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ORIGINAL PAPER

Applying HFMEA to Prevent Chemotherapy Errors

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Abstract To evaluate risk and vulnerability in the chemotherapy process using a proactive risk analysis method. Healthcare failure mode and effect analysis (HFMEA) was adopted to identify potential chemotherapy process failures. A multidisciplinary team is formed to identify, evaluate, and prioritize potential failure modes based on a chemotherapy process flowchart. Subsequently, a decision tree is used to locate potential failure modes requiring urgent improvement. Finally, some recommended actions are generated and executed to eliminate possible risks. A total of 11 failure modes were identified with high hazard scores in both inpatient and outpatient processes. Computerized physician order entry was adopted to eliminate potential risks in chemotherapy processes. Chemotherapy prescription errors significantly decreased from 3.34% to 0.40%. Chemotherapy is regarded as a high-risk process. Multiple errors can occur during ordering, preparing, compounding, dispensing, and administering medications. Subsequently, these can lead to serious consequences. HFMEA is a useful tool to evaluate potential risk in healthcare processes.

Keywords Healthcare failure mode and effect analysis (HFMEA) · Chemotherapy process · Risk analysis · Computerized physician order entry

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Introduction

Chemotherapy process is regarded as potentially risky for patients because of its complex processes, multiple drug uses, provision of dangerous compounds, and high utilization rates in outpatient departments. Typically, chemotherapy is administered as an infusion of a potent and potentially toxic drug solution. Doses are computed based on body weight or other factors and are usually adapted to body surface area or renal function of patients. Errors in multiple-dose administration can result in catastrophic reaction or death [1]. Some chemotherapy errors occur because of understaffing, poor communication, human error, fatigue, or environmental factors [2]. Possible errors listed by Schulmeister [3] include underdosing and overdosing, scheduling and timing errors, administering incorrect drugs or hydration, improperly preparing drugs, and giving chemotherapy to the wrong patient. For patient safety, an effective risk analysis method to reduce error rates of the chemotherapy process should be prioritized in medical clinics and hospitals.

Chemotherapy errors affect patient health: thus they should not be ignored. According to Greenall [4], chemotherapy ordering, preparing, dispensing, and administering are highly connected and susceptible to errors. Hence, recognizing and preventing potential failure modes in the chemotherapy process are essential. Our research hospital collected data from 22,550 inpatient and outpatient prescriptions (2007 to 2009) and found a chemotherapy prescription error rate of 3.34%. Although most adverse effects were near-miss events, the chemotherapy process remains a high-alert medication process and thus requires an effective proactive risk analysis method in order to avoid errors. Failure mode and effect analysis (FMEA) is a systematic and prospective risk evaluation method initially adopted in the industrial field. Notably, its administration outcomes are excellent. Recently, the concept of risk prevention has been adopted with the introduction of the healthcare mode and effect analysis (HFMEA), and since then has been used to reduce medication errors.

FMEA has been widely used by engineers to improve the reliability, quality, and safety of their products and to reduce potential risks [5, 6]. The most important function of FMEA is to identify potential failure modes for each subsystem or component. A risk priority number (RPN) is determined by multiplying three risk parameters in the following formula: RPN = $S \times O \times D$, where S is the severity rate, O is the occurrence rating, and D is the detection rating.

In 2000, the US Joint Commission on Accreditation of Healthcare Organizations (JCAHO) promoted HFMEA in their prospective analysis of healthcare processes in order to prevent possible medication errors. Since 2002, JCAHO has been requesting its subordinate medical institutions to analyze at least one high-risk medical process per year [7]. Subsequently, prospective risk analysis has been popularized in medical operations [8, 9]. Risk evaluation indexes used in FMEA were modified substantially for HFMEA. Hazard scores are now used in HFMEA in order to prioritize failure modes and to determine recommended actions based on decision tree analysis.

Methods

Study design

This study applied HFMEA to the chemotherapy process at Cathay General Hospital, a 600-bed university-affiliated medical center located in Downtown Taipei, Taiwan. The research hospital has expected a significant reduction in chemotherapy prescription errors with the adoption of preventive actions.

Duration

The implementation of HFMEA began in July 2007 with the formation of the HFMEA team. Meetings lasting approximately 1½ hours were conducted monthly. The entire project involved 12 meetings, comprising more than 140 h.

HFMEA application

Team

An eight-member multidisciplinary team was formed to implement HFMEA. With a medical vice-superintendent functioning as the project leader, the team comprised of individuals from the quality management center, cancer prevention committee, and relevant departments, including information technology, nursing, and pharmacy. The team was supervised by two external process engineers from the National Tsing Hua University to provide guidance in the detailed steps of HFMEA. Individuals from the quality management center, cancer prevention committee, nursing, and pharmacy departments were responsible for drawing the whole procedure of chemotherapy process. The information technology department was in charge of the data collection and possible computer-based support.

Procedure

The HFMEA procedure examine the potential failures in the chemotherapy was adopted from the HFMEA guidelines [14]. The following are the key steps in the HFMEA process:

Step 1. Define the HFMEA topic.The topic should be of high risk or worthy to invest resources in.

Step 2. Assemble the team.The multidisciplinary team is organized to deal with the missions of HFMEA. The team should include subject matter experts and an advisor to ensure that various perspectives are considered.

Step 3. Graphically describe the process.The HFMEA team draws a full description of the chemotherapy medication process and constructs a flow diagram. The diagram should identify all subprocesses and consecutively enumerate these subprocess steps.

Step 4. Conduct a hazard analysis.All possible failure modes for each of the subprocesses should be listed and numbered consecutively. Various sources and tools can be used for identifying potential failure modes, such as brainstorming, cause-and-effect diagramming, root cause analysis, working

experience, and reference to other medical clinics. Thereafter, determine the severity and probability of the identified potential failure modes. In general, the severity score is a measure of how a potential failure would affect patients or patient care. Ratings are divided into four degrees: catastrophic, major, moderate, and minor. Probability is a measure of the frequency of potential failure. Accordingly, probability ratings are made based on the definitions published of Derosier et al. (2002): frequent (several times in 1 year), occasional (several times in 2 years), uncommon (sometimes in 2 to 5 years), and remote (sometimes in 5 to 30 years). Severity multiplied by probability refers to hazard score. When hazard score equals or exceeds 8, the failure mode is regarded as high risk and further analysis is warranted. The HFMEA decision tree is used to determine whether the failure mode warrants further action. In making a decision tree, all potential causes for each identified failure mode are listed first. A single weakness point indicates that if this part of the process fails, the entire system will fail; meaning that the component in question is critical for the entire system. An effective control corresponds to a design that can eliminate or significantly reduce the possibility of failures. Detectability measures the likelihood of detecting failure or the effect of failure before it occurs.

Step 5. Actions and outcome measuresA description of actions should be developed, and outcome measures for each failure mode should be recognized. In addition, the individuals responsible for implementing and ensuring the completion of each action should be identified. Recommended actions are submitted to the top managements of the hospital after which they would consider the feasibility of the recommendations based on available resources, financial consequences, and other issues required for the implementation of a quality improvement campaign. After implementing the actions, it is important to ascertain whether these actions have actually resulted in improvements. HFMEA defines the recurrence of adverse events and reassesses hazard score as outcome endpoints.

Results

Process map

A process map (Fig. 1) divides the chemotherapy process into inpatient and outpatient components. Only one difference can be observed. In the outpatient setting, prepared medication does not need to be transported to patients because the administration room is next to the preparation room.

Baseline HFMEA

The HFMEA team have discussed the inpatient and outpatient chemotherapy processes in detail and analyzed the severity and probability of each failure mode in order to determine recommended actions. Table 1 summarizes the decision tree used to determine whether recommended actions were necessary.

By brainstorming, the HFMEA team summarized 15 potential causes that could result in 7 failure modes in the inpatient process. Similarly, the team identified 11 potential causes that could result in 4 failure modes in the outpatient process. The results of the decision tree showed 14 potential causes that must be addressed. Figure 2 shows the potential causes that needed correction or prevention. The team recommended three actions to the hospital management for approval: (1) adopting an appropriate computerized physician order entry (CPOE) system; (2) the use radiofrequency identification (RFID) or bar codes in verifying patients and medications, and (3) constructing an automatic alert system for detecting medication exosmosis.

The top management selected CPOE as the initial improvement campaign. Because of finite resources and possible ward renovation, RFID and automatic alert system will be considered in the future.

Recommended CPOE system

The CPOE system prototype was built in March 2008. Pilot testing was set for one month. Based on end-user requirements, the system had to perform the following: (1) check past medication administration sheets, (2) calculate the dosage of medications based on body surface area, (3) search for laboratory information system in order to provide liver or renal function insufficiency alerts, and (4) automatically show medication quantity (vial, ampule, or pill) according to required dosages.

The formal CPOE system was released in April 2008, when its accompanying user manual was delivered. All physicians were required to establish their chemotherapy protocols. Handwritten prescriptions for chemotherapy were prohibited, and all chemotherapy orders had to go through the system. HFMEA hazard scores were reassessed six months after CPOE implementation. In accordance with limited CPOE recommendatory approval by the top management, the reassessment considered only potential causes of failure modes.

As mentioned earlier, in general, the CPOE system checks past medication administration sheets, selects pro-

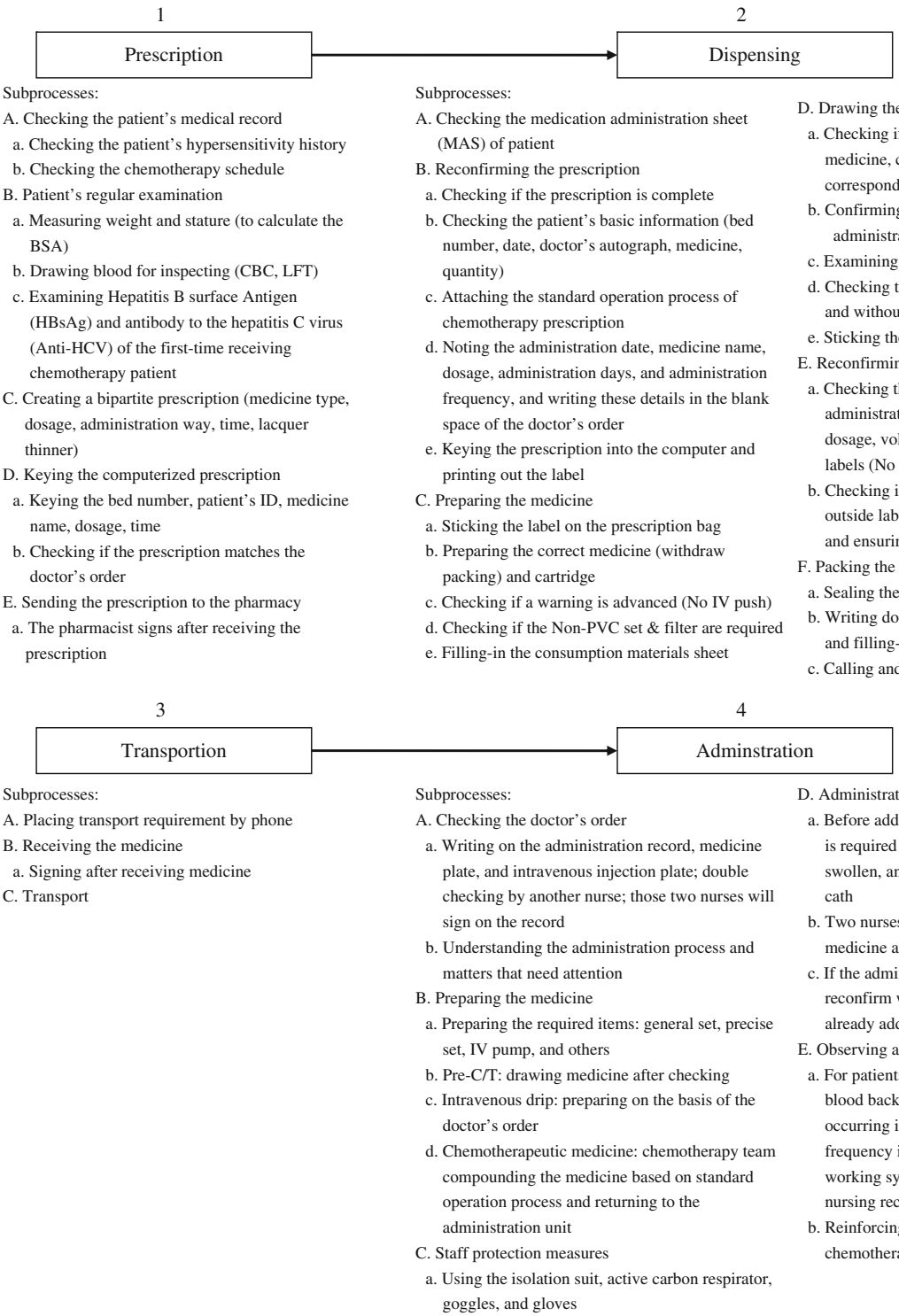

Fig. 1 Inpatient chemotherapy process

tocols, and automatically calculates body surface areas and dosages. These interfaces are shown in Fig. 3. Incorporated as well is a liver and renal alert system to remind prescribing physicians about patient functions, and to prevent overdosing.

The Chi-square goodness of fit test was used to illustrate the difference among three conditions, namely "Before CPOE", "After CPOE", and the "Liver/Renal Alert System". The analyzed results in Table 2 show that these three conditions are significantly different ($P<0.05$). In addition,

Table 1 HFMEA inpatient chemotherapy process decision tree

HFMEA Step 4—Hazard Analysis									HFMEA Step 5—Identify Actions and Outcomes				
Failure Modes: First evaluation failure mode before determining potential causes	Potential Causes		Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Detectable?	Proceed?	Action Type (Control, Accept, Eliminate) or Rationale for Stopping	Action	Outcomes Measure	Person Responsible
1C The prescription is obscure and/or wrong	→		Cat.	Occ.	12	→	N	N	Yes				
	1C I	The handwriting of prescription is blurred	Ma.	Fre.	12	→	N	N	Yes	Eliminate	Adopt the chemotherapy computerization physician order entry (CPOE)	CPOE completion date	Information department
1D The computerized prescription is wrong	→		Cat.	Occ.	12	→	N	N	Yes				
	1D I	There are versions of computerized prescriptions and each version is different	Cat.	Fre.	16	→	N	N	Yes	Control	Set the chemotherapy medication protocol	The number of setting protocols	Cancer committee
	1D II	The previous data was not deleted and was easily confused with the newest data	Cat.	Occ.	12	→	N	N	Yes	Eliminate	CPOE can show the past MAS	The function of checking the past MAS	Information department
	1D III	Personal key in error	Ma.	Rem.	3	Y	N	N	Yes	Control	Adopt the chemotherapy CPOE	Chemotherapy prescription error rate	Information department
2Be While inputting data, the dosage of medicine was erroneously keyed	→		Cat.	Occ.	12	→	N	N	Yes				
	2Be I	The decimal point key in error	Min.	Occ.	3	Y	N	N	Yes	Eliminate	CPOE can automatically calculate required medicines on the basis of patient's features (stature, weight, etc.)	The function of automatically calculating the required medicines	1. Pharmacy department 2. Information department
	2Be II	When calculating the required dosage, the staff fills in wrong data	Cat.	Occ.	12	→	N	N	Yes	Eliminate			
	2Be III	The mistake of seeing the wrong decimal point	Cat.	Rem.	4	Y	N	N	Yes	Eliminate			
	2Be IV	The staff is getting the incorrect total amount of medicines	Cat.	Rem.	4	Y	N	N	Yes	Control	Employ the bar code taking required medicines	The frequency of taking incorrect medicines	
3Ba The transporter take back the wrong box when the medicine is empty	→		Mod.	Occ.	6	N	→	→	N				
	3Ba I	The transporter does not know if the cartridge is empty or not	Mod.	Unc.	4	N	→	→	N				
3Ba The medicine is allotted to the wrong sickroom	→		Cat.	Unc.	8	→	N	N	Yes				
	3Ba I	The transporter takes multiple medicines simultaneously and allots them to the incorrect sickroom	Mod.	Unc.	4	Y	N	N	Yes	Control	Enforce training for transporter	The frequency of allotting incorrect medicines	Nursing department

Table 1 (continued)

HFMEA Step 4—Hazard Analysis									HFMEA Step 5—Identify Actions and Outcomes				
Failure Modes: First evaluation failure mode before determining potential causes	Potential Causes		Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Detectable?	Proceed?	Action Type (Control, Accept, Eliminate) or Rationale for Stopping	Action	Outcomes Measure	Person Responsible
4Db Vital information are not verified	→		Cat.	Occ.	12	→	N	N	Yes				
	4Db I	The process is complicate and difficult to execute	Ma.	Unc.	6	Y	N	N	Yes	Control	Adopt RFID or bar code system	System completion date	1. Nursing department 2. Information technology department
	4Db II	Because of too many affairs, the staff forgets to verify vital information before administrating medication	Ma.	Unc.	6	Y	N	N	Yes	Accept	Enforce training and education of staff	The number of unverified the patient information	Nursing department
4E After injecting medicine into patient, the staff does not notice that exosmosis has occurred	→		Cat.	Occ.	12	→	N	N	Yes				
	4E I	The staff leaves immediately after injecting medicine and does not monitor the condition of patient	Cat.	Unc.	8	→	N	N	Yes	Accept	Enforce training and education of staff	The rate of medicine exosmosis	Nursing department
	4E II	Over the span of time of injecting medicine, exosmosis occurred	Cat.	Unc.	6	Y	N	N	Yes	Control	Add an automatic alert system to prevent the exosmosis situations	The rate of medicine exosmosis that occurred after staff leaves	
	4E III	Exosmosis occurred because the patient turned around	Cat.	Occ.	12	→	N	N	Yes	Control		The rate of medicine exosmosis caused by the patient turning	

Ca. catastrophic; *Ma.* major; *Mo.* moderate; *Mi.* minor; *Fr.* frequent; *Oc.* occasional; *Un.* uncommon; *Re.* remote

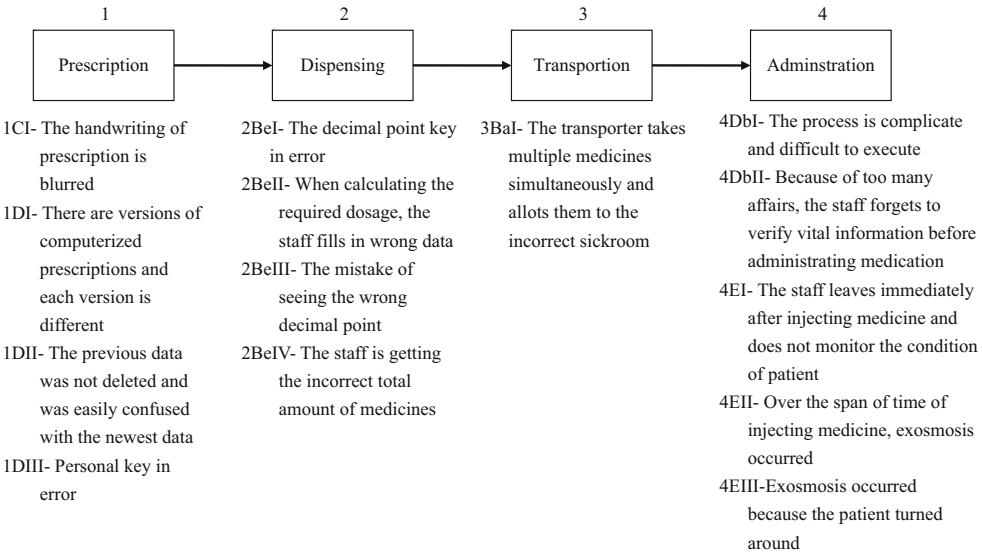

Fig. 2 Potential causes of failure modes in the inpatient chemotherapy process

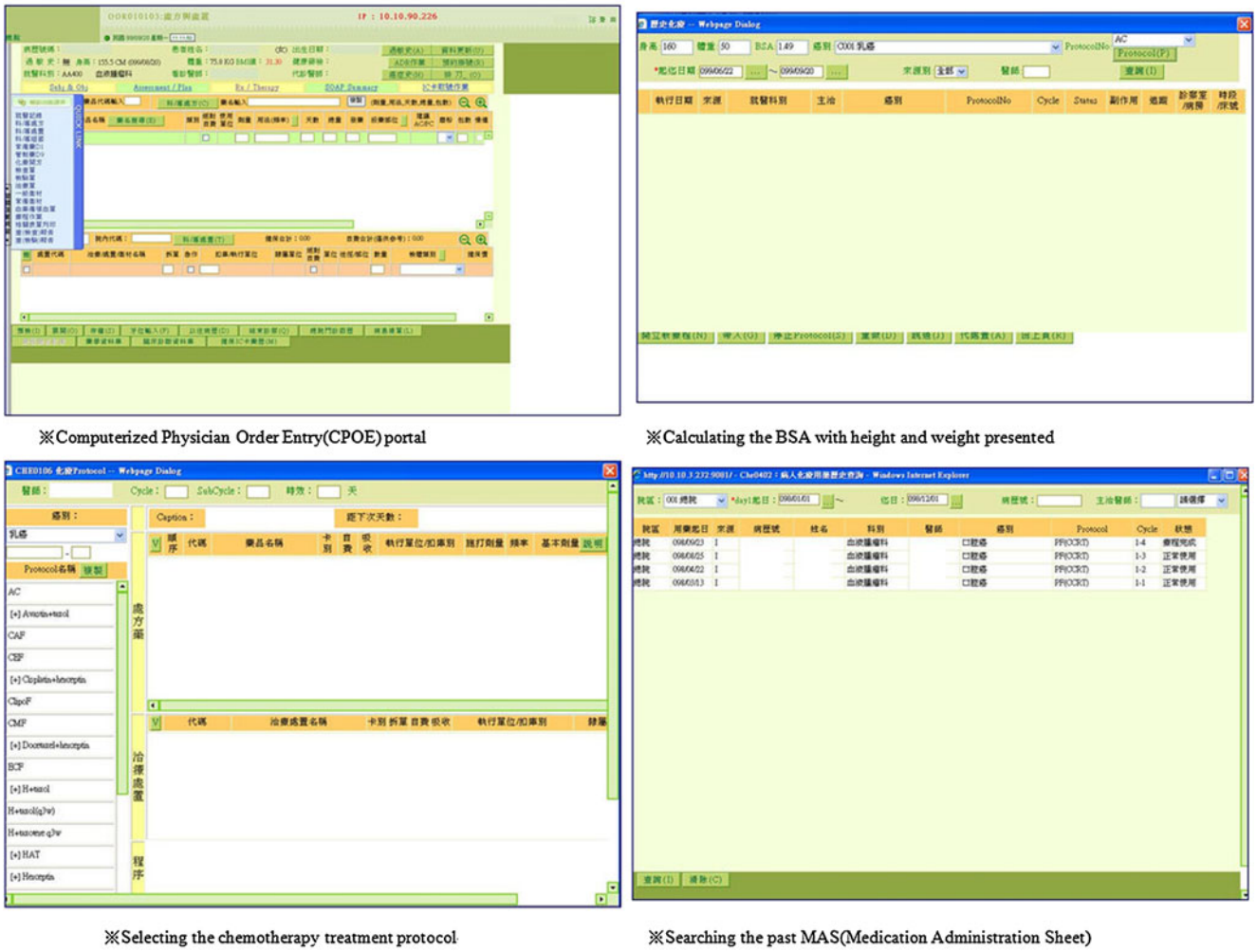

Fig. 3 CPOE system interfaces

Table 2 Reduction in Chemotherapy Prescription Errors (2007/6–2009/8)

	Before CPOE (2007/6–2008/4)			After CPOE (2008/5–2009/5)			Liver/Renal Alert System (2009/5–2009/8)			*P* Value
	Prescription	Error	Error Rate (%)	Prescription	Error	Error Rate (%)	Prescription	Error	Error Rate (%)	
Division										0.001*
General Surgery	1752	37	2.1	2029	8	0.4	667	1	0.1	
Hematology	4380	72	1.6	5976	19	0.3	2308	1	0.04	
Liver Center	37	8	21.6	199	3	1.5	28	0	0	
Urology	494	4	0.8	552	4	0.7	156	0	0	
OB/GYN	1541	151	9.8	1320	6	0.5	622	2	0.3	
Immunology	66	6	9.1	67	0	0	17	0	0	
Pediatrics	40	3	7.5	19	1	5.3	1	0	0	
Service										0.04*
Ambulatory	3686	41	1.1	4088	12	0.3	1318	0	0	
In-patient	4731	240	5.1	6185	29	0.5	2542	4	0.2	

*$p<0.05$

the chemotherapy error rate significantly decreased from 3.34% to 0.40%. The improvement affirms the effectiveness of the CPOE system in reducing medication errors.

Discussion

The chemotherapy process starts with prescription, dispensation, and delivery, and then ends with administration. Each step is highly risky for patients and can cause significant harm, which sometimes can be lethal. Some studies [10–12] have reported chemotherapy error rates ranging from 0.45% to 15%, with a mean error rate of 3.34% for research hospitals even before improvement has been initiated. Introduction of the CPOE system has decreased the error rate from 15% to 5% (compared with an error rate of 13.5% for handwritten prescriptions) in one study [10]. In 2003, the Institute for Safe Medication Practices [13] reported that cancer chemotherapy tops the list of high-alert medications, outranking intravenous potassium chloride and insulin as potential threats to patient safety. The volume of patients with cancer and the repetition of chemotherapy-related adverse events have prompted research hospitals to prioritize chemotherapy process safety and to adopt immediate amendment.

In the summer of 2001, the Veterans Affairs National Center for Patient Safety [14] extensively reviewed the FMEA system used in engineering and then modified it for healthcare. HFMEA is a proactive analysis tool to calculate systematically any potential process risks using a two-variable equation. Since then, JCAHO Standard LD.5.2 has required facilities to select on annual basis at least one high-risk process for proactive risk assessment. It has been uniformly agreed that HFMEA is a useful tool for systematic analysis, prioritization of recommended actions, and identification of unrecognized errors [15–19]. However, only few effects of HFMEA have been reported in those studies, most of which describe the applications of the tool rather than focusing on the generated improved actions.

In 1996, the American Society of Health-System Pharmacists [20] proposed the following seven measures to prevent medication errors in cancer chemotherapy: educate healthcare providers, verify the dose, establish dosage limits, standardize the prescribing vocabulary, work with drug manufacturers, educate patients, and improve communication. In the past, verifying the dose, establishing dosage limits, and standardizing the prescribing vocabulary depended on healthcare personnel (physicians, pharmacists, and nurses) in preventing potential errors. With the advancement of healthcare information technology, hardware and software became available for healthcare organizations, which altogether facilitated a safe environment for patients. Studies have demonstrated the progress and effect of computerization in reducing chemotherapy error rates. According to Voeffray et al [10], errors have decreased from 15% (141 of 940) to 5% (75 of 1505) after implementation of CPOE, with a 13.1% error rate for handwritten prescriptions (22-fold higher than the error rate for computerized prescriptions). According to Kim et al. [21], with CPOE deployment in pediatric oncology, significant reduction in the overall error rate has been documented, such as fewer daily chemotherapy orders with

improper dosing, incorrect dosage calculations, missed cumulative dose calculations, and incomplete nursing checklists.

The chemotherapy process at our hospital used to comprise several risky procedures, including human key-in error, incorrect dosing calculation, and reliance on personnel to prevent errors. With the application of HFMEA and a dedicated multidisciplinary team, our hospital has identified potential risks, although there were some difficulties in applying this tool. For example, a couple of months were required before the initial analysis was completed. In addition, implementing the recommended actions was longer than expected. Moreover, a consensus was sometimes difficult to reach among team leaders coming from the different disciplines. Changing the work process (especially moving from handwritten to computerized orders) has elicited strong negativity from physicians and led to increased errors during the learning curve. Despite these difficulties, HFMEA reduced chemotherapy errors at our hospital effectively.

In conclusion, the complexity of chemotherapy renders it vulnerable to error, and the consequences can be catastrophic. With introduction of HFMEA and CPOE, we have reduced the error rates of chemotherapy prescriptions at our hospital from 3.34% to 0.40%. Evidently, HFMEA is a useful tool to evaluate potential risks in healthcare processes, and CPOE is an effective technology to prevent human errors.

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