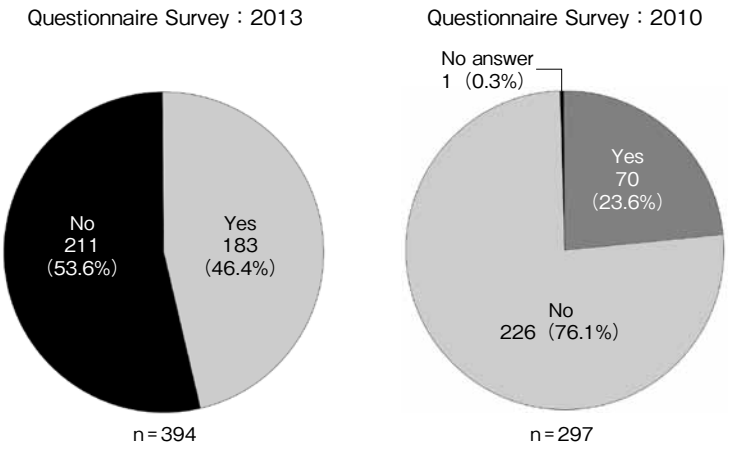


Fig.10 Incidents associated with inappropriate blood pump handling

in the vicinity of the cardiopulmonary bypass device or within the room to perform the procedure was limited to 84.3% (**Fig.9**). These instruments need to be available at all times in order to ensure their immediate use in emergencies. In the present survey, manual handling had occasionally been necessary due to some causes, suggesting the necessity of considering methods to ensure the availability of hand cranks or handles in each facility.

On the other hand, incidents due to inappropriate blood pump handling had occurred in 44 (11.2%) facilities. In the Cardiopulmonary Bypass Questionnaire Survey 2013, which was conducted following that by the JaSECT in 2010 to examine extracorporeal circulation-related incidents, accidents, and safety measures (Questionnaire Survey 2010)[4] as a series, 37 (12.5%) facilities had experienced such incidents. In both surveys, they had occurred at a frequency of higher than 10%, and the most frequent cause was accidental backflow when using centrifugal pumps. Since answers to this question also included the inappropriate setting of the roller pump tube size or rotation direction, as well as inappropriate occlusion, it may be possible to reduce incidents by adding this item to pre-procedure checklists (**Fig.10**).



Level of influence on patients	Cases	Frequency *
0	147	0.2%
1-3a	168	0.23%
3b-5	29	0.04%

No answer：14

* Rate to the total number (72,015) of cases using cardiopulmonary bypass during the 2-year period.

Fig.11　Oxygenator-related incidents

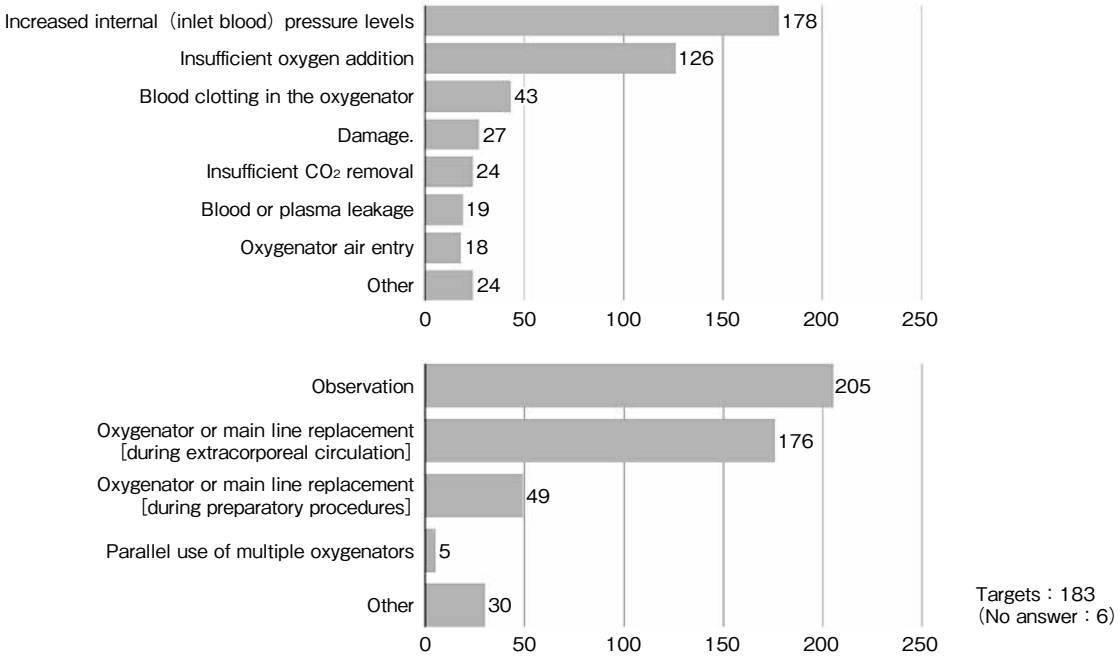


Fig.12　Causes and management of oxygenator-related incidents

2. Oxygenators

Oxygenator-related incidents had occurred in 183 (46.4%) facilities, at 344 (0.5%), revealing a significant increase from 70 facilities (23.6%) in the Questionnaire Survey 2010. Oxygenator-related accidents had also occurred, at 29 (0.04%) (**Fig.11**).

Oxygenator-related incidents had been resolved by replacing the oxygenator or entire main line during cardiopulmonary bypass in 176, while they were managed only through observations in 205 cases (**Fig.12**).

Fisher et al.[5] examined increases in the oxygenator inlet blood pressure, and reported that the oxygenator had been replaced to manage such abnormalities in 1 per 1,228 cases. They also noted that, even when the oxygenator inlet blood pressure increases immediately after the initiation of extracorporeal circulation, the pressure gradually decreases to the previous level in some cases. On the other hand, Hiraki et al.[6] reported that pressure abnormalities had occurred in 24 out of the 1,033 cases, whereas oxygenator replacement or normal inlet blood pressure recovery had rarely been observed in these cases.

Since the range of normal oxygenator inlet blood pressure levels was not defined in the present survey, and the necessity of oxygenator replacement and ob-

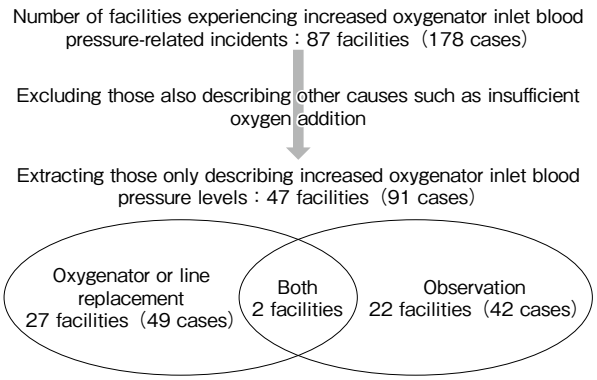


Fig.13 Management of increases in the oxygenator inlet blood pressure

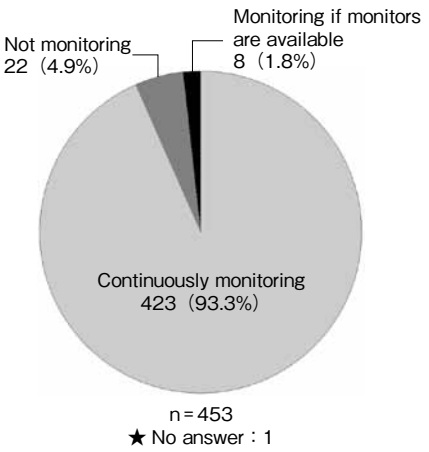


Fig.14 Status of oxygenator inlet blood pressure monitoring

servations had been determined based on the facilities' own criteria, it is inappropriate to simply compare results with the above-described findings. However, it is important to note that, among the 47 facilities (91 cases) in which only an increased oxygenator inlet blood pressure had been responsible for the incident, excluding those also describing other causes such as insufficient oxygen addition from 87 (178) answering that an increased oxygenator inlet blood pressure level had been the cause, incidents had been managed by replacing the oxygenator or line in 27 (49), observing in 22 (42), and combining both in 2 (**Fig.13**).

The necessity of oxygenator replacement and observations needs to be determined in consideration of the situation after sufficiently examining each risk. Since oxygenator replacement takes time, it may be necessary to previously simulate this process.

Abnormal increases in blood pressure when using oxygenators have increasingly been reported in recent years, possibly in response to the "Criteria for Safety Measures When Using Cardiopulmonary Bypass[7]" (JaSECT Recommendations) established by the JaSECT to define oxygenator inlet blood pressure monitoring as mandatory.

In the JaSECT Questionnaire Survey 2014, the oxygenator inlet blood pressure had been continuously monitored in 423 (93.3%) facilities, and the remaining 8 (1.8%) and 22 (4.9%) answered that they would have performed such monitoring if monitors had been available and they had not yet performed it, respectively (**Fig.14**). Since insufficient oxygenator inlet blood pressure monitoring may prevent rapid increases in the oxygenator inlet blood pressure from being detected in the early stages, consequently leading to accidents, it may be necessary for these facilities to review their monitoring systems.

The necessity of oxygenator replacement and observations needs to be determined in consideration of the situation after sufficiently examining each risk. Oxygenator replacement takes time; therefore, it may be necessary to simulate this process in advance.

3. Items to be available

In the Cardiopulmonary Bypass Questionnaire Survey 2013, safety management was also examined, in addition to the statuses of cardiopulmonary bypass-related incidents and accidents. The number of facilities in which emergency kits containing materials to rapidly replace devices, such as spare tubes and clean scissors, as countermeasures against incidents during cardiopulmonary bypass had been available markedly increased from 184 (61.9%) in the Questionnaire Survey 2010 to 279 (70.8%), while revealing that such kits had remained unavailable in more than 100 facilities (**Fig.15**).

Devices to immediately manage emergencies, including cardiopulmonary bypass circuits, had been available in a large number of facilities. However, when limiting the location to "within the room to perform cardiopulmonary bypass", availability markedly decreased, presumably due to spatial limitations or storage conditions.

Vacuum-assisted venous drainage (VAVD) had been used as a method of assistance for venous return in 238 (60.4%), indicating that a large number of facilities had adopted it after the previous survey. Among these 238 facilities, safety measures for VAVD had been implemented in 235; this simultaneously revealed that some facilities had not completely

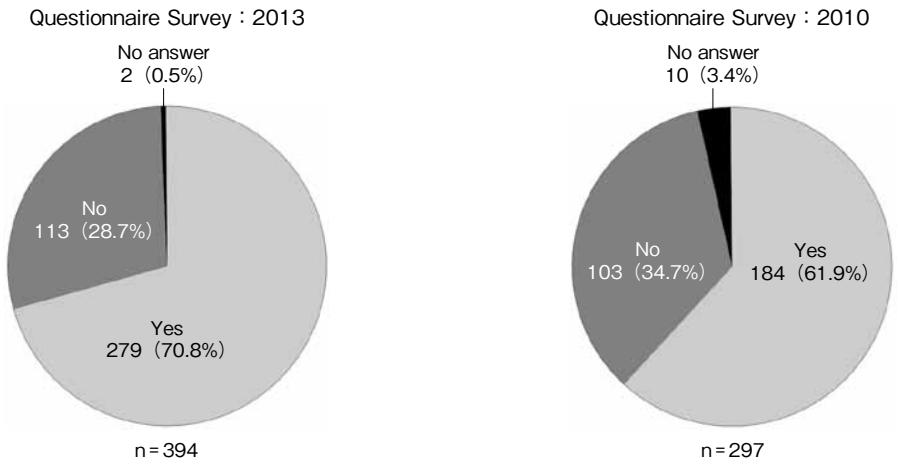


Fig.15 Availability of emergency kits

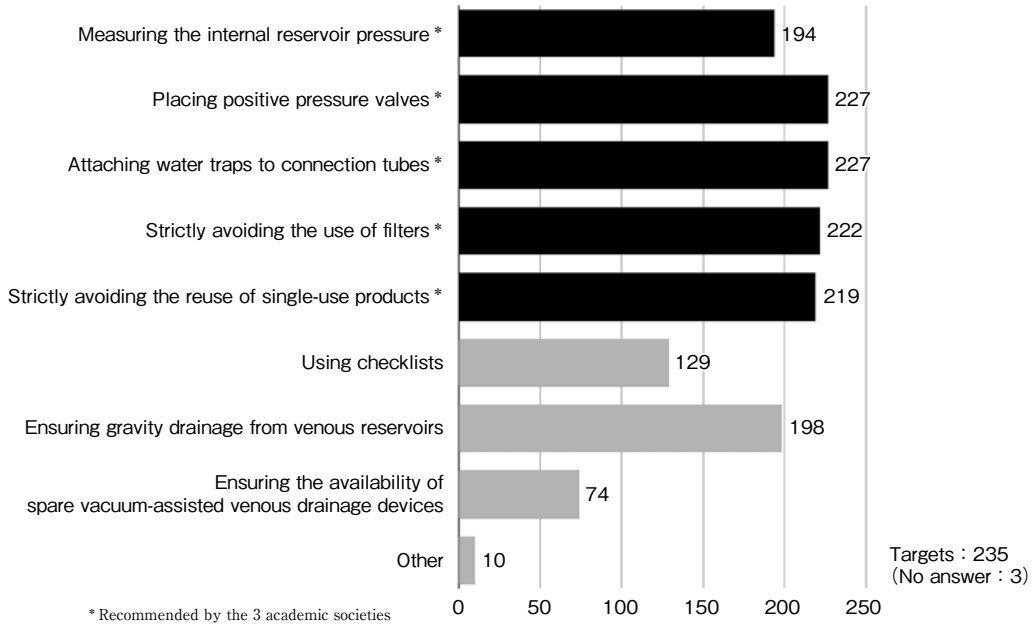


Fig.16 Safety measures for VAVD

followed the "Recommendations on Extracorporeal Circulation with VAVD" by 3 academic societies : the Japanese Association for Thoracic Surgery, Japanese Society for Cardiovascular Surgery, and Japan Society for Artificial Organs (**Fig.16**).

4. Preventive measures against incidents

Preventive measures against incidents include : implementing verification procedures using checklists and performing the double-check process. The JaSECT Questionnaire Survey 2014 confirmed that verification procedures using checklists prior to extracorporeal circulation had been performed in 412 (92.4%) facilities. The rates of compliance with mandatory and strongly recommended items defined by the JaSECT were high, at 97 and 85%, respectively. Despite these measures, the frequency of incidents had remained high.

Tanaka [8, 9] conducted experiments on the double-check process, and reported that, when it is performed by a group, the workload occasionally decreases with increases in the number of group members ; therefore, under some conditions, multiple confirmations may show an adverse effect. In other experiments, it was noted that excessive dependence on safety devices may lead to delays in the detection of abnormalities when they become defective, resulting in serious accidents.

The use of checklists and double-check processes or safety devices is necessary in terms of risk management ; however, regarding the first 2 items,

Table 5 An incident survey report (by the Japan Council for Quality Health Care)

Item	Incorrect medical practices				Total
	Not executed			Executed	
	Level of influence (if the relevant incorrect medical practice had been executed)				
	Possibly leading to death or critical conditions	Possibly leading to conditions requiring high-level care and/or treatment	Possibly leading to conditions requiring low-level care and/or treatment or not requiring any care or treatment		
(1) Drug administration	387	3,032	63,431	135,003	201,853
(2) Transfusion	106	127	1,195	1,997	3,425
(3) Treatment/care	199	1,004	7,873	23,631	32,707
(4) Medical devices and equipment	114	447	6,283	11,452	18,296
(5) Drains and tubes	115	1,026	17,037	76,287	94,465
(6) Examination	135	1,001	16,039	33,247	50,422
(7) Long-term care support	178	1,689	38,975	97,382	138,224
(8) Others	346	1,341	29,437	38,566	69,690
Total	1,580	9,667	180,270	417,565	609,082

Japan Council for Quality Health Care Division of Adverse Event Prevention : Project to Collect Medical Near-Miss/Adverse Event Information 2013 Annual Report. http://www.med-safe.jp/pdf/year_report_2013.pdf

their usage is also important. If they had been appropriately used, some of the incidents that occurred may have been prevented. Similarly, safety devices must only be used as complementary instruments.

In the 72,015 cases registered within the 2-year period of the Cardiopulmonary Bypass Questionnaire Survey 2013, the frequencies of incidents and accidents were 1 per 152 and 1 per 1,469, respectively. According to Mejak et al.,[10] their frequencies in the United States were 1 per 138 and 1 per 1,453, respectively. In a study conducted by Groenenberg et al.[11] in the Netherlands, the frequency of accidents during a 2-year period in 23,500 cases was 1 per 1,236. Since the study content and items vary among these Western countries, it is difficult to simply compare data.

An examination of the level of influence on patients was initiated from the present survey. During the 2-year period, the numbers of incidents (1-3a) and accidents (3b-5) were 473 (0.66%) and 49 (0.07%), respectively, while that of near-miss events was 801 (1.11%) (**Table 3**).

On the other hand, in a survey conducted by the Public Interest Incorporated Foundation Japan Council for Quality Health Care to examine the status of near-miss events in medical institutions throughout Japan as part of their activity to collect medical accident-related information,[12] the number of events that had occurred in 561 facilities was 609,082 in 2013, among which incorrect medical practices had and had not been (near-miss events) executed in 417,565 and 191,517 cases, respectively. Furthermore, regarding the level of the potential influence of each near-miss event, the relevant incorrect medical practices may have led to death or critical conditions, those requiring high-level care and/or treatment, and those requiring low-level care and/or treatment or not requiring any care or treatment in 1,580 (0.8%), 9,667 (5.0%), and 180,270 (94.1%) cases, respectively (**Table 5**). Based on this finding, the 801 near-miss events extracted in the Cardiopulmonary Bypass Questionnaire Survey 2013 may also include those in which the relevant incorrect medical practices may have led to death or critical conditions or those requiring high-level care and/or treatment.

When examining the results of questionnaire surveys similar to this one, the frequency of accidents and their details attract attention. However, in addition to clarifying their statuses, it is also important to focus on incidents and near-miss events and improve facility systems in order to prevent their recurrence. These measures may enable medical professionals to offer safer extracorporeal technology to patients.

Ⅴ. Conclusion

Cardiopulmonary bypass-related incidents, accidents, and safety were analyzed in the JaSECT Questionnaire Survey 2013.

The results obtained may provide each facility with a useful basis for incident prevention. In order

to establish safety measures, it may be necessary to continuously conduct similar surveys.

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