Initial Medical Errors After the Implementation of a Clinical Information System in an Intensive Care Unit and Intermediate Medical Care Unit

TWMUJ 5: 84-92, 2021

Original

Initial Medical Errors After the Implementation of a Clinical Information System in an Intensive Care Unit and Intermediate Medical Care Unit

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(Accepted March 2, 2021)
(Advance Publication by J-STAGE April 13, 2021)

Background: The implementation of clinical information systems (CISs) alone and with hospital electric medical records in intensive care units (ICUs) can lead to numerous errors. This study aimed to investigate errors in an ICU and intermediate medical care unit (IMU) for 9 months after implementing of a CIS.

Methods: A CIS was incrementally implemented in the general ICU and IMU of a university hospital over 3 months and was used for all patients by April 2019. The errors encountered over 9 months were extracted from the hospital's incident reporting system.

Results: Overall, 122 and 140 errors in the ICU and IMU, respectively, during the study period. Incidence rates of the errors in the ICU and IMU were 31.7 (95% confidence interval [CI] 26.3-37.8) and 51.3 (43.2-60.6) events per 1,000 patient-days, respectively. There were 17 (14%) and 15 (11%) CIS-related errors in the ICU and IMU, respectively. The incidence rates of errors in the ICU and IMU were 5.3 (3.1-8.5) and 6.5 (3.6-10.7) events per 1,000 CIS operation patient-days, respectively.

Conclusions: Thirteen percent of the errors in the ICU and IMU were related to the CIS, and the incidence did not vary with the staffing intensity of both care units.

The study was registered at the University Hospital Medical Information Network Clinical Trials Registry (UMIN 000039402).

Keywords: clinical information system, intensive care unit, electric medical record, errors

Introduction

Clinical information systems (CISs) have been developed for intensive care units (ICUs) to aggregate information, promote operational efficiency, and accurately record patients' physical status. Major components of CIS include critical care flowsheets, computerized physician order entry (CPOE), and records of vital signs and parameters from ventilator or external monitors. The advantages of implementing a CIS include increased efficiency, improved quality of care, data availability and security, reduced length of stay in ICU, reduced documentation time, and reduced medication prescribing error rates.[1-7] However, CIS also has disadvantages, including the emergence of CIS-related errors, decreased speed and efficiency owing to poor system usability, disruption of es-

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doi: 10.24488/twmuj.2020015

tablished workflow, or system failure.[6, 8-10]

Although hospital electronic medical record (hEMR) systems are used for a number of tasks in many hospitals, hEMRs are not generally optimized for use in ICU. Thus, the implementation of a CIS in ICUs may be required. However, in settings where both CIS and hEMR systems operate together, differences in the systems' operability and performance of the systems or a lack of coordination between the two systems can lead to new errors. To successfully implement a CIS, information about the nature, number, and incidence of CIS-related errors is necessary. However, few studies have examined the incidence rate and the types of errors recorded soon after implementing a CIS in ICUs. This study aimed to investigate the incidence rate and the type of errors in an ICU and intermediate medical care unit (IMU) for 9 months after implementing a CIS.

Materials and Methods

Study design and setting

This study was performed in the general ICU (18 beds, nursing-to-patient ratio 1 : 2) and IMU (15 beds, nursing-to-patient ratio 1 : 4) at a university hospital (1,335 beds). The ICU was for critically ill patients requiring invasive monitoring and advanced intervention including vasopressors, mechanical ventilation, mechanical circulatory support. The IMU was for patients requiring detailed observation or intervention including support for a single organ system or postoperative care and those stepping down from the ICU. An hEMR (HOPE EG-MAIN™, Fujitsu FIP, Tokyo, Japan) was used throughout the hospital. The hEMR along with paper-based order and recording forms were used in both the ICU and IMU. A CIS (PrimeGaia™ PRM-7400, Nihon Kohden, Tokyo, Japan) was implemented in the ICU and IMU. The CIS was used for all patients by April 2019, following an incremental implementation over 3 months. We conducted this retrospective analysis of errors in both the ICU and IMU using data from the incident reporting system of our hospital. This study was approved by the Tokyo Women's Medical University Institutional Review Board (Approval No. 5224), and the requirement for informed consent was waived because of the retrospective nature of the study. The study was registered at the University Hospital Medical Information Network Clinical Trials Registry (UMIN000039402).

Clinical information system

The implemented CIS had critical care flowsheet (**Figure 1**) and CPOE components (**Figure 2**) and could record vital signs and parameters from bedside monitors, ventilators, and external monitors such as Vigilance™, Vigileo™ (Edwards Lifesciences, Irvine, CA, USA), and INVOS™ (Medtronic, Minneapolis, MN, USA). The hEMR and CIS were used together in the ICU and IMU, and the tasks in the units were assigned to each system (**Figure 3**). However, there was limited coordination between the hEMR and CIS. Most drugs used in the ICU could be ordered with the CIS, and the orders were sent to the hEMR. However, blood products and some drugs, including narcotics, and drugs that require approval or registration (broad-spectrum antibiotics, drugs for chemotherapy, and rarely used drugs), need to be ordered in both systems. The CPOE did not contain a clinical decision support system owing to the specifications of the system and the cost. In addition, laboratory tests, imaging tests, and oral medications needed to be ordered in the hEMR. Although laboratory test results were displayed in the CIS, imaging findings were shown only in the hEMR. Since the ICU staff needed to use both systems simultaneously, the bedside computers were equipped with dual displays to improve efficiency.

Data collection

Data related to the patients' treatment department and length of stay in the ICU and IMU were collected from the CIS. Data on the errors in the ICU and IMU in the 9 months after implementing the CIS (from January to September 2019) were extracted from the hospital's incident reporting system, and the incidence rate was determined. In this study, all events reported in the incident reporting system were defined as errors. In the incident reporting system, errors were classified into eight levels depending on the severity and influence of the errors based on the classification made by the National University Hospital Council of Japan (**Table 1**).[11]

Figure 1. Critical care flowsheet of the clinical information system in the intensive care unit.

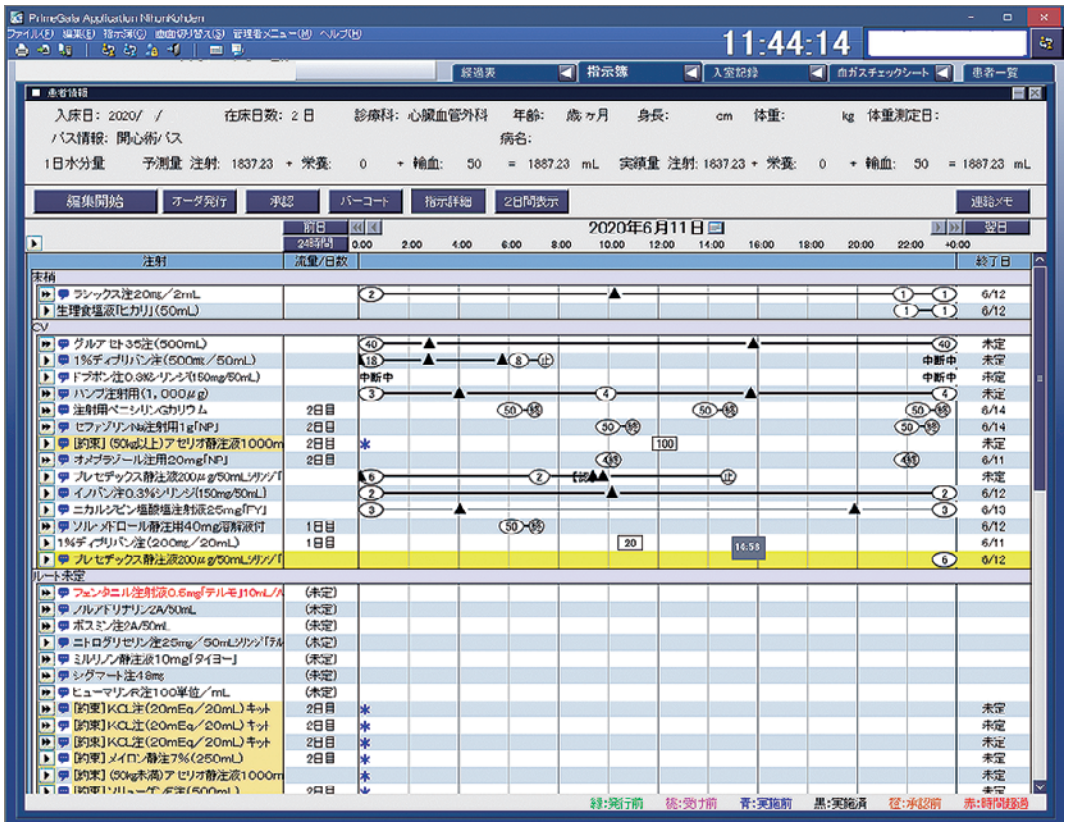

Figure 2. The screenshot of computerized physician order entry of the clinical information system in the intensive care unit.

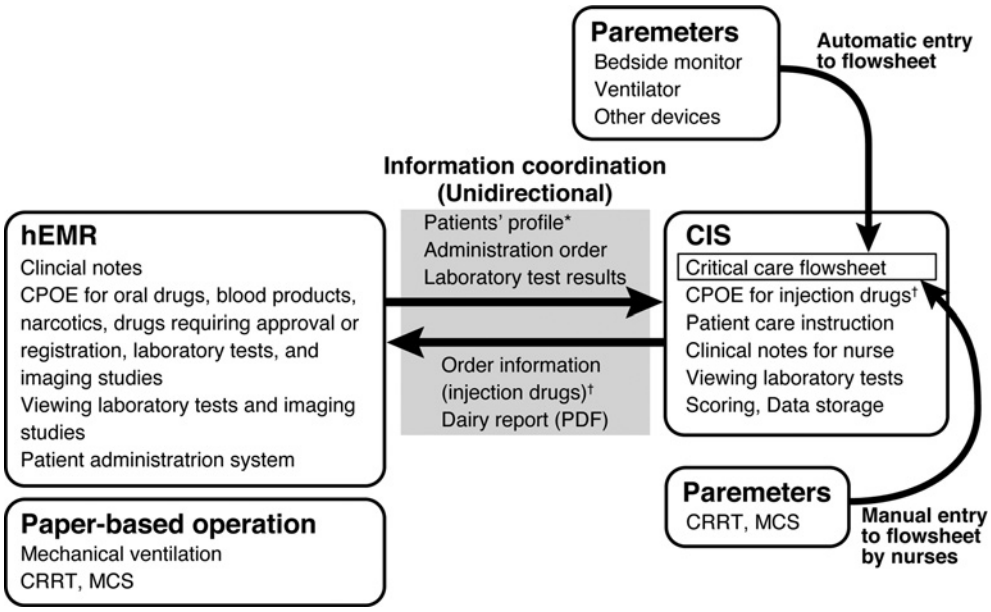

Figure 3. Relationship between the clinical information system in the intensive care unit and the hospital electronic medical record.

*Patients' basic profile is sent from the hEMR to CIS except for information on their allergies and contraindications.

†Blood products, narcotics, and drugs that require approval or registration (broad-spectrum antibiotics, drugs for chemotherapy, and rarely used drugs) need to be ordered in both hEMR and CIS. Each order was not coordinated.

CIS, clinical information system; CPOE, computerized physician order entry; hEMR, hospital electronic medical record; PDF, portable document format; CRRT, continuous renal replacement therapy; MCS, mechanical circulatory support.

Table 1. Classification of level of severity and influence of errors recommended by the National University Hospital Council of Japan.

Level	Continuity of injury	Severity of injury	Description
0			Error or malfunction in medicines and medical devices occurred but did not reach the patient
1	None		There was no actual harm to the patient (but there was a possibility of some influence)
2	Transient	Mild	Treatment was not required (enhanced patient observation, mild change in vital signs, examination for confirmation of safety, etc.)
3a	Transient	Moderate	Simple procedure or treatment was required (disinfection, poultice, skin suture, administration of analgesics)
3b	Transient	Severe	Substantial procedure or treatment was required (significant change in vital signs, use of mechanical ventilation, surgery, prolongation of hospital stay, hospitalization, fracture, etc.)
4a	Permanent	Mild-moderate	Permanent disability or sequelae remained without significant functional impairment or cosmetic problems
4b	Permanent	Moderate-severe	Permanent disability or sequelae remained with significant functional impairment or cosmetic problems
5	Death		Death (excluding those due to the natural course of the underlying disease)
Others			

Statistical analysis

Categorical variables are expressed as a frequency and percentage, and Fisher's exact test was used to analyze the significance. Continuous variables are expressed as the median (interquartile range). A non-parametric test (Mann-Whitney U) was used to assess continuous variables. Poisson distribution was used to calculate the 95% confidence interval (CI) of the incidence rate of events. A P-value < 0.05 was considered statistically significant. All statistical analyses were performed using the statistical software R (R Foundation for Statistical Computing, version 4.0.2).

Table 2. Patient demographic data.

	ICU	IMU	P-value
Number of patients admitted, n	1,046	1,439	
Total stay, patient-days	3,854	2,728	
Length of stay, day, median (IQR)	1.6 (0.9-3.0)	0.9 (0.7-1.9)	P < 0.001
Number of patients using the CIS, n (%)	942 (90.1)	1,278 (88.8)	
Duration of using the CIS, patient-days	3,200	2,311	
Treatment department, n (%)			P < 0.001
Cardiovascular surgery	324 (34.4)	307 (24.0)	
Neurosurgery	287 (30.5)	82 (6.4)	
Gastrointestinal surgery	74 (7.9)	319 (25.0)	
Thoracic surgery	131 (13.9)	70 (5.5)	
Urology and renal transplantation	42 (4.5)	245 (19.2)	
Endocrine surgery	6 (0.6)	141 (11.0)	
Miscellaneous surgery	25 (2.7)	64 (5.0)	
Medical	53 (5.6)	50 (3.9)	

CIS, clinical information system; ICU, intensive care unit; IMU, intermediate medical unit; IQR, interquartile range.

Results

From January to September 2019, the CIS was used for 942 (90.1%) of the 1,046 patients admitted to the ICU and 1,278 (88.8%) of the 1,439 patients in the IMU. The total stay in ICU and IMU was 3,854 and 2,728 patient-days, respectively, and the duration of CIS use was 3,200 and 2,311 patient-days, respectively (**Table 2**). The treatment department composition differed between the ICU and IMU. For patients treated in the ICU, the most common departments were cardiovascular surgery (34.4%), neurosurgery (30.5%), and thoracic surgery (13.9%), while for those treated in the IMU, the most common departments were cardiovascular surgery (24.0%), gastrointestinal surgery (25.0%), and urology (19.2%).

There were 122 and 140 errors in the ICU and IMU, respectively. The incidence rates of the total errors in the ICU and IMU were 31.7 (95% CI 26.4-37.8) and 51.3 (43.2-60.6) events per 1,000 patient-days, respectively. There were 17 (13.9%) and 15 (10.7%) CIS-related errors in the ICU and IMU, respectively. The incidence rates of errors in the ICU and IMU were 5.3 (3.1-8.5) and 6.5 (3.6-10.7) events per 1,000 CIS operation patient-days, respectively (**Table 3**). The proportion and incidence rate of CIS-related errors were not different between the ICU and IMU. Although the composition of the level of severity and influence of the total errors was significantly different between the ICU and IMU, the levels of most errors were 1, 2, and 3a. The levels of CIS-related errors were 0, 1, and 2. Approximately 40% of the errors related to the CIS occurred in patients who underwent cardiovascular surgery.

The quarterly incidence rates of the total errors and errors related to the CIS in the ICU and IMU decreased over time. The quarterly incidence rates of CIS-related errors in the first and third quarters were 11.7 (95% CI 4.7-24.0) and 3.8 (1.2-9.0) events per 1,000 CIS operation patient-days, respectively, in the ICU. The quarterly incidence rate was reduced by 68%. In contrast, the quarterly incidence rates of CIS-related errors in the first and third quarters were 16.1 (95% CI 6.5-33.2) and 6.1 (2.2-13.3) events per 1,000 CIS operation patient-days respectively, in the IMU. The quarterly incidence rate was reduced by 62%.

Most CIS-related errors occurred in the CPOE component (29/32). The major reasons for CIS-related errors were unfamiliarity with the software (11/32), inadequate coordination between the CIS and hEMR (11/32), specifications of the CIS (7/32), and others (3/32) (**Table 4**). The number of errors owing to unfamiliarity with the CIS and lack of coordination between the systems decreased with each quarter. Examples of CIS-related errors are shown in **Table 5**.

Discussion

In this study, we made three important clinical observations. First, 13% of the errors in the ICU and IMU were

Table 3. Errors that occurred in the ICU and IMU.

	ICU	IMU	P-value
Total number of errors	122	140	
Incidence rates, per 1,000 patient-days	31.7	51.3	
95% CI	26.3-37.8	43.2-60.6	
Level of severity and influence, n (%)			P < 0.001
Level 0	9 (7.4)	14 (10.0)	
Level 1	38 (31.1)	57 (40.7)	
Level 2	34 (27.9)	35 (25.0)	
Level 3a	32 (26.2)	15 (10.7)	
Level 3b	6 (4.9)	2 (1.4)	
Others	3 (2.5)	17 (12.1)	
Number of errors related to the CIS, n (%)	17 (13.9)	15 (10.7)	P = 0.55
Incidence rates, per 1,000 CIS operation patient-days	5.3	6.5	
95% CI	3.1-8.5	3.6-10.7	
Level of severity and influence, n (%)			P = 0.12
Level 0	3 (17.6)	6 (40.0)	
Level 1	11 (64.6)	4 (26.7)	
Level 2	3 (17.6)	5 (33.3)	
Treatment department, n (%)			P = 0.61
Cardiovascular surgery	9 (52.9)	6 (40.0)	
Neurosurgery	2 (11.8)	0 (0.0)	
Gastrointestinal surgery	3 (17.6)	3 (20.0)	
Thoracic surgery	0 (0.0)	0 (0.0)	
Urology and renal transplantation	1 (5.9)	2 (13.3)	
Endocrine surgery	0 (0.0)	2 (13.3)	
Miscellaneous surgery	1 (5.9)	0 (0.0)	
Medical	1 (5.9)	2 (13.3)	

CIS, clinical information system; ICU, intensive care unit; IMU, intermediate medical unit.

Table 4. Major reasons for CIS-related errors.

Causes, n (%)	JAN-MAR 2019	APR-JUN 2019	JUL-SEP 2019	JAN-SEP 2019
Unfamiliarity with the software	8 (57.1)	2 (28.6)	1 (9.1)	11 (34.4)
Inadequate coordination	6 (42.9)	3 (42.9)	2 (18.2)	11 (34.4)
Specifications of the CIS	0 (0.0)	2 (28.6)	5 (45.5)	7 (21.9)
Others	0 (0.0)	0 (0.0)	3 (27.3)	3 (9.4)
	14	7	11	32

CIS, clinical information system.

related to the CIS, and the incidence rates of CIS-related errors did not depend on the composition of the treatment departments or staffing intensity of both care units. Second, the incidence rate of CIS-related errors decreased over time. Third, most CIS-related errors were attributed to the CPOE component. The major reasons for CIS-related errors were unfamiliarity with the software, inadequate coordination between the CIS and hEMR, and specifications of the CIS.

Thirteen percent of the errors in the ICU and IMU were related to the CIS during the initial launch phase at our hospital, and the incidence rates of CIS-related errors did not depend on the composition of the treatment departments and staffing intensity of the care units. The incidence of errors in ICUs differs among studies. In a previous study on the incidence and nature of adverse events and medical errors in an ICU and coronary care unit, the incidence rate of adverse events was 80.5 events per 1,000 patient-days.[12] Another study reported that the incidence rate of sentinel events in an ICU was 38.8 (95% CI, 34.7-42.9) per 100 patient-days.[13] Medication is a common cause of errors in ICUs, with incidence rates ranging from 1.2 to 947 errors per 1,000 patient-days.[12-16] In contrast, there are little data on the incidence of CIS-

Table 5. Examples of CIS-related errors.

Unfamiliarity with the software	
Case 1	When a doctor ordered another drug, methylprednisolone, which had already been administered, was reordered accidentally and administered.
Case 2	A doctor ordered to change the infusion rate from 150 to 80 mL/h on the CIS, but the water balance was not calculated correctly because a nurse did not perform the "execution" procedure, and the order was not reflected in the balance calculation.
Inadequate coordination between the CIS and hEMR	
Case 3	A non-steroidal anti-inflammatory drug was administered to a patient with renal dysfunction because allergy and contraindication information was not coordinated between the CIS and hEMR.
Case 4	Orders for drugs that required an order from both the CIS and hEMR differed between the two systems.
Specifications of the CIS	
Case 5	A doctor mechanically performed the "continuation of orders" procedure for the next day without considering the need for drugs. Consequently, unnecessary orders were continued.
Case 6	The infusion rate on the infusion labels was not updated with changes in the infusion rate on the CIS. A nurse set the infusion rate before the change was scheduled to occur by only confirming it on the labels. The regulations of our ICU require nurses to check the infusion rate on the CIS.

CIS, clinical information system; hEMR, hospital electronic medical record; ICU, intensive care unit.

related errors. Given that most CIS-related errors were attributed to the CPOE component in the present study, the results of studies on CPOE may be extrapolated. Incidents associated with CPOE were reported to be 13% of all incidents in medical ICUs and 6% in surgical ICUs.[17] A study on duplicate medication order errors after CPOE implementation found that the incidence rate of duplicate medication orders increased from 11.6 errors per 1,000 patient-days to 41.6 errors per 1,000 patient-days.[18] There are also few studies on the impact of CIS implementation and CIS-related errors on clinical outcomes. As a result of the introduction of CPOE, there has been a meta-analysis that found a 12% reduction in ICU mortality rates and no change in ICU length of stay, while there has been a report of an unexpected increase in mortality in a pediatric ICU.[7, 8]

Despite introducing a new system, errors occurred less frequently in our study compared with those in previous studies. One possible explanation is that the implementation project team worked effectively. Our project team comprised physicians, nurses, pharmacists, and clinical engineers working in the ICU and hospital system engineers. The team had a meeting once a week to discuss the implementation, nature of errors, and preventive measures and make decisions regarding the system and operational changes. The team also prepared hands-on briefing sessions and manuals. In addition, our nurses and physicians working in the ICU and IMU adapted rapidly to the new system. Generally, the resistance of clinicians to changes in their routine practice is a common problem encountered with the implementation of CIS in ICUs.[19] However, our staff worked hard to get accustomed to the system quickly through pre-deployment simulation training and bedside on-the-job training. Consequently, the number of errors was low.

CIS-related errors were more common for patients who underwent cardiovascular surgery in both units. Errors in the administration of parenteral drugs in ICUs have been reported to be associated with specific classes of drugs, including vasopressors and catecholamines, sedation and analgesia, antimicrobial, coagulation related, electrolytes, and insulin.[15] Since all of these drugs are usually used in patients after cardiovascular surgery, and dosage changes are frequent, the risk of error would be high. Therefore, we implemented the CIS for use with cardiac surgical patients last. This step-by-step approach may have also contributed to fewer errors.

In this study, the reduction rate of errors was confirmed to be over 60% in 9 months. This is the first report of the error rate reducing after implementing a CIS in an ICU. The project team also contributed to this reduction by modifying the system and operational procedures after the system worked. Furthermore, for smooth adaptation, we opted for a step-by-step implementation despite the risk of mixing the two systems considering the heterogeneity of patients, physicians, and nurses in the ICU and IMU.

The major reasons for the CIS-related errors were unfamiliarity with the software, inadequate coordination between the CIS and hEMR, and specifications of the CIS. CIS may induce new errors owing to software design flaws, poor system usability, poor system performance,

inappropriate workflows, poor decision support, inadequate user training, human error, and using the system in ways not intended by the system developer.[6, 10] Training, maintenance of manuals, and operability improvement may be effective in reducing errors related to unfamiliarity. It has been reported that differences in the user interface of hEMR affected task load and error rates.[9] In addition to these measures, the workflow and ordering policies in the ICU should be reviewed for compatibility with the system because system modifications and operational training have limitations, and it is often easier to change the rules for smooth system operation. Meanwhile, the lack of coordination between the CIS and hEMR resulted in a number of errors in the present study. In Japan, information coordination between CIS and hEMR is limited owing to differences in data formats and a lack of channels for data communication. Absence or incomplete integration among hospital databases is considered one of the major obstacles in improving workflow.[20] Since the improvement of information coordination cannot be achieved in a short period, we have no choice but to take measures such as standardization of handover and confirmation of orders by multiple professionals. It appears that an integrated system is required to solve the problem of insufficient coordination between CIS and hEMR, reduce errors, improve quality, and optimize workflow.[20]

There are several risk factors for unsuccessful implementation, including a lack of commitment from management, poorly perceived system usefulness, project ambiguity, and misalignment of a system with local practice processes.[6] In addition, although the specifications and usability of the system tend to be focused on when implementing CIS, it is important to not only design the system but also know how it is implemented, how it coordinates with clinical processes and workflows, and how users use it in routine clinical care to prevent medical errors.[10] Successful implementation requires changes in the way health care professionals think and act, i.e., the standardization of orders from physicians, the abandonment of personal style, and the development of trust in the system.[21]

This study had several limitations. First, this study was conducted in a single institute. As working setting and resources in ICUs differ among hospitals, different errors may occur in the same system. Second, there were limitations to the voluntary self-reporting system. Since reporting of errors is dependent on the ICU staff involved in errors, all errors may not be reported. Consequently, small errors might be underreported, and some bias can occur. Third, the results of this study could apply only to a single system, and a single combination of CIS and hEMR. There are many CIS and hEMR systems in use. Furthermore, the settings in which the system is used vary by ICU and hospital, and the system and coordination between systems are usually customized. Therefore, it is expected that the number and/or type of errors will be different among hospitals.

Conclusion

Our study revealed that 13% of errors in the ICU and IMU were related to the CIS and that the incidence did not vary with the composition of treatment departments and staffing intensity of both care units. The incidence rate of CIS-related errors decreased over time. During the initial implementation, CIS-related errors occurred because of unfamiliarity with the software, inadequate coordination between the CIS and hEMR, or the specifications of the CIS. Finally, the formation and effective operation of our multidisciplinary implementation project team seems to have been useful in minimizing errors during the CIS implementation.

Conflicts of Interest: The authors declare that there are no conflicts of interest regarding the publication of this article.

Author Contributions: YS managed the implementation of the system, designed the study, collected and analyzed the data, and wrote the manuscript. NS and MI helped to manage the implementation of the system and prepare the manuscript. TN helped to design the study and reviewed the manuscript.

Acknowledgments: The authors would like to thank all of the nurses and doctors in the ICU and IMU at Tokyo Women's Medical University for implementing the CIS while having heavy workloads and improving the system. The authors would also thank the pharmacists in the ICU and IMU for their daily review of drug orders and advice to avoid errors during the system implementation period. The authors specifically thank Masako Shimada, Atsuko Suzuki, Sonomi Kurita (head nurses of units), Satoko Konuma (chief nurse of IMU), Haruka Yoshida (nurse of ICU), Harumi Suzuki (head

nurse of clinical path office), Yujiro Geka (pharmacist in units), Toru Sorimachi (hospital information technology department), Hirofumi Yoshioka, Hitoshi Terasaki (Department of Patient Safety Management), Yujiro Narita, Yasuhito Mori, Kumiko Hayashi, and Shinichi Saeki (Nihon Kohden Corporation).

We would like to thank Honyaku Center Inc. (www.honyakucenter.jp) for English language editing.

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