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Evaluation and Outcomes of Multidisciplinary-Reported Incidents Regarding Patient Safety Management at Special Functioning Hospital in Japan

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Abstract

Background: It is an important study to investigate incident reports submitted by multidisciplinaries in the Special Functioning Hospitals of Japan. We clarify the characteristics of the incidents and evaluate the outcomes obtained from a polygonal analysis. **Material and Methods:** We collected 1638 incident reports submitted by multidisciplinaries for one year from April, 2016 to March, 2017. The incidents were retrospectively analyzed by profile, levels, distribution, and ratios. **Results:** The majority of incidents (94.7%, 1551/1638) were distributed between the levels 0 to 3a, on the other hand, the incidents of a level higher than 3b occupied 5.3%. The reports from nurses were 75.3% (1234/1638) and those from doctors were 12.8% (209/1638). The level 3b totalled 30.6% (64/209) of the doctor-reported incidents. In contrast, the level 2 totalled 33.8% (417/1234) of the nurse-reported incidents. The levels of the doctor-incidents were comparatively higher than those of the nurse-incidents. The profiles of the incidents were categorized as drug administration (n = 439, 26.8%), nursing care (n = 399, 24.4%), drain and tube (n = 258, 15.8%), medical treatment and care (n = 199, 12.1%), medical examination (n = 141, 8.6%), medical equipment (n = 99, 6.0%), giving instructions (n = 66, 4.0%) and blood transfusion (n = 12, 0.7%). **Conclusions:** It is important for multidisciplinaries to report incidents because they can learn novel experiences from the incidents for preventing a recurrence. By proper utilizing of the incident-reporting system, it could be an effective tool that helps the medical staff build a strong patient safety culture, and a safer work-

day would improve their quality of healthcare.

Keywords

Multidisciplinary, Doctor, Nurse, Incident, Report, University Hospital

1. Introduction

Patient safety and quality improvement are rapidly evolving disciplines in human medicine involved the reduction of harm directly caused to patients by the healthcare they are receiving. The voluntary reporting and analysis of safety incidents are considered as key elements of these disciplines [1] [2]. Incident reports can be viewed as a "window on the system" in which they provide valuable insights into gaps and inadequacies in healthcare provisions [3]. A subsequent system analysis, which aims to identify failures within a healthcare system and an organization as a whole rather than focusing on individual failures, can highlight both current weaknesses and future problems, facilitating tailored interventions and improvements to the healthcare provision [1]. To date, this area of study has received little attention in veterinary medicine.

Since the publication of the US Institute of Medicine report "To err is human" [3] and the UK Department of Health report "An organization with a memory" [4], there has been increasing recognition of the need for healthcare organizations to monitor and learn from patient safety incidents. Internationally, there is increasing recognition of the need to collect and analyze data on patient safety incidents, to facilitate learning and develop solutions. Proposals on how to accomplish this have included the use of reporting systems. The roles of an incident report system are summarized and described as bellows: 1) as a tool of relapse prevention (prevention of recurrence of similar incidents); 2) as an extraction of an adverse event (not to produce severe accidents and to find iatrogenic adverse events); and 3) as a symbol of patient safety (creating a patient safety culture by each of the hospital staff monitoring the risk at the medical front). In a healthcare system, to perform a medical examination with treatment and care, an incident means an occurrence of deviated behavior and an undesired situation, which were different from the way it should be done. Based on the concept of patient safety, to learn medical safety management, it would be ideal for a hospital organization that incidents, adverse events, and unexpected complications should always be reported. The science of safety has now matured to describe how communication breakdowns, diagnostic errors, poor judgment, and inadequate skill can directly result in patient harm and death. As top management of our university hospital, there generally needs clinical research, education, and contributions to the community. In addition, we think patient safety, infection control, and clinical ethics are realistically basic and the most important issues in hospital management.

At the busy clinical site, in addition to the shortage of doctors and medical

staffs in the multidisciplinaries, individuals and interdisciplinary teams have been busy doing everyday routine work including emergency response and also have been making efforts in order to prevent medical accidents. In such busy clinical sites, if once an incident has occurred, it produces extra-work and staff efforts, which should make it difficult to spend much time submitting an incident report. However, such a poor situation can never produce a good hospital patient safety culture. That status would be prone to neglected incident reports and also be difficult to correct wrong problems and a lost opportunity to improve them.

Although there may be benefits to be gained from the establishment of large reporting systems [5] [6], there are challenges that accompany their development, both at the individual reporting level and at the data-handling and analysis level. Many incidents still go unreported with doctors being less likely than nurses to report them [7] [8]. Barriers to reporting include time constraints, lack of knowledge about how and what to report, fear of blame, lack of feedback and a perceived lack of value in the reporting process [9] [10] [11].

To write an incident report by auditing the causes and situation and to provide relapse prevention measures would require a lot of time and take much effort. As a clinical practical scene is very busy, there is one opinion that medical staffs have no time to spend on such a routine business, just only desiring for using the novel limited time for care of their patients. However, in order to maintain safety and to improve the quality in everyday work in healthcare, and also in consideration of the management of decreasing errors, controlling a risk and protecting some conflicts, an incident-reporting system should give us a novel reflection opportunity, which would teach us about relapse prevention. In that situation, in our university hospital, in order to improve the total quality management and patient safety, it should become very important to evaluate incident reports submitted by the multidisciplinary staffs.

Retrospectively, we collected and investigated multidisciplinary-reported incidents from the Special Functioning Hospitals in Japan. We will clarify their characteristics and evaluate the outcomes from a polygonal analysis. Although the obtained data were collected from a single institute of the university hospital, we would like to use the novel experience for developing our patient safety culture in the near future.

2. Materials and Methods

2.1. Detailed Information of the Special Functioning Hospitals

The purpose of the Special Functioning Hospitals is described below. As part of the efforts to systematize medical facility functions, the Minister of Health, Labor and Welfare approved individual hospitals having the capabilities of providing advanced medical care, development of advanced medical technologies, and conducting advanced medical care training.

The roles of the Special Functioning Hospitals are described as follows: Pro-

vide advanced medical care, develop/evaluate advanced medical technologies, and conduct advanced medical care training. The requirements for approval are to have the capabilities of providing, developing, evaluating, and conduct training of advanced medical care, and to providing medical care to patients who are referred to by other hospitals and clinics. The number of beds must be 400 or more, staff deployment doctors is twice as many as in ordinary hospitals, etc. Facilities must have intensive care units, sterile rooms, drug information management rooms, etc.

The number of beds in our hospital is 632.

In 2016, the total number of hospitalized patients was 199 thousand, the average number of outpatients per day was 1058, and the total number of outpatients was 263 thousand. The number of surgeries was 6909/year, the occupancy rate of beds was 86.5%, and the average number of days in the hospital was 16.9 day.

2.2. Incident Report

The period of investigation of the incident reports was one year between April 1, 2016 and March 31, 2017. We have collected 1638 incident reports submitted by the multidisciplinary staffs of our hospital facility. The breakdown of the reported occupations was by doctor, dentist, nurse, midwife, pharmacist, radiological technologist, medical technologist, clinical engineer, physiotherapist, etc. This study was approved by the University of Miyazaki Hospital Clinical Research Ethics Board (No. 2015-129).

2.3. Incident Reporting System

Our hospital uses the original incident reporting system produced by a system engineer, the application tool of which is based on the design items defined by the Council of Medical Safety Management of National University Hospital.

Based on the ranges to be reported and influence levels, the person concerned and/or discovered an incident is recommended to inform the division of medical safety management and to report it within 3 days or as soon as possible.

The classification of the level of incidents is defined by the Council of Medical Safety Management of National University Hospital (Table 1). At the point of

Table 1. The classification of the level of incidents (Council of Medical Safety Management of National University Hospital).

Level of influence (A time-point of report)	Continuity of injury	Degree of injury	Contents
Level 0	-	-	There were some errors and failures of drug medicine and medical device, however, which were not performed for patients.
Level 1	none	-	There was no actual harm (there could not be denied to affect some influences on the patients).
Level 2	Temporaly	mild	There was no medical treatment and care (enhancement of patient-observation, mild changes of vital sign, necessity of medical examination to confirm patient safety).

Continued

Level 3a	Temporaly	moderate	There needed to perform simple care and medical treatment (disinfection, wet cloth, skin suture, medication of painkiller).
Level 3b	Temporaly	severe	There needed to perform rich care and medical treatment (severe changes in vital sign, necessity of respirator, surgery, extended duration of hospitalization, admission of outpatients, bone fractures).
Level 4a	Permanent	mild to moderate	Permanent disorders and aftereffects have not been remained, however, it was not accompanied by significant functional disorders and cosmetic problems.
Level 4b	Permanent	moderate to severe	Permanent disorders and aftereffects have remained, however, it was accompanied by significant functional disorders and cosmetic problems.
Level 5	Death	-	Death (except for natural course of primary disease).
Others	-	-	-

The above incidents includes which were occurred by force majeure, mistake, and unexpected events.

submitting an incident report, the level is classified from 0, 1, 2, 3a, 3b, 4a, 4b, and 5. These eight levels are determined based on the continuity and degree of injury, and the content of treatment and disturbance. The incidents included force majeure, mistake, and unexpected. In the case of an occurrence at a higher level than the 3b incident classified by the degree of patient influence, the hospital and medical staff should inform the risk manager at the owned department as soon as possible, they have to take theory emergency measures, which were reported to the head of the hospital via the medical safety management.

2.4. Range of the Reported Incidents Recommended for Medical Safety Management in our University Hospital

2.4.1. Subject of Incidents

The incidents are classified into three categories: 1) situation of the occurrence of an injury to a patient (except for the items described in **2.4.2. Exclusion of subject of incidents**), 2) situation of the possible occurrence of an injury to a patient, and 3) claim from the patients and the family (which is related to medical treatment). For situations 1) and 2), they deal with the failure of medical equipment (medical materials and instruments), tumbles and falls, suicide and suicide attempts, leaving without permission, medication mistakes of patient self-management drugs, and patient needle-stick. Although complications were suggested, the medical staff should report unexpected complications, "hiyari-hatt" (in Japanese word) (similar to near-miss in English) of medical staff, results of a severe adverse event, complication events could not be denied as a delayed discovery, delayed correspondence, and delayed treatment.

2.4.2. Exclusion of Subject of Incidents

The exclusion of the subject of incidents is as follows: hospital-acquired infections, food poisoning cases, needle-stick injury of member of the staff, violence and bodily injury cases, robbery cases, claim from the patient and the family (non-related to medical treatment), and natural course of primary disease. These items are excluded because another reporting system has been developed by the Council of Medical Safety Management of National University.

2.5. Incidental Items Recommended to Report in Each Department

2.5.1. Incidental Items Recommended to Report in Department of the Operating Room

For the department of the operating room, incidental items recommended to be reported include mistaken patient identify, incorrect surgical site, intraoperative death, intraoperative cardiac arrest, surgery without obtaining informed consent, unscheduled surgery (especially surgery without informed consent), incorrect surgery, unexpected extension of a scheduled operating time (>6 hours, consumption of more than two times the scheduled time), unexpected excessive hemorrhage (≥5000 ml), admission to the intensive care unit, death within postoperative 48 hours, nerve injury, dermopathy (burn, bedsore, etc.), foreign body remaining in situ (surgical instrument, remnant, surgical sponge and gauze), intraoperative rupture of surgical instrument, occurrence of an accident due to failure of medical equipment, occurrence of the accident due to medical equipment (improper operation), unexpected contamination of operating field and clean area, physical damage during tracheal intubation and extubation, anesthetic accident connected to certain death, extension of postoperative awakening from anesthesia (>4 hours), accident involving drug administration and instillation, accident involving blood transfusion, missing of resected specimen, misidentification of resected specimen, patient injury during transportation and transfer, intraoperative discovery of foreign body, defective surgery application, and other unexpected events.

2.5.2. Incidental Items Recommended to Report in Inpatient and Outpatient Wards

In the inpatient and outpatient wards, incidental items recommended for reporting include mistaken patient identify, medication error, incorrect examination (involving drawing blood), incorrect treatment, and occurrence of accident due to inadequate instruction (oral instruction). Also, unexpected extension of examination and therapy, treatment time (>two times the scheduled time), unexpected excessive hemorrhage during examination and therapy, treatment (required for blood transfusion), postponement and cancellation of surgery due to influence of drug administration, examination, therapy, and treatment. Also included is nerve injury, dermopathy (burns, bedsores, etc.), and tumble and falls (accidents due to imperfect informed consent). Also corruption of the medical equipment during examination and treatment, accidents due to the failure of medical equipment, accidents due to improper operation and/or setup mistakes of the medical equipment. Physical damage during tracheal intubation and extubation, physical damage during gastric lavage, and physical damage during cardiopulmonary resuscitation are also included along with accidents of artificial respiration, accidental extubation and or self-extubation of drain or tube. Also, accidental pollution of clean regions, accident during blood transfusion, poor documentation in medical records, acts of self-harm, suicide, and suicide at-

tempt. Also, lost and damage of patient belongings (medications brought in, dentures, outfits, glasses), violence by fellow patient, sexual harassment, and other unexpected events.

2.5.3. Incidental Items Recommended to Report to Department of Laboratory Medical Examination

For the department of laboratory medical examination, incidental items recommended to report include changes in patient status when drawing blood (nerve injury, etc.), changes in patient status at physiological laboratory, accidents by tumble and fall of patient, accidents by misidentification of patient and specimen, damage of specimen by trouble with analytical instruments (accidents require retake of specimen), lost and damage of laboratory specimen, abnormal laboratory data by failure of analytical instruments, missing report of laboratory data by abnormal specimen (fibrin extraction), interruption and stopping of laboratory examination by problems with analytical instruments, accidents during input of laboratory results (insufficient confirmation and data input mistakes), and infection of human body by infectious specimen and infectious microorganism, or infectious contaminate in clinical laboratory room.

2.5.4. Incidental Items Recommended to Report to the Department of Radiology

For the department of radiology, incidental items recommended to report include mistake of registration of patients, error in ordering, error in image-printing (mistaking identification number, name, and birthday on images, mistaking registration of images, tumble and fall from examining and treatment table, physical injury during examination and treatment, bruise accompanying with wobble after magnetic resonance imaging examination, changes in patient status after examinations, suspension and extension of examination and treatment due to device problems, bringing of magnetic material into examination room of magnetic resonance imaging, extravascular explosion of contrast agents, dosing errors of drugs, not obtaining agreement document, trouble with intravenous route (accidental removal, cutting of route, etc.), irradiation by wrong radiation dose calculation, irradiation of wrong site due to error of determining the coordinates of central location and its process during radiation treatment planning, difference in irradiation dose due to no validation of dose calculation by radiation treatment planning system, mistaking of irradiation by no validation of setting up patient during radiation treatment, malfunction of device due to the failure to providing quality control of treatment equipment, incorrect operation of radiation therapy equipment, and failure to comply with the therapy assistant duties while holding breath during radiation therapy and fixation of visual point.

2.5.5. Incidental Items Recommended to Report to Center of Emergency Medicine

For the department of center of emergency medicine, incidental items recommended to report include mistaking correct patient, accidents during drug administration and intravenous administration, mistaken medical examinations

and treatment, inappropriate transfer instructions, unexpected complications during medical examination and treatment, tumble and fall, improper informed consent, corruption of medical equipment during medical examination and treatment, accident due to defective medical equipment, accident due to errors during operation and configuration of medical equipment, physical injury during tracheal intubation and extubation, physical injury during gastric lavage, physical injury during cardio-pulmonary resuscitation, accidents during artificial respiration, accidental extubation and self-extubation of drains and tubes, accidental pollution of sterile regions, accident during blood transfusion, poor description of medical records, causing self-harm, and lost and damage of patient belongings (medications brought in, dentures, outfit, glasses).

2.5.6. Incidental Items Recommended to Report to Department of Optical Diagnosis and Treatment

For the department of optical diagnosis and treatment, incidental items recommended to report include mistaking correct patient, mistaking examination contents, examination without agreement documents, tumble and fall from examination table and beds in recovery room, tumble and fall during transfer, trauma from pinching due to machinery during examination, suspension and discontinuation of examination due to abnormality of medical equipment, pulmonary aspiration (onset of aspiration pneumonia), inappropriate drug administration (mistaking drug-type and applied dose, side effects of respiratory depression and arrest, and cardiac arrest), extubation, cutting, obstruction, and pulling-out of intravenous drip tube and drains, unexpected hemorrhage accompanied with examination and treatment, gastrointestinal perforation and its accompanying accidental disease (hemorrhage, peritonitis, subcutaneous emphysema, and mediastinal emphysema), improper sampling of specimen, poor examination and treatment, applied medicine, and change in bed rest level.

2.5.7. Incidental Items Recommended to Report to Department of Pharmacy

For the department of pharmacy, incidental items recommended to report include mistaking correct patient, mistaking drugs, standards, and quantity, mistaking measurement of powdered medicine and liquid medicine, mistakes of counting of oral medicine, external medicine, and injection drug, forget to give medicine, printing mistake on pharmacy bag and powder paper, inadequate protocol management, provide leakage of drug information (effect, side effect, interaction, dosage and administration), mistakes of providing drug information, forgetting to deliver referral documents on drug information, contamination of foreign body, unexecuted correction request of prescription, forgetting to tell doctors of mistaking prescription, and lack of confirmation of contraindications.

2.6. Items of Analysis

The collected reports were analyzed by the classification of levels, breakdown,

ratio according to the occupations, profile, the time zone of incident occurrence, years of occupational experience, profiles of incidents about drug administration (prescription and medication, management of dispensing and pharmaceutical preparation, and management of drug and blood derivative), profile of incidents about nursing care (tumbles, falls, care and life of medical treatment, and hospital meals and nourishment),profile of incidents about drain and tube, profile of incidents about medical treatment and care, and profile about incident during medical examination.

2.7. Statistical Analysis

A statistical technique using the seven techniques for qualitative analysis, which are collectively called the seven tools for quality control (QC seven tools). To analyze the frequency of appearance of the incident levels, a pareto chart was used from the QC seven tools, *i.e.*, quality control. The data in this study were analyzed by a breakdown of the stratified analysis, distribution of numbers, and ratio.

3. Results

3.1. Transition of the Reported Incident Numbers from Multidisciplinary

Figure 1 shows the transition of the reported incident numbers from the multidisciplinary over 16 years in our hospital from April, 2001 to March, 2017. The reported numbers have been gradually increasing every year. The ratio of the reported numbers from the doctors and dentists per total reports have also been increasing and are more than 10%, especially, the ratio was 12.9% in 2016. The ratio of doctor-reported incidents remained high.

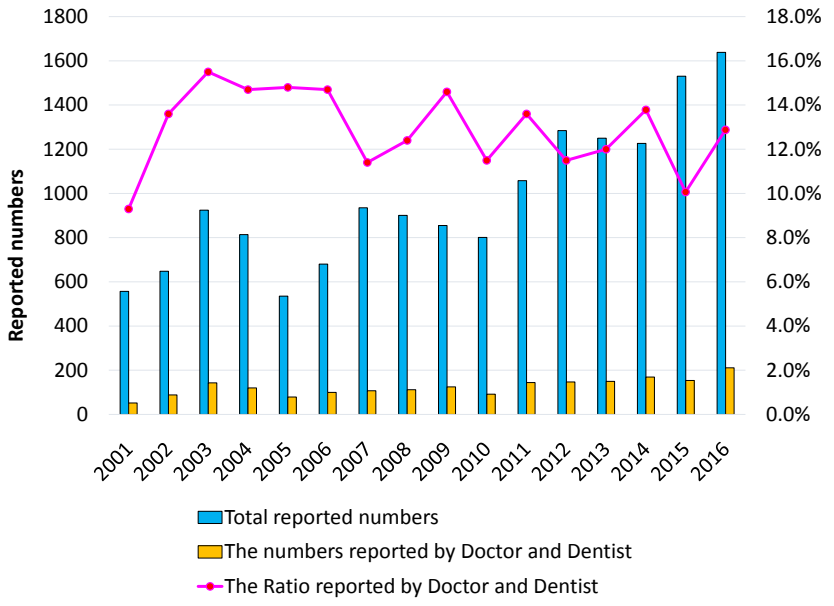


Figure 1. Transition of the numbers and ratio reported by multidisciplinary.

3.2. Distribution of the Reported Incident Numbers by the Level of the Incidents and Multidisciplinary

Table 2 shows the distribution of the reported incident numbers by the level of incidents and multidisciplinary. The majority of incidents was 94.7% (1551/1638) between levels 0 to 3a. On the other hand, incidents higher than level3b were 5.3% of the total. Based on the reported numbers by occupation, Figure 2 shows a pareto diagram of the distribution of the multidisciplinary. The first place was nurses (75.3%, 1234/1638), and the second was doctors (12.8%, 209/1638), while the third was pharmacists (2.6%, 42/1638). The ratio of report numbers by the doctors and nurses per total occupied was almost about 90% of all the incidents (88.1%, 1443/1638). Based on the multidisciplinary-reported incidents, the first place was level 1 (30.1%, 493/1638), the second was level 2 (29.5%, 483/1638), the third was level 3a (20.1%, 329/1638), and the fourth was level 0 (15.0%, 246/1638).

Figure 3(a) and Figure 3(b) show pareto diagrams of the difference in the levels of the incidents from the doctors and nurses. The levels of the doctor-reported incidents (Figure 3(b)) were comparatively higher than those of the nurse-reported incidents (Figure 3(a)), while the levels of the nurse-reported incidents were comparatively lower than those of the doctor-reported incidents (Figure 3(b)). Based on the nurse-reported incidents (Figure 3(a)), the first place was level 2 (33.8%, 417/1234), and the second one was level 1 (31.7%, 391/1234).On another front, for the nurse-reported incidents, the ratio of those of less than level-3a, that is mild incident levels and hiyari-hatt (n = 1225, 99.3%, 1225/1234). On the other hand, based on the doctor-reported incidents (Figure 3(b)), the first place was level 3b (30.6%, 64/209) and the second was level 3a (22.0%, 46/209). For the doctor-reported incidents, the ratio of those of higher than level 3b occupied about one-third (36.4%, 76/209).

Table 2. Distribution of the reported incident numbers by the level of the incidents and occupations.

Level	Doctor	Dentist	Nurse	Midwife	Pharmacist	Radiological Technologist	Medical Technologist	Clinical Engineer	Physiotherapist	Others	Total	%
0	27	0	144	1	30	6	17	1	0	20	246	15.0
1	30	0	391	12	10	8	6	3	1	32	493	30.1
2	30	0	417	14	2	8	4	0	7	1	483	29.5
3a	46	1	273	2	0	3	0	0	3	1	329	20.1
3b	64	0	9	0	0	1	0	0	0	0	74	4.5
4a	0	0	0	0	0	0	0	0	0	0	0	0.0
4b	1	0	0	0	0	0	0	0	0	0	1	0.1
5	8	0	0	0	0	0	0	0	0	0	8	0.5
Others	3	1	0	0	0	0	0	0	0	0	4	0.2
Total	209	2	1234	29	42	26	27	4	11	54	1638	
%	12.8	0.1	75.3	1.8	2.6	1.6	1.6	0.2	0.7	3.3		

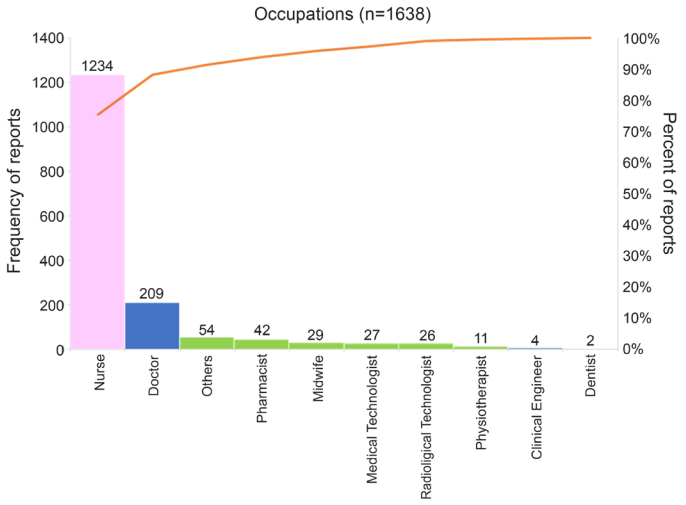


Figure 2. A pareto diagram of total incidents reported by occupation.

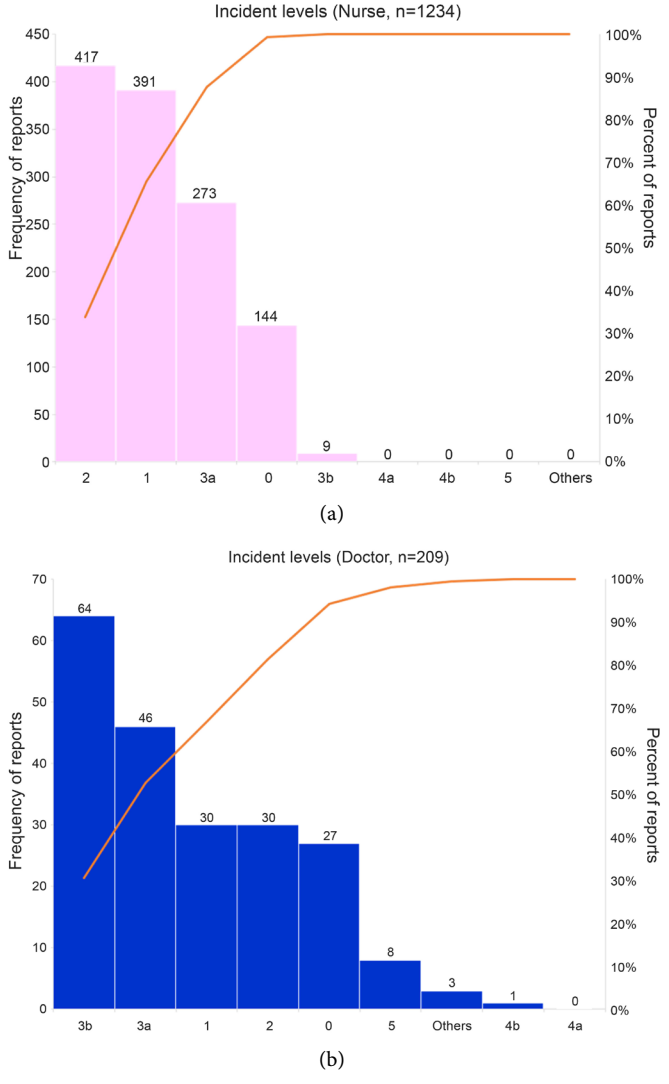


Figure 3. (a) A pareto diagram of incidents reported by nurse; (b) A pareto diagram of incidents reported by doctor.

3.3. Distribution of the Time Zone of the Incident Occurrences

The occurrence of incidents from nurses was observed at any time during the day time and night, however, for the doctors, it was mostly observed in the daytime (data not shown). Figure 4 shows the distribution of total incident occurrences based on the 24 hour day of multidisciplinary. In the time zones of 8:00-9:00 and 12:00-13:00, there were observed two peaks, which overlaps with the message time (8:00-9:00) by the nurse's work shifting hours and patient's lunch time and nurse's break time around noon (12:00-13:00). During these time zones, the medical staff should take care regarding the occurrence of incidents.

3.4. Distribution of the Experienced Years

Figure 5 shows the number of multidisciplinary-reported incidents based on the years of experience in each occupation. The submitting of incident reports was observed for all years of multidisciplinary experience. The greater the number of years, the fewer the number of incident reports. Especially, within 2 years of experience, there were the most commonly observed problems by the multidisciplinary staff having a low level of experience. To educate and to have a consciousness of patient safety, the younger staff should report their experience of incidents.

3.5. Distribution of the Level of the Incidents and the Profile of Incidents

Table 3 shows the distribution and relationship of the levels and profiles of the total incidents. Figures 6(a)-(f) are pareto diagrams of the incident profiles based on each level of the incidents. In Table 3 and Figure 6(a), the first place was "drug administration" (26.8%, 439/1638), the second was "nursing care" (24.4%, 399/1638), and the third was "drain and tube" (15.8%, 258/1638).

Table 3. Distribution of the levels and the profile of incidents.

Profile of incidents	Levels									Total	%
	0	1	2	3a	3b	4a	4b	5	Others		
Drug administration	86	207	107	35	4	0	0	0	0	439	26.8
Nursing care	37	72	213	74	3	0	0	0	0	399	24.4
Drain and tube	4	46	48	157	3	0	0	0	0	258	15.8
Medical treatment and care	6	24	52	50	56	0	1	7	3	199	12.1
Medical examination	39	59	37	1	5	0	0	0	0	141	8.6
Medical equipment	26	45	16	9	2	0	0	0	1	99	6.0
Giving instructions	28	28	8	2	0	0	0	0	0	66	4.0
Blood transfusion	8	3	1	0	0	0	0	0	0	12	0.7
Unknown	12	9	1	1	1	0	0	1	0	25	1.5
Total	246	493	483	329	74	0	1	8	4	1638	
%	15.0	30.1	29.5	20.1	4.5	0.0	0.1	0.5	0.2		

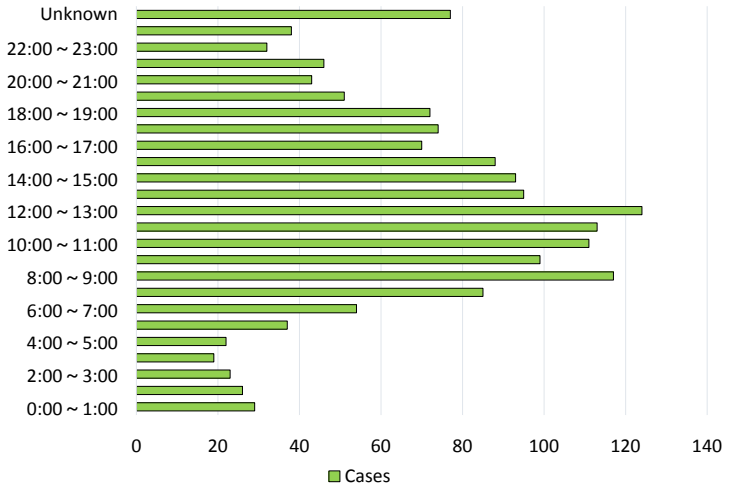


Figure 4. Distribution of time zone for occurrence of incidents.

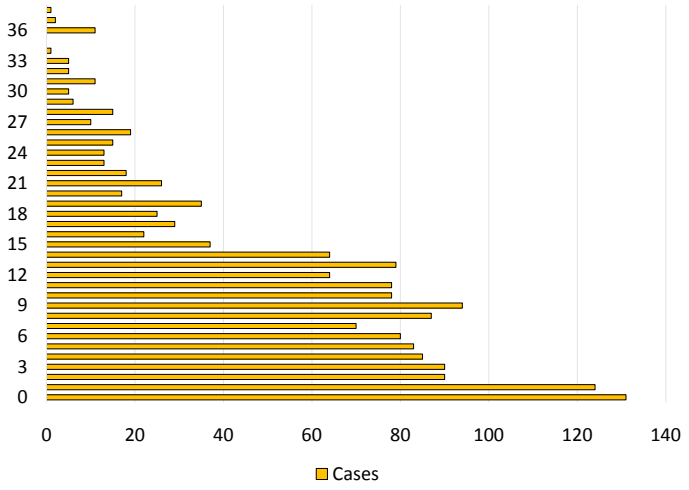
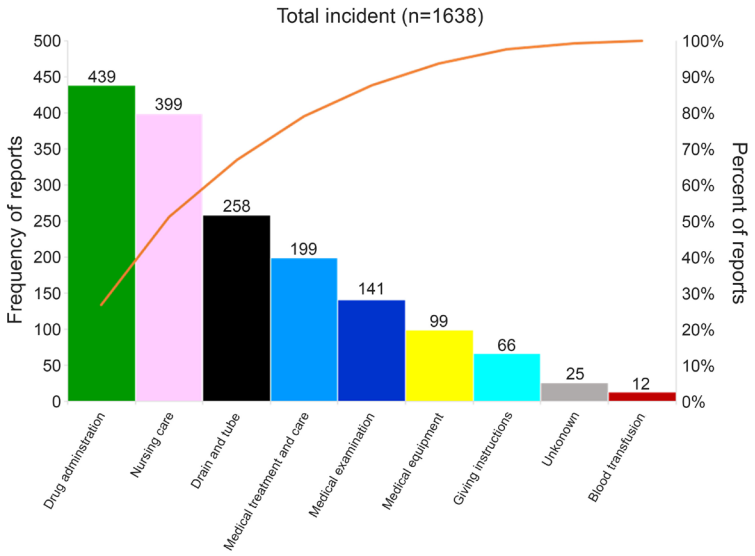
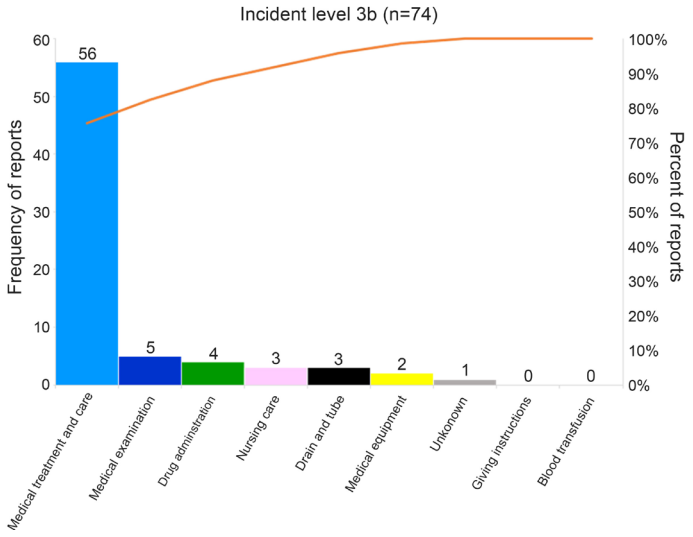


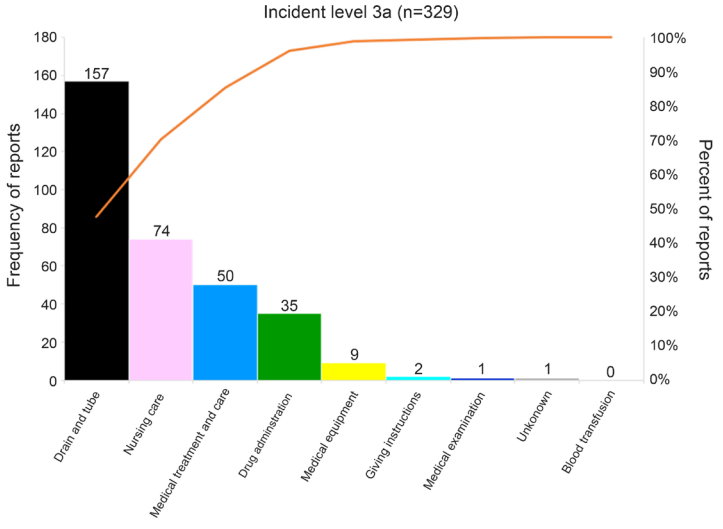
Figure 5. Distribution of years of experience in occupation.



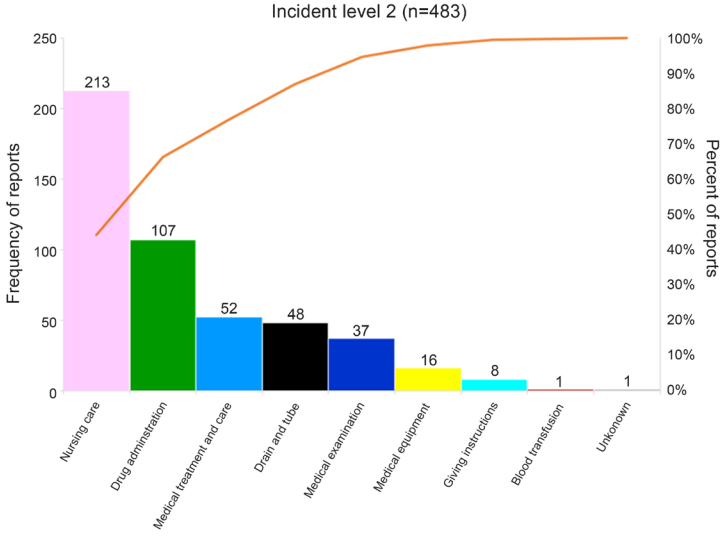
(a)


Incident level 3b (n=74)
Frequency of reports
Percent of reports
56
5
4
3
3
2
1
0
0
Medical treatment and care
Medical examination
Drug administration
Nursing care
Drain and tube
Medical equipment
Unkonown
Giving instructions
Blood transfusion

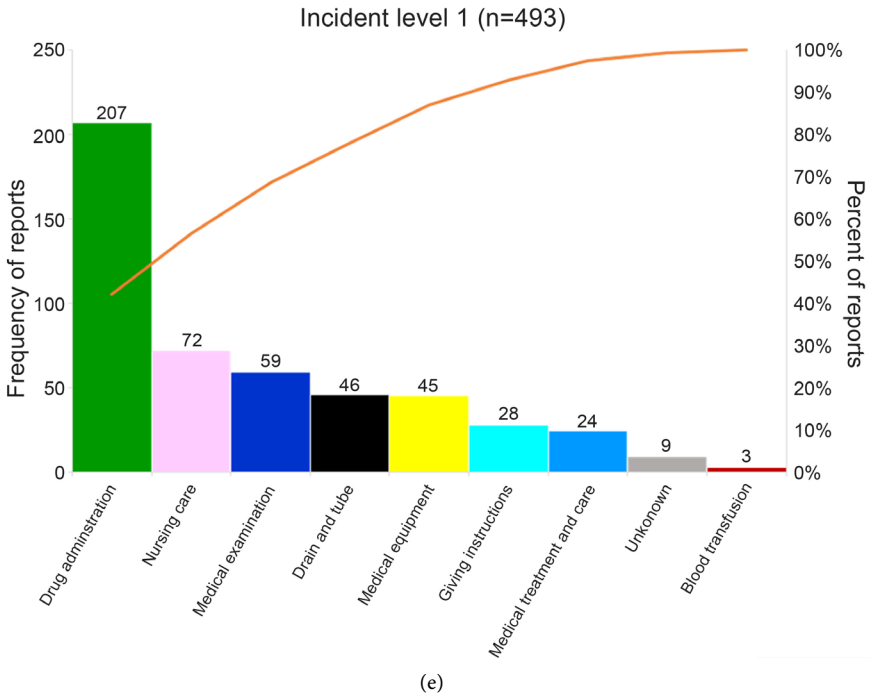
(b)


Incident level 3a (n=329)
Frequency of reports
Percent of reports
157
74
50
35
9
2
1
1
0
Drain and tube
Nursing care
Medical treatment and care
Drug administration
Medical equipment
Giving instructions
Medical examination
Unkonown
Blood transfusion

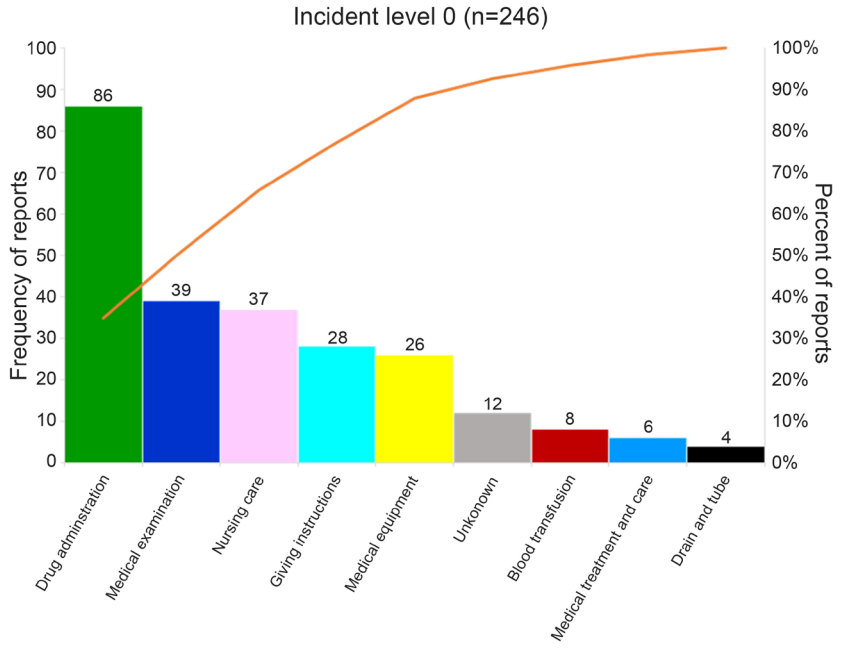
(c)


Incident level 2 (n=483)
Frequency of reports
Percent of reports
213
107
52
48
37
16
8
1
1
Nursing care
Drug administration
Medical treatment and care
Drain and tube
Medical examination
Medical equipment
Giving instructions
Blood transfusion
Unkonown

(d)



(e)



(f)

Figure 6. (a) A pareto diagram of the profile of total incidents (n = 1638); (b) A pareto diagram of the profile of incident level 3b (n = 74); (c) A pareto diagram of the profile of incident level 3a (n = 329); (d) A pareto diagram of the profile of incident level 2 (n = 483); (e) A pareto diagram of the profile of incident level 1 (n = 493); (f) A pareto diagram of the profile of incident level 0 (n = 246).

In Table 3, in the item of "drug administration", the first place was level 1 (47.2%, 207/439). In the item of "nursing care", level 2 (53.4%, 213/399) was observed as the most common. In the item of "drain and tube", level 3a (60.9%,

157/258) occurred most often than any other level. In the item of "medical treatment and care", level 3b (n = 56, 28.1%, 56/199) was in first place.

Based on the pareto diagram of incident level 3b (n = 74) (**Figure 6(b)**), the "medical treatment and care" occupied 75.7% (56/74). In incident level 3a (n = 329) (**Figure 6(c)**), the "drain and tube" occupied 47.7% (157/329). In incident level 2 (n = 483) (**Figure 6(d)**), the "nursing care" occupied 44.1% (213/483). In incident level 1 (n = 493) (**Figure 6(e)**), the "drug administration" occupied 42.0% (207/493). In incident level 0 (n = 246) (**Figure 6(f)**), the "drug administration" occupied 35.0% (86/246). In order to implement a prevent measure in patient safety, we have to know and focus on these results based on the incident levels.

3.6. Profiles of Incidents in Drug Administration.

Table 4 displays the profile of incidents in "drug administration" (n = 439, 26.8%, 439/1639), which shows the "prescription and medication" (n = 361, 82.2%, 361/439), the "managing of dispensing and pharmaceutical preparation" (n = 55, 12.5%, 55/439), and the "managing of drug and blood derivative" (n = 23, 5.2%, 23/439). On the breakdown of "prescription and medication", **Figure 7** shows that the top was "No drug medication" (n = 105, 23.9%, 105/439). On the breakdown of "managing of dispensing and pharmaceutical preparation", the top was "Mistake of dispensing of drug" (n = 14, 3.2%, 14/439).On the breakdown of "managing of drug and blood derivative", the top was "Mistake of description of label of pharmacy bag and bottle" (n = 5, 1.1%, 5/439). The preventative measures are performed for "No drug medication", "Excess medication, "Mistake of time and date of drug medication, and "Underestimate medication".

Table 4. Profile of incidents on drug administration.

Items	Cases (n = 439)	%	Breakdown	Cases (n = 439)	%
Prescription and medication	361	82.2	No drug medication	105	23.9
			Excess medication	37	8.4
			Mistake of time and date of drug medication	36	8.2
			Underestimate medication	30	6.8
			Too fast a rate of administration	13	3.0
			Too slow a rate of administration	12	2.7
			Mistake of drug medication	10	2.3
			Mistake of route of administration	7	1.6
			Duplicated medication	6	1.4
			Patients mistake	4	0.9
			Mistake of unit	3	0.7
			Mistake of the amount of drug	2	0.5
			Combination of contraindicant	0	0.0
			Others	96	21.9

Continued

Managing of dispensing and pharmaceutical preparation	55	12.5	Mistake of dispensing of drug	14	3.2
			Mistake of dispensing of standard of drug	8	1.8
			Mistake of dispensing of quantities	7	1.6
			Mistake of folding in pharmaceutical preparation	2	0.5
			Mistake of inspection of prescription of medicine and injection	1	0.2
			Mistake of apply of dispensing and pharmaceutical preparation	0	0.0
Managing of drug and blood derivative	23	5.2	Mistake of using expired drug	0	0.0
			Mistake of identifying correct patient	0	0.0
			Mistake of unit in pharmaceutical dispensing	0	0.0
			Others	23	5.2
			Mistake of description of label of pharmacy bag and bottle	5	1.1
			Mistake of mixing	4	0.9
			Fall into disrepair	2	0.5
			Contamination	0	0.0
			Others	12	2.7

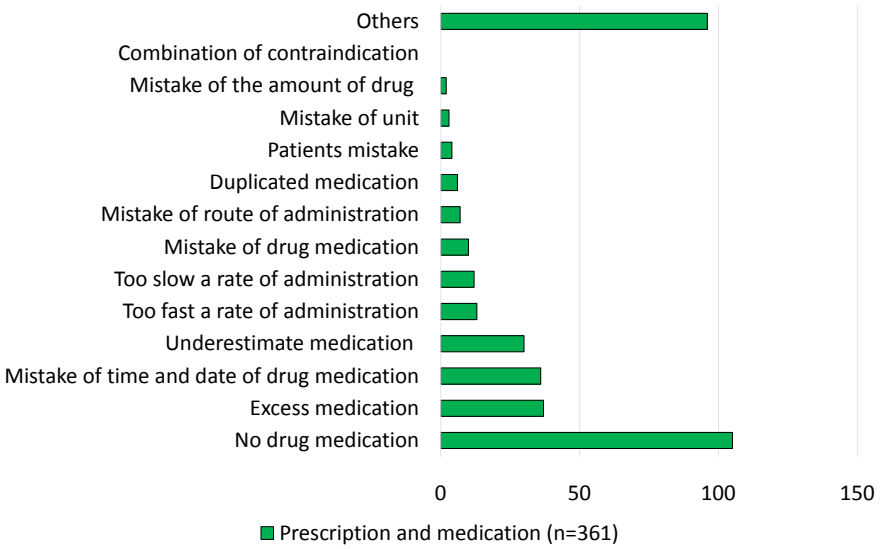


Figure 7. The profile of incidents about drug administration. Prescription and medication (n = 361).

3.7. Profiles of the Incidents in Nursing Care

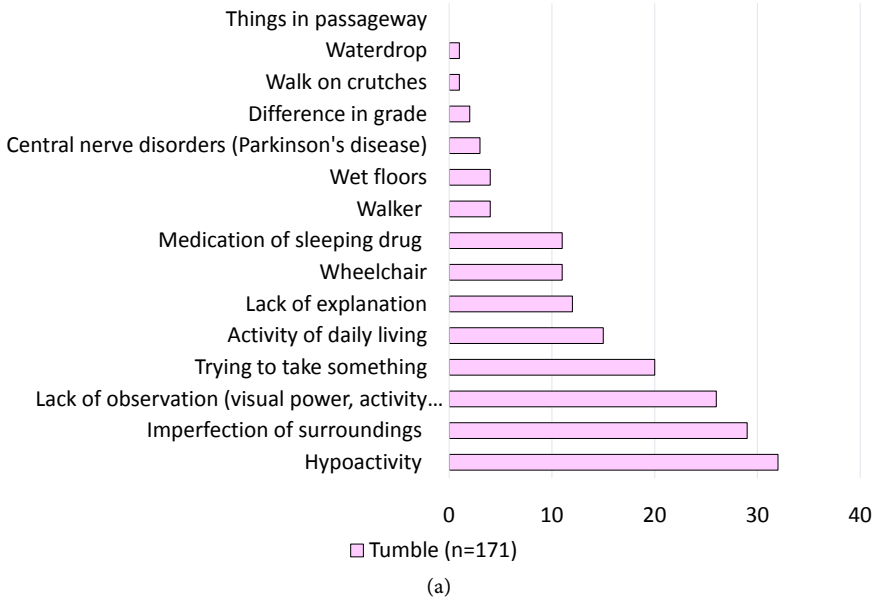
Table 5 displays the profile of incidents in the "nursing care" (n = 399, 26.8%, 399/1638), which contains "tumble" (n = 171, 10.4%, 171/1638), "fall" (n = 33, 2.0%, 33/1638), "care and life of medical treatment" (n = 143, 8.7%, 143/1638), and "hospital meals and nourishment" (n = 52, 3.2%, 52/1638).

Table 5. Profile of incidents on nursing care.

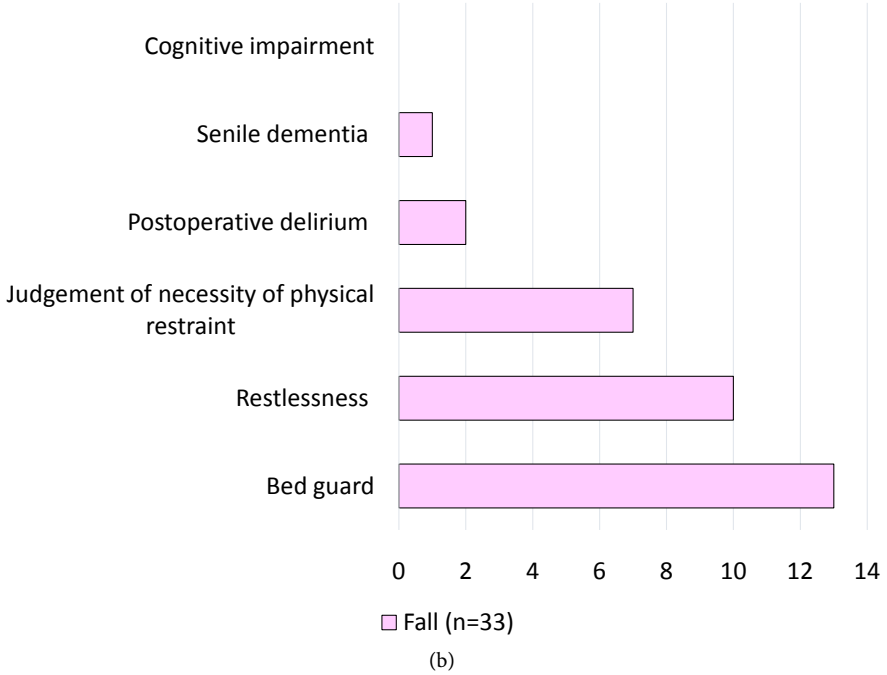
Items	Cases (n = 399)	%	Breakdown	Cases (n = 399)	%
Tumble	171	42.9	Hypoactivity	32	8.0
			Imperfection of surroundings	29	7.3
			Lack of observation (visual power, activity of daily living)	26	6.5
			Trying to take something	20	5.0
			Activity of daily living	15	3.8
			Lack of explanation	12	3.0
			Wheelchair	11	2.8
			Medication of sleeping drug	11	2.8
			Walker	4	1.0
			Wet floors	4	1.0
			Central nerve disorders (Parkinson's disease)	3	0.8
			Difference in grade	2	0.5
			Walk on crutches	1	0.3
			Waterdrop	1	0.3
			Things in passageway	0	0.0
Fall	33	8.3	Bed guard	13	3.3
			Restlessness	10	2.5
			Judgement of necessity of physical restraint	7	1.8
			Postoperative delirium	2	0.5
			Senile dementia	1	0.3
			Cognitive impairment	0	0.0
Care and life of medical treatment	143	35.8	Self-management of drugs (others)	15	3.8
			Medication of sleeping drug	13	3.3
			Self-management drugs (absent and/or staying out overnight without leave)	6	1.5
			Conveyance and transport (others)	6	1.5
			Nonfulfillment of required rest in bed	4	1.0
			Collision	2	0.5
			Conveyance and transport (mistake)	1	0.3
			Physical restriction and restraint	1	0.3
			Conveyance and transport (forgetting)	0	0.0
			Accidental ingestion	0	0.0
			Others	95	23.8
Hospital meals and nourishment	52	13.0	Mistake of dietary management	16	4.0
			Forgetting of delayed meal	2	0.5
			Mistake of food requirement	2	0.5
			Forgetting of suspended meal	1	0.3
			Others	31	7.8

Figure 8(a) shows the distribution of the incidents in "tumble" (n = 171, 42.9%, 171/399). The top eight were "Hypoactivity" (n = 32, 8.0%, 32/399), "Imperfection of surroundings" (n = 29, 7.3%, 29/399), "Lack of observation (visual power, activity of daily living)" (n = 26, 6.5%, 26/399), "Trying to take something" (n = 20, 5.0%, 20/399), "Activity of daily living" (n = 15, 3.8%, 15/399), "Lack of explanation" (n = 12, 3.0%, 12/399), "Wheelchair" (n = 11, 2.8%, 11/399), and "Medication of sleeping drug" (n = 11, 2.8%, 11/399).

Figure 8(b) shows the breakdown of the incidents in "falls" (n = 33, 8.3%,



(a)



(b)

Figure 8. (a) Profile of incidents on nursing care. Tumble (n = 171); (b) Profile of incidents on nursing care. Fall (n = 33).

33/399). The top three were "Bed guard" (n = 13, 3.3%, 13/399), "Restlessness" (n = 10, 2.5%, 10/399), and "Judgement to require physical restraint" (n = 7, 1.8%, 4/399).For the "Care and life of medical treatment", the top two were "Self-management of drugs (others)" (n = 15, 3.8%, 15/399), "Medication of sleeping drug" (n = 13, 3.3%, 13/399). For the "Hospital meals and nourishment, the top one was "Mistake of dietary management" (n = 16, 4.0%, 16/399).

Based on the results of "tumble" and "falls", as the increasing number of elderly patients receive healthcare, incidents of tumble become to increase, and we have to focus on the prevention of tumbles and falls.

3.8. Profiles of Incidents in Drain and Tube

Table 6 displays the breakdown of the profiles of incidents in the "drain and tube" (n = 258, 15.7%, 258/1639). Figure 9 shows a pareto diagram of the "drain and tube". The top five were "Self-removal" (n = 113, 43.8%, 113/258), "Damage and cutting" (n = 29, 11.2%, 29/258), "Coming off a connection socket" (n = 23, 8.9%, 23/258), "Natural removal" (n = 17, 6.6%, 17/258), and "Occlusion" (n = 12, 4.7%, 12/258). The management of the drain and tube should become an important issue for the reduction of their self-removal.

3.9. Profiles of Incidents Related to Medical Treatment and Care

Table 7 shows a breakdown of the profiles of incidents in "medical treatments and cares" (n = 197, 12.0%, 197/1639). The top two were "Mistake of methods (technique)" (n = 18, 9.1%, 18/197) and "Not implemented and forgetting" (n = 13, 6.6%, 13/197). Performing the right methods and not forgetting should be important.

3.10. Profiles of Incidents in Medical Examination

Table 8 shows the breakdown of the profiles of incidents in "medical examination" (n = 141, 8.6%, 141/1639).The top was "Mistake of specimen collection" (n = 23, 16.3%, 23/141). Collecting a specimen should become important.

Table 6. Profile of incidents on drain and tube.

Items	Breakdown	Cases (n = 258)	%
Drain and tube	Self-removal	113	43.8
	Damage and cutting	29	11.2
	Coming off a connection socket	23	8.9
	Natural removal	17	6.6
	Occlusion	12	4.7
	Mistake of a connection socket	5	1.9
	Extravasation of drip infusion	2	0.8
	Error of root clamp	0	0.0
	Mistake of manipulation of T-shape stopcock	0	0.0
	Others	57	22.1

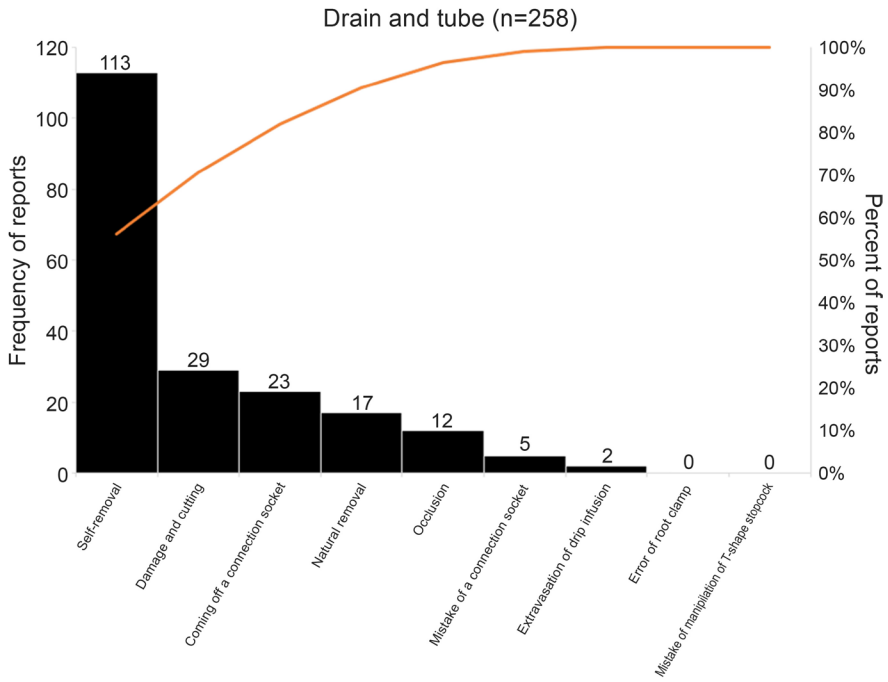


Figure 9. A pareto diagram of the drain and tube (n = 258).

Table 7. Profile of incidents on medical treatment and care.

Items	Breakdown	Cases (n = 197)	%
Medical treatment and care	Mistake of methods (technique)	18	9.1
	Not implemented and forgetting	13	6.6
	Mistake of others in medical examination and treatment	6	3.0
	Accidental ingestion and pulmonary aspiration	4	2.0
	Mistake of site	3	1.5
	Vestigial remnant of foreign body in body	3	1.5
	Mistake of disinfecting and aseptic manipulation	2	1.0
	Implementation of unnecessary medical practice	2	1.0
	Mistake of medical supplies	1	0.5
	Mistake of date and time	1	0.5
	Cancellation and postponement	1	0.5
	Mistake of correct patient	0	0.0
	Out of sequence	0	0.0
	Others	143	72.6

4. Discussion

The definitions of an adverse event, near miss, error, and mistake are critical to learning from errors. One of the barriers to learning from an error is the failure to recognize it [12] [13]. An adverse event is defined as "an unintended injury

Table 8. Profiles of incidents on medical examination.

Items	Breakdown	Cases (n = 141)	%
Medical Examination	Mistake of specimen collection	23	16.3
	Mistake of specimen	9	6.4
	Mistake of correct patients	8	5.7
	Mistake of laboratory technique and judgement technique	6	4.3
	Report of results	5	3.5
	Laboratory equipment, preparation of medical instrument	3	2.1
	Damage of specimen	3	2.1
	Contamination of specimen	2	1.4
	Mistake of data management	2	1.4
	Management of reagent	1	0.7
	Calculation, inputting, memorizing	0	0.0
	Management of analytical instrument and laboratory equipment	0	0.0
	Others	79	56.0

caused by medical management rather than the underlying disease or condition of the patient" [14]. A near miss is "any event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention" [1]. An error is "an unintended act, either of omission or commission, or an act that does not achieve its intended outcome" [15]. An error of execution is defined as "the failure of a planned action to be completed an intended", and an error of planning is "the use of a wrong plan to achieve an aim" [15]. A mistake is defined by Wu and colleagues [16] as "a commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were negative consequences" [17].

Martin A.M. *et al.* [18] calculated a mean rate of death from medical errors of 251,454 per year using the studies reported by the 1999 Institute of Medicine report and extrapolating to the total number of US hospital admissions in 2013 [3]. They estimated that "medical error" (251 k) is the third most common cause of death in the US, 2013: all causes (2597 k) involve heart disease (661 k), cancer (585 k), medical error (251 k), COPD (149 k), suicide (41 k), firearms (34 k), and motor vehicles (34 k). They believe this understates the true incidence of death due to medical errors because the cited studies rely on errors extractable in documented health records and include only inpatient deaths. A literature review by James estimated preventable adverse events using a weighted analysis and described an incidence range of 210,000 - 400,000 deaths a year associated with medical errors among hospital patients [4].

Several studies have been conducted using an electronic event reporting system to describe the extent and type of adverse events reported in hospital set-

tings. Milch *et al.* [19] analyzed 92,547 adverse events from 26 acute-care hospitals. Their study found that 33% of the adverse events were related to medication errors, 15% involved laboratory problems, 13% were falls, 13% were administration mistakes, and the remaining 19% were miscellaneous non-medication errors [19]. A similar study at an academic medical center in Missouri found that 26% of events were medication-related, 11% were related to therapeutic intervention, 9% were falls, and there was a significant variety of miscellaneous events [20]. Paradis *et al.*'s [21] electronic event reporting system at three hospitals in Oregon found that 38% of the events were medication errors, 39% were the results of a treatment procedure, and 9% were related to falls [21].

Indistinguishable from adverse events in all but the outcome, near-misses are viewed by high reliability organizations as opportunities for quality improvements [22]. Experts estimate that near-misses occur 3 - 300 times more often than adverse events in healthcare settings [23], and that they typically precede a related adverse event. Despite the opportunity they provide for safety improvement, however, near-misses are under-reported in healthcare. The systematic reporting and analysis of near-misses can improve system performance, mitigate risk, and prevent liability [24].

The causes of medical errors are often characterized by statements such as "neglected to check" and "lack of experience", in association with the physical characteristics and condition of the patients. Day-today changes in patients should be monitored and many errors can be avoided by experience. The avoidance of medical errors requires education that emphasizes the risk to staff with the goal of increasing awareness and response capabilities in individual risk management. Interventions to improve communication and attention to cognitive workload balance are also required.

For surgeons, improving the quality of care by minimizing surgical complications and adverse events is an important goal [12]. Several national initiatives have been launched in the U.S. to enhance the quality of surgical care and the avoidance of surgical errors [13] [14] [15]. Improving surgical quality requires data systems for reporting and categorizing problems that occur. Many hospitals and integrated health systems now have a national electronic event reporting system to identify and analyze adverse events, so that appropriate quality assurance measures can be undertaken [17] [25].

Patient safety education focuses on the acquisition of knowledge, attitudes and skills to support changes in behavior in order to deliver safer care [26]. A major part of the patient safety principles involves non-technical skills and therefore are not necessarily discipline-specific [27]. An important patient safety related topic is the voluntary and non-punitive reporting of unintended or unexpected events which might or did lead to harm for one or more patients [26]. This can be a valuable method to gain both insight into the occurrence and causes of incidents and to identify risk factors which should be acted upon to improve patient safety [23] [28]. Systems for reporting incidents have been demonstrated to

be useful as they resulted in a measurably safer system [23]. There are three principal conditions for creating an effective reporting system: 1) healthcare workers must be aware of the importance of reporting incidents (attitudes), 2) they need to know how to report an incident (knowledge), and 3) they must be able to recognize risky situations (skills) [29]. Patient safety education is perceived as a successful method to achieve these principal conditions and to stimulate an active reporting culture [27].

The analysis of adverse events is a powerful learning method within healthcare systems in hospitals to organize [30]. High reporting rates are generally associated with a safety-focused culture [31] [32], and increases in incident reporting are assumed to improved patient safety [33]. It is necessary to establish effective and continuous incident reporting systems in hospitals to promote patient safety. However, it has been reported that voluntary incident reporting systems identify only a small fraction of incidents [34] [35] [36] [37] [38]. Research on reporting quality has shown that education reduces the stress and fear of reporting [7] [35] [39] [40]. In addition, providing healthcare staff feedback increases their voluntary reporting [35]. Most studies have not measured the longitudinal effect of such interventions, and the overall effectiveness and sustainability of educational interventions related to voluntary incident reporting has not been fully proven [41] [42].

In other studies targeting multiple professional groups, it was found that the majority of adverse incident reports are generated by nurses [7] [36]. Accidental fall is a common health problem in older adults [43], and the incidence of falls increases with age [44] [45]. Injuries occur in approximately half of falls and 10% lead to serious injuries such as fracture, head injuries or injuries to joints [46]. In hospitals, falls are mostly reported as common adverse events accounting for 20% - 30% of all incident reports [47]. The subsequent need for longer hospitalization is a cost burden to society [44] [48] [49]. Regarding the incidence of accidental falls in hospitalization, the prevention of falls has become one of the most important issues in medical safety [50].

There are some conventional arguments, that is, many incident-reportings are the wrong situation and rather, a few numbers of incidents are better. For a hospital organization which has not fostered a patient safety culture, they are in a poor situation which they have not noticed the existence of an incident. More many incident reports can be submitted and be used in an open disclosure atmosphere, a situation which contributes to a good patient safety culture to form an optimal health status.

The role of an incident-reporting system is that, 1) as a tool of prevention of recurrence (to protect a recurrence of similar incidents), 2) as a tool of determining an adverse event (useful to extract a severe medical accident and adverse event), and 3) as a symbol of medical and patient safety (each medical staff continues to monitor the risk at clinical level and foster medical safety culture.) [51]. Some concerns about reporting an incident are summarized as 1) no time to de-

scribe a report, 2) psychologically painful to submit a report (feeling of being blamed), 3) not sure of incident case in order to report, and 4) not sure of objective and effectiveness of report of incident [51]. Dan H. *et al.* [52] reported that the input time of one incident report took an average of 30 minutes per one case and the one year of total input time required about 2000 hours and they should have to review the current situation that medical staffs at the clinical level have been swayed in making incident reports. In our hospital, in case of the submitting a hiyari-hatt incident report, we have already decreased the number of input items to our incident-reporting system.

In Japan, the Faculty of Medicine Affiliated Hospital of National University developed an incident reporting system for patient safety activities. In our University of Miyazaki Hospital, doctors, nurses, and medical staff should have to report incidents, which they have aggressively submitted, and **Figure 1** shows the past 16 years of transition. No matter who discovered the incident, they are supposed to report it to the division of patient safety. It takes a lot of effort and time for the medical staff to make an incident report. For a busy clinical site, the medical staff has the opinion which they don't have much time to make a report, however, when considering the risk and safety management, in order to perform quality improvement and safety development, which provides a novel feedback opportunity and plays the role of preventing a currency.

The significance of submitting an incident report to a hospital organization is to secure patient safety. The end result of the hospital organization is that they can intervene in the reported adverse event promptly, which make it possible to start the best medical treatment for the patient in a cross-sectional review. The sharing of an incidental event is useful for the hospital top management to grasp not only the issue, such as an individual and/or single department, but also the matters of hospital jurisdiction. To obtain transparency, if a medical staff submits an incident report, at least, at that time, which becomes evidence of no malicious hiding and concealment. To receive a formal support from a hospital organization, that is, not only to back up treatment, but also to provide the total support from the hospital organization, the concerned medical staff can receive them, even though the reported incident case may have developed into a disputed case. Only one incident report can clarify a systematic deficiency of the hospital, which should make it possible to implement a systematic improvement of the hospital.

Retrospective analyzes of cases where patients have been harmed favor a "systems approach" for safe care delivery, rather than a focus on an individual physician [1]. The system approach suggests that adverse events often arise from multiple failures during the entire patient care [53], where minor errors can accumulate and lead to a major patient safety incident (e.g., performing a procedure on the wrong patient). Never events are serious preventable incidents that further highlight the importance of the prevention of error [54]. Furthermore, there is growing awareness that human factors are heavily implicated in medical

errors. This has been well established in drug errors [55], intensive care [56], anesthetics [57], and surgery [58].

Regarding the limitations of our study, it was based on a retrospective analysis and we did not investigate each incident in detail and we did not measure the quality indicator of patient safety for a long-term follow up. This study is based on the analysis of the characteristics of incident reports, case numbers, ratio, profiles, tendency, and breakdown at the single institute of the prefectural University Hospital in Japan.

In our future work, as a quality indicator, we selected the monitoring of venous thromboembolism (VTE). We intend to construct a taskforce team with a cross-departmental multidisciplinary, and to determine the minimal requirement of the VTE risk assessment during hospital admission, development of electronic medical record for VTE assessment and the ordering system, implement preventive measures, and to measure the outcome of the occurrence of adverse events from VTE before and after the preventative intervention.

5. Conclusion

It is important for the hospital top management to aggressively develop a reliable patient safety system. It is also important for us that we have to have an exact understanding and practice the right behavior in medical safety management. An incident reporting system would be a useful tool for the hospital medical staff. The reporting of an incident will give us a good opportunity to review our medical safety behavior and to improve our medical quality. A high level of medical care and difficult medical treatment should be precisely provided to the patient without an atrophic attitude.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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