Risk Analysis of Pediatric Chemotherapy Processes

Principal Investigator: Jerry L. Shenep, MD
Co-Investigator: Donald K. Baker, PharmD
Co-investigator: John Rodman, PharmD
Co-investigator: Ivy Cole, MBA
Oncologist: Gregory Hale, MD
Oncologist: Sheri Spunt, MD
Oncology Nurse: Alice Morrell, RN
Clinical Pharmacist: Richard Clark, PharmD
Pharmacy Informatics Specialist: Bruce Warren, MS
Project Manager: Brian Barnes, MBA
Re-engineering Analyst: Don Sanderlin, MBA
Re-engineering Analyst: Teresa Browning, RN, MBA
QI/Performance Improvement Specialist: Daphne Willis, MSA
Clinical Research Specialist: Cheryl Chanaud, PhD
Statistician: Shesh Rai, PhD

St. Jude Children's Research Hospital
332 North Lauderdale Street
Memphis, Tennessee 38105-2794

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Abstract

Purpose: To formally evaluate the risks associated with each step of a complex chemotherapy process for possible failure points before and after utilization of a commercially available integrated CPOE system at a leading children's cancer center.
Scope: Before implementing CPOE systems in complex treatment areas such as oncology, all aspects of the meds process require careful analysis to ensure that the risk of error actually will be reduced.
Methods: FMEA was used to evaluate each step of the chemo meds process based on the consequences of the failure, likely frequency of the failure, and likelihood that the failure would be detected.
Results: The chemotherapy process used at SJCRH includes multiple layers designed with patient safety in mind. Beginning with approved preprinted order sheets, the process includes multiple redundant checks for protocol compliance, dosage recalculation by nurses and pharmacists, transcription into a pharmacy computer system, and administration documentation on standardized forms. Due to software development delays, an FMEA of the proposed future electronic process was assessed only in components of the CPOE system, not in a fully integrated system.
Conclusions: A commercially available software system designed to accomplish CPOE, automated safety checks, pharmacy dispensing, and electronic documentation of medication administration was examined in a pediatric oncology setting to determine if its available series of integrated applications is as safe as a long-established paper-based process with multiple redundant checks. Based on initial assessment of the individual components of the system, an integrated system, once available, appears promising. Further evaluation is needed.

Key Words: chemotherapy, computerized physician order entry (CPOE), electronic orders, patient safety, failure modes and effects analysis (FMEA)

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Purpose

A primary goal of patient care is to ensure the delivery of safe and effective therapies. In the field of oncology, in which chemotherapy medications typically have narrow therapeutic indices, the potential to compromise patient safety through medication errors is especially high. The chemotherapy medications processes used in hospitals and outpatient settings can be quite complex because of the need for multiple redundant checks to prevent errors from reaching patients. St. Jude Children's Research Hospital (SJCRH) is a pediatric research center devoted to finding cures and providing treatment for children with catastrophic diseases. The possible points of failure for the current chemotherapy medications process at SJCRH (handwritten orders, transcription into pharmacy information system, handwritten documentation of administration) and the anticipated chemotherapy medications process after implementation of a commercially available "computerized physician order entry" (CPOE) system integrated with the pharmacy information system and electronic medication administration documentation system were compared and contrasted to evaluate the benefits and risks of electronic chemotherapy orders.

Hypothesis: The overall risk of a critical failure occurring within the chemotherapy medications process at a children's cancer research center will be reduced with the implementation of CPOE integrated with a pharmacy information system and electronic medication administration documentation (integrated CPOE).

Aim 1. A formal risk assessment analysis of chemotherapy medication administration processes was undertaken using Failure Mode and Effects Analysis (FMEA).

- 1.1 The risks associated with each step of a complex chemotherapy medications process were identified and documented for the current paper-based system and planned CPOE system fully integrated with a pharmacy information system and electronic medication administration record.
- 1.2 Possible failure points before and after the planned use of an integrated CPOE system were assessed, prioritized, and compared.

Aim 2. Approaches to eliminate identified risks of the chemotherapy CPOE process were developed and assessed in a test environment prior to final comparison of identified risks of chemotherapy administration with integrated CPOE versus our current paper-based process.

Based on the results of this analysis using preliminary test environments, St. Jude is proceeding with the evaluation and implementation of electronic orders, including complex chemotherapy order sets. Drs. Shenep and Baker are scheduled to present the findings of this analysis at the Cerner Health Conference in Orlando, Florida, on October 9-12, 2005.

Scope

Background

Patient safety is at the forefront of our nation's consciousness at governmental levels, within hospitals, with healthcare professionals, and with individuals who are patients within our healthcare systems. Medication safety is often cited as a particularly high-risk area of patient

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safety, has been one of the most closely studied domains in this field, and is an area that can most likely be improved through the use of technology.

A commonly proposed patient safety recommendation is the implementation of computerized physician order entry systems. These recommendations often cite a need to respond to the Institute of Medicine's report, "To Err is Human." This report, issued in 1999, outlined the risks to patient safety found in our nation's hospitals and alarmed healthcare consumers nationwide. Medication errors were highlighted in the report and were stated to account for over 7000 deaths and upward of 2 billion dollars in increased hospital costs annually in the United States.

In response to this problem of patient safety risks, a group of 140 public and private organizations that provide healthcare benefits formed a coalition called the Leapfrog Group. Their stated aim was "to help save lives and reduce preventable medical mistakes by mobilizing employer purchasing power to initiate breakthrough improvements in the safety of healthcare and by giving consumers information to make more-informed hospital choices." This group then focused its efforts on three principles that would have a high impact on saving lives by reducing preventable mistakes in our nation's hospitals. One of the three principles is CPOE.

The vast majority of hospitals still have not implemented CPOE systems, even though large numbers are considering their implementation. Even in hospitals with CPOE, chemotherapy orders are often excluded because of their complexity and risk. Though it is a commonly held belief that CPOE will result in improved patient safety, this belief has not been supported by objective, compelling data.

Five trials assessing CPOE and seven assessing clinical decision support systems were reviewed in detail for the effects of the use of these technologies on medication error rates. The authors concluded that, although the "use of CPOE and isolated clinical decision support systems can substantially reduce medication error rates, studies have not been powered to detect differences in adverse drug events and have evaluated a small number of homegrown systems." The authors went on to conclude that more research is needed to evaluate commercial systems and to "identify factors related to the successful implementation of these systems."

Chemotherapy medications are, by design, highly toxic agents, typically having very narrow therapeutic windows. The difference between a dosage that causes the desired effect (killing cancer cells) and a dosage that causes undesired or toxic effects can be quite small. As the benefits of combination chemotherapy regimens have been realized, regimens used in a variety of malignancies have become more and more complex. With this increased complexity comes an increased risk of error and potential harm.

This study was designed to objectively assess the potential benefits of an optimized process of chemotherapy administration by CPOE in children. Expanding the scope of the benefits from this effort, we anticipate that the principles and lessons derived from the study of chemotherapy administration in children in most instances will be applicable to adult oncology and may be applicable to other fields involving administration of high-risk drugs. This analysis was done in anticipation of subsequent implementation of a carefully designed and critically assessed process of chemotherapy administration using integrated CPOE.

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Preliminary Studies

After careful analysis, our organization made the decision to purchase a commercially available, integrated suite of software applications from Cerner Corporation, Kansas City, Missouri, to meet our clinical and research software needs.

A phased-in approach to installation of this suite of applications began in 1997 with implementation of an Oracle relational database and an application (Powerchart) to view the laboratory information stored in this core database. Since then, patient registration, health information management, patient scheduling integrated with orders, research protocol management, research protocol enrollment, outpatient pharmacy, radiology with CPOE, PACS, and management reporting applications have been fully implemented. Together, this system serves as the electronic medical record for the institution. A pilot project of comprehensive CPOE in two non-oncology clinics has been active since December 2002 and serves as a testing ground for CPOE prior to its planned implementation in oncology clinics and inpatient areas. This pilot has included an occasional chemotherapy order for hematology patients, providing a means to validate system design. The implementation of comprehensive CPOE throughout the institution is expected to be completed by the end of 2006 after incremental, smaller-scale implementations in outpatient pediatric oncology clinics during 2005 and early 2006.

CPOE is not simply an electronic version of a paper order but is a window to sophisticated electronic rules, alerts, prompts, and decision support. The medication administration process is a complex process, beginning with the physician deciding upon the specific treatment and documenting the treatment plan in a protocol or written treatment plan and ending with the clinician monitoring the results of treatment and adjusting the treatment plan as necessary. There are multiple points in which integrated computerized applications can support this process.

In preparation for a comprehensive CPOE system, a considerable amount of effort has already taken place to optimize patient safety with CPOE as it relates to medication orders. Order entry formats have been created specifically for chemotherapy medications to ensure consistency with existing institutional policies, procedures, and processes (see Figure 1 below). Only approved generic names (no brand names, no abbreviations) of chemotherapy medications will be available for selection by physicians. Values used in calculations of drug dosages, such as body surface area and weight, are provided within the order entry screens. Drug dosages are expressed in metric notations, and only the metric notations that are applicable to the ordered drug are be displayed (e.g., “mg” is the only available dosage unit available for carboplatin; “units” is the only available dosage unit for asparaginase). Similarly, only those routes of administration that are pertinent to each medication will be displayed for selection. Tall man lettering is being utilized when necessary to distinguish between look-alike and/or sound-alike drug names (e.g., VinCRIStine, VinBLAStine). Through use of the system security, only physicians identified as having chemotherapy prescribing privileges have access to the “OK to Give” order sentence. The OK to Give sentence is not available in the order depicted in the figure below, because the clinician signed onto the system is not privileged. Each chemotherapy order must be approved individually by the oncologist within 48 hours of administration. Rules will be written that require specific protocol enrollment, as independently verified and keyed by our Protocol Office staff based on signed consents, before certain order sets or research drugs can be accessed through CPOE (protocol version and amendment as well as the applicable protocol document are currently available and displayed in our integrated system). These

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special methodologies demonstrate some of the special requirements of chemotherapy medication orders that would not be critical for standard medications. These methodologies also depict some of the patient safety opportunities only available in a fully integrated system.

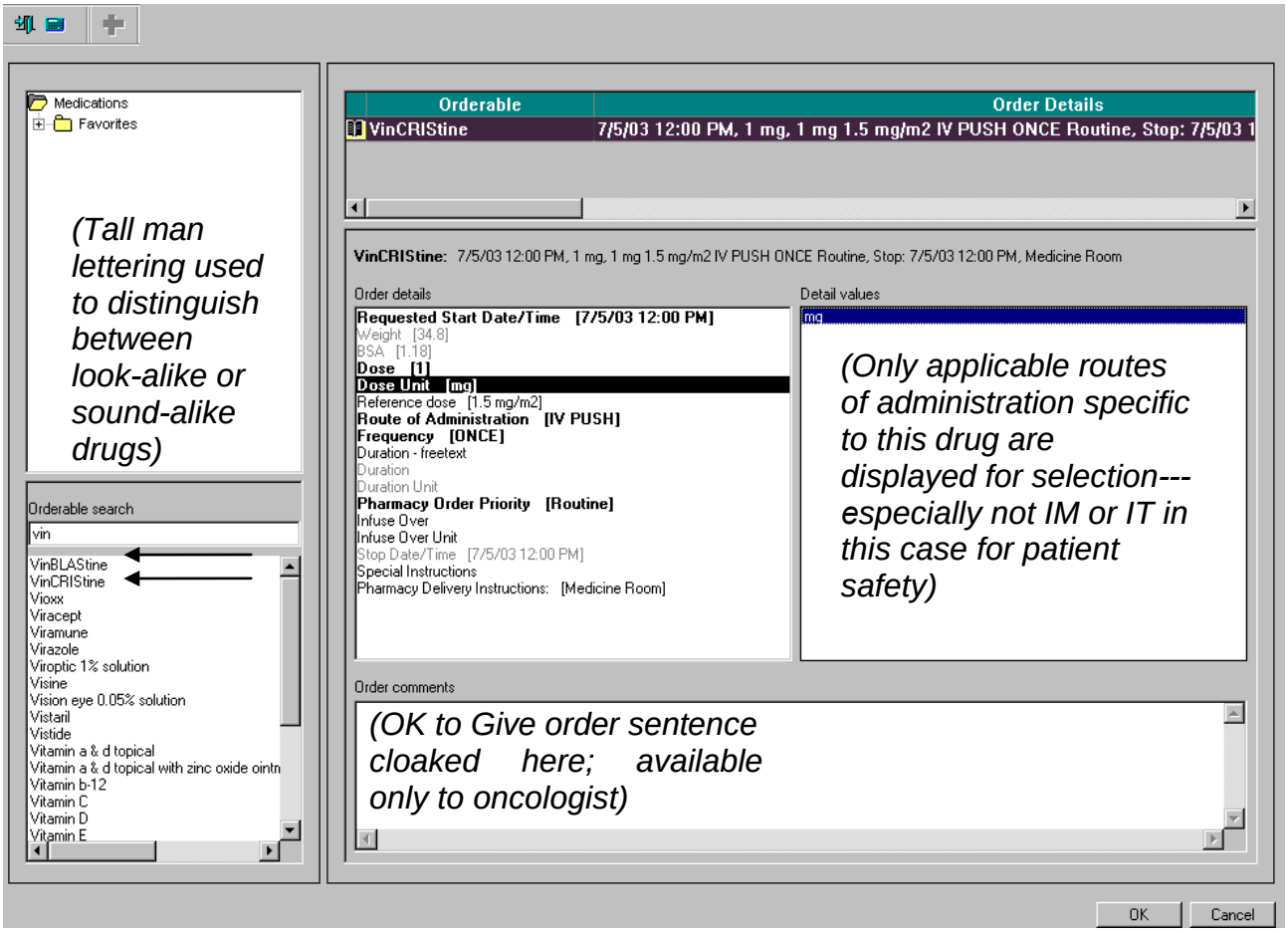

Figure 1: Screen print of order entry format from CPOE system. Patient safety features incorporated into the order entry screens are noted parenthetically.

Methods

Failure Mode and Effects Analysis (FMEA) was used as the method to evaluate how individual components of the process used to generate and carry out complex chemotherapy orders out in a comprehensive pediatric cancer center could fail.

A team was assembled to include individuals directly involved in the chemotherapy process and included physicians, nurse practitioners (NPs), and physician assistants (PAs) who generate chemotherapy orders; nurses from those clinic areas where the orders are generated; pharmacists and technicians who receive, check, transcribe, prepare, and deliver these orders; nurses who receive, check, and carry out these orders, including administration of chemotherapy to patients; re-engineering analysts, quality improvement specialists; and informatics specialists. A consultant with FMEA expertise was brought in early in the project to provide educational training sessions to the team on the use and practical application of FMEA. The team's makeup was specifically designed to utilize staff members with several

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years of experience with this process as well as relatively new staff members to provide a mixture of experience levels.

Initial meetings with the entire team introduced the purpose of the project, provided education and training on the analysis method to be used, and provided background information regarding previous efforts to analyze the chemotherapy process at SJCRH. The major components of the overall process were identified and flowcharted.

Consensus was then reached among the team that the overall process contained three major subprocesses: the ordering process, the pharmacy process of reviewing and processing the medication portion of the orders, and the nursing process of reviewing and carrying out the orders. Teams were then developed for these three major subprocesses. The makeup of these teams was designed to include clinical practitioners directly involved in these processes on a day-to-day basis, and, at least, a re-engineering analyst, a quality improvement specialist, and an informatics specialist. Weekly 2-hour meetings were conducted to develop specific workflow maps to identify the current state for each subprocess.

After flowcharting the three major process components, the overall team was reassembled to review and discuss the individual detailed process and make any necessary modifications to the overall process flow map. Upon reaching consensus on the overall process flow map and individual detailed process flow maps, each subprocess team reconvened in weekly 2-hour meetings to conduct the FMEA process.

Meetings to identify failure modes and their effects and to prioritize failure modes for the current processes were facilitated by a quality improvement specialist. Each process step was evaluated for potential failure points, identifying the potential cause(s) and effect(s) and the detection method of each potential failure point. Each potential failure point was then scored by team members for severity (effect to the patient if the failure occurred), occurrence (how often does this occur), and likelihood to detect the failure prior to completion of the process. A 10-point scale (10=worst, 0=best) was used to score severity, occurrence, and likelihood of detection. Each component score was then multiplied together to create a Risk Priority Number (RPN).

	Severity Scale		Occurrence Scale		Detectability Scale	
Rating	Description	Definition	Description	Definition	Description	Definition
1	Minor effect or no effect	Neither error nor harm occurred. No effect on patient or subsequent process activity.	Remote to nonexistent/ almost never	Reserved for automated systems	Certain to detect	Almost always detected immediately. Current controls almost always detect the failure.
2	Very slight effect	Actual error occurred. Error did not reach the patient. Very slight on subsequent process activity.	Remote	Reserved for automated systems	Very high	Very high likelihood that controls will detect. Review effectiveness >95%.

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3	Slight effect	Error reached the patient. Patient is not harmed. Patient experiences slight annoyance.	Very slight, low likelihood	Reserved for automated systems	High likelihood	Likely to be detected. Good likelihood that current controls will detect.
4	Minor effect	Actual error occurred. Error reached the patient. Slight effect on the patient, but patient is unharmed. Minor effect on process.	Slight	Reserved for automated systems	Moderately high	Moderately high likelihood that current controls will detect. Peer checking. Review effectiveness of 80%.
5	Moderate effect	Actual error occurred and reached the patient. The patient requires an increase level of care, monitoring, or observation. Moderate effect on process.	Low to moderate likelihood	2-3 per 1000 events. Documented infrequently; the condition has a reasonable chance to occur. Occasional failure likely.	Moderate likelihood	Moderate likelihood of detection. Self-checking. Review effectiveness of 60%.
6	Significant effect/ Minor injury	Actual error occurred and reached the patient. Patient requires treatment or intervention as a result.	Medium	1 in 100 events. Moderate number of failures.	Low	Low likelihood that current controls will detect. Review effectiveness of 50%.
7	Major effect	Actual error occurred and reached the patient. Patient requires prolonged hospitalization. Patient temporarily harmed.	Moderately high to high likelihood	3-4 per 100 events. Documented and frequent; the condition occurs very regularly and or during a reasonable amount of time. High number of failures likely.	Slight likelihood	Slight likelihood that controls will detect. Hidden symptoms of failure.

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8	Extreme effect/major injury	Actual error occurred and reached the patient. Error would result in a major injury for the individual served, including permanent patient harm. Process fails.	High	1 in 10 events. High number of failures likely.	Very slight	Very slight likelihood that current controls will detect. Hidden or obscure symptoms of failure.
9	Serious effect	Actual error occurred and reached the patient. Patient experiences near death event. Process fails.	Very high	1-3 per 10 events. The condition will inevitably occur during long periods typical for the step or link. Very high number of failures likely.	Almost certain not to detect	Remote likelihood that current controls will detect.
10	Catastrophic effect; terminal injury or death	Actual error occurred and reached the patient. Patient death occurs. Process fails.	Almost certain	4 or more per 10 events. Failure almost certain. History of failures.	Impossible to detect	No known control available to detect the failure.

RPN values are used within the FMEA process to prioritize failure points for review, determine the root cause of the failure, and redesign the process as necessary. An RPN value above 150 was used as a cutoff for further review and analysis.

Available functionalities within the existing electronic medical record were presented to team members to determine their overall acceptability within the context of complex chemotherapy orders. Two available strategies and one strategy planned for future development by the software vendor for generating electronic orders were presented to clinicians who generate complex chemotherapy orders and nursing staff members who practice where these orders are generated. The two available strategies were 1) individually initiating each order for chemotherapy and associated medications and

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2) using an electronic care set that presents orders as a logical group to the end user. The strategy planned for future development by the software vendor presents orders together in logical groupings and provides functionality to develop time dependencies between orders.

Results

Principal Findings

The chemotherapy medications process flow as determined by current state process flow meetings is described below. An oncologist must request a single set of preprinted order sheets developed specifically for that clinical trial and approved by the principal investigator of the trial. This set of preprinted order sheets is then placed into the paper medical record for future treatment courses. Prior to initiating any chemotherapy order regimen, the clinician is expected to review the protocol document for all pertinent information. They then complete the preprinted order set for the appropriate day or week of treatment, calculating and filling in each medication dosage as well as the expected date and/or time of treatment. If a nonphysician generates these orders, they are available within the medical record for co-signature by a physician with chemotherapy prescribing privileges within the organization. The orders are reviewed by a nurse working within the clinic area where the orders are generated to determine protocol compliance and double check all calculations. Orders may then remain in a holding state until close to the date/time treatment is scheduled to be administered. An independent evaluation of the patient's clinical status and any protocol-required laboratory or procedures must be confirmed to be in compliance with the protocol. If so, a chemotherapy-certified oncologist is required to generate an order to indicate that it is now "OK to Give" or acceptable to administer the planned chemotherapy regimen on the scheduled date.

After the nurse has performed the necessary safety checks, orders are communicated to receiving departments, primarily the pharmacy and infusion center within the hospital. Parallel processes then take place within these areas for further safety-related checks and balances to ensure protocol enrollment, protocol compliance of the planned treatment, correct timing of therapy, dosage calculations, etc. Both the pharmacy and the infusion center require independent checks by at least two licensed professionals (pharmacists for pharmacy, nurses for the infusion center). The pharmacy process includes transcription of the orders into the pharmacy information system, which provides automated allergy and drug interaction warnings, printing of labels to be affixed to the final dosage formulations, preparation of the medications, and delivery of the medications to the patient care area ONLY after confirming the receipt of the "OK to Give" order.

The nursing process in the ambulatory infusion center includes an initial review of the orders prior to patient arrival followed by receipt of the patient's medical record, receipt of the drug(s) from the pharmacy; planning out the intended treatment regimen; performing the dual safety checks referred to above as well as comparing the drugs received from the pharmacy against the orders for correct drug, dosages, diluent type and volume, infusion duration, etc.; dual, independent verification of the patient's identity using at least two methods (e.g., name and medical record number or date of birth); verifying appropriate venous access; administering the ordered chemotherapy and related medications; completing all necessary documentation; observing the patient and providing all necessary care during treatment; and, finally, discharging the patient with appropriate education.

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In summary, the individual ordering the chemotherapy regimen is expected to carefully evaluate the treatment regimen to be ordered against a reference document and to carefully complete the order document for which a template has been developed and provided for consistency and safety reasons followed by redundant checks of the same information by at least three groups (at minimum, five individuals) of healthcare professionals. Subprocesses also include at least one redundancy check to make certain one individual does not complete their portion of the process without review.

The three subprocess groups developed more detailed process maps for each step in the process. These steps are outlined below:

Process Map Summary
Chemo Ordering Process and ACU Administration

Sequence: 1 Request Preprinted Orders
Accomplished by: Chemotherapy-certified physician (CCP), usually an oncologist
Story: Preprinted protocol order sheets are received from Clinical Protocol and Data Management Office initially and then are kept in the patient's chart thereafter. In some cases, notably, nonprotocol treatment plans, the preprinted order sheets are generated by the pharmacy for a specific patient.

Potential failure identified from FMEA:
1.. Incorrect preprinted orders sent from protocol office; RPN score: 120

Sequence: 2 Review the Roadmap & Protocol
Accomplished by: Chemotherapy-certified physician, NP, PA, or physician in training
Activities:
1. Verify that the patient is on the correct day or week according to the research protocol.
2. Verify that the set of orders is correct (i.e., if the patient is on week 2 of the protocol, confirm that the orders are for week 2).
3. Verify that the patient meets clinical requirements as prescribed by the protocol or accepted clinical practice.
4. Get additional consents if required.
5. Review the need for dosage adjustments based on toxicity, renal function, or AUC in a manner consistent with the protocol.
Potential failures identified from FMEA:

2.1 Clinician fails to check appropriate criteria or clinical information	RPN score: 150
2.2 Clinician fails to check protocol information	RPN score: 150
2.3 Clinical data received after check is made	RPN score: 150
2.4 Consent not obtained	RPN score: 150
2.5 Data reviewed but appropriate change in treatment not made	RPN score: 150

Sequence: 3 Complete Orders
Accomplished by: Chemotherapy-certified physician, NP/PA, or fellow
Story: In some instances, this may be done prior to the preceding step. If clinical requirements are not met, then the "OK to Give" is not initiated.
Activities:
1. Calculate the drug dosage.

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2. Refer to the road map and/or protocol for dosage adjustments.
3. Review the clinical assessment, such as labs, echocardiograms, results in electronic medical record.

Potential failures identified from FMEA:

3.1 Illegible order	RPN score: 80
3.2 Orders generated on wrong patient	RPN score: 100
3.3 Incorrect date written for orders to be carried out	RPN score: 70
3.4 Incorrect dosage written	RPN score: 100
3.5 Incorrect preprinted order set used to generate orders	RPN score: 80

Sequence: 4 Co-sign Chemo Orders
Accomplished by: Chemotherapy-certified physician
Story: All orders generated by an NP, PA, or fellow require co-signature by a CCP. Plus, all activities performed in the previous two sequences are independently performed again prior to the CCP cosigning the orders.
Potential failures identified from FMEA: Because this is a review process that cannot in and of itself insert additional risk, it was not scored using FMEA.

Sequence: 5 Generate an order indicating the planned chemotherapy is OK to Give
Accomplished by: Chemotherapy-certified physician
Story: For preprinted order sheets, the OK to Give is indicated by checking the OK to Give check box and by signing, dating, and timing the order sheet. The "OK to Give" is valid for 72 hours.
Potential failures identified from FMEA:
5.1 OK to Give order generated by chemotherapy-certified physician without having obtained and reviewed all required information. Request made to nonphysician provider to hold the order until last piece of pertinent clinical data is available before transmitting to receiving departments. Order transmitted prior to results becoming available. RPN score: 360

Sequence: 6 Review Chemotherapy Orders
Accomplished by: Clinic nurse
Activities:
1. Review the road map and/or protocol for the correct week and drugs.
2. Recalculate the dosage. If the dosage doesn't match the order, the clinic nurse will review the chart for adjustments; if none are found, the clinic nurse will consult the ordering physician.
Potential failures identified from FMEA: Because this is a review process that cannot in and of itself insert additional risk, it was not scored using FMEA.

Sequence: 7 Fax Order
Accomplished by: Clinic nurse
Story: Orders are faxed to the appropriate pharmacy and the ambulatory infusion center.
Activities:
1. After the order is faxed, the clinic nurse dates and times the order sheet, indicating that the order was reviewed and completed, and then places it in the paper medical record.
2. The paper medical record is then forwarded to scheduling if necessary.
Potential failures identified from FMEA:
7.1 Facsimile machine fails to effectively transmit order

Sequence: 8 Review Order (1)
Accomplished by: Pharmacist

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Sequence: 8.1 Review Order (2)
Accomplished by: Ambulatory infusion center nursing staff
Story: If orders are received prior to the day that the order is to be carried out, they are placed in a file folder until the day the patient arrives.

Sequence: 9 Prepare Drug
Accomplished by: Pharmacy
For detailed pharmacy process, see *Chemo Pharmacy Dispensing Current State*

Sequence: 9.1 Retrieve Chart
Accomplished by: Ambulatory infusion center nursing staff
Activities:
1. Check for patient arrival.
2. Check that resources are available.
3. Check protocol parameters in electronic medical record.
4. In some cases, when the drug shelf life is short, the ambulatory infusion center nurse will call the pharmacy to notify them that the patient has arrived so that drug preparations can begin.

Sequence: 10 Deliver Drug
Accomplished by: Pharmacy

Sequence: 10.1 Prepare Medication Staging Area
Accomplished by: Ambulatory infusion center nursing staff
Story: Staging point for each patient's premeds and chemo drugs
Activities:
1. Label plastic container with patient's first name and last initial.

Sequence: 11 Sign for Drug
Accomplished by: Ambulatory infusion center nursing staff
Story: Each morning, a staff member of the ambulatory infusion center prints a copy of their scheduling report for the day and gives it to the ambulatory infusion center pharmacist. As each drug is delivered to the ambulatory infusion center, the nurse initials the report, indicating that the drug was received from the pharmacy. For patients who may be added on during the day, the names are written on the report and initialed as the drugs are delivered.
Activities: Sign initials on report to indicate the receipt of the chemo drug.
Potential failures identified from FMEA:
11.1 Report initialed in wrong spot on the report RPN score: 20
11.2 Nurse fails to sign report upon receipt of drug RPN score: 90

Sequence: 12 Place Drug in Appropriate Patient's Plastic Container
Accomplished by: Ambulatory infusion center nursing staff

Sequence: 13 Call Patient to Ambulatory Infusion Center
Accomplished by: Ambulatory infusion center nursing staff using overhead paging system

Sequence: 14 Check Patient In
Accomplished by: Ambulatory infusion center nursing staff
Activities: 1. Start clinical documentation.

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Sequence: 15 Review Order (3)
Accomplished by: Ambulatory infusion center nursing staff
Story: If a mistake is found in the order, the clinic is notified so that a new order can be generated. Likewise, if a mistake is found after the drug is dispensed, the drug is returned to the pharmacy for them to re-dispense the correct medication and dosage.
Activities:
1. Check for OK to Give by chemo-certified physician (CCP) issued within the past 72 hours.
2. Verify clinical privileges of the CCP if unsure.
3. Confirm dose and drug against the protocol.
4. Confirm dose calculation.
5. Check the dose/day or deviations from protocol.
6. Check protocol parameters as defined in the protocol (e.g., lab values).
7. Check for a signed consent form in the chart.

Sequence: 16 Check Premeds
Accomplished by: Ambulatory infusion center nursing staff

Sequence: 17 Review Order (4)
Accomplished by: Ambulatory infusion center nursing staff
Story: The same activities are performed to review the order as were stated in Review Order (3). Review Order (3) and Review Order (4) are done either together or independently.

Sequence: 18 Check Line Placement & Start Premeds/Fluids
Accomplished by: Ambulatory infusion center nursing staff
Potential failures identified from FMEA:

18.1 Premedication indicated but not ordered	RPN score: 210
18.2 Prehydration fluids not administered	RPN score: 105
18.3 Premedication ordered but not administered	RPN score: 105
18.4 Line placement not checked	RPN score: 120

Sequence: 19 Check Chemo Med & Label (1)
Accomplished by: Ambulatory infusion center nursing staff
Activities:
1. Check that the med is mixed in the appropriate diluent and to the appropriate concentration.
2. Visually verify that the drug in the bag matches the drug indicated on the label and order (e.g., confirm that a dose of doxorubicin is red in color).

Sequence: 20 Check Chemo Med & Label (2)
Accomplished by: Ambulatory infusion center nursing staff
Story: A second nurse performs the same activities as the first nurse.

Sequence: 21 Positive Patient Identification (1)
Accomplished by: Ambulatory infusion center nursing staff
Activities:
1. Check and verify the patients arm band, noting both the patient name and MRN.
2. Check and verify that the medication is the correct med for the patient.
3. Document PPID on the chemotherapy sheet.
Potential failures identified from FMEA:

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21.1 First nurse fails to check multiple patient identifiers RPN score: 126
21.2 First nurse checks identifiers but fails to recognize an error RPN score: 105

Sequence: 22 Positive Patient Identification (2)
Accomplished by: Ambulatory infusion center nursing staff
Story: A second nurse performs the same verifications that the first nurse performed. This verification is performed independently of the first nurse.
Potential failures identified from FMEA:
22.1 Second nurse fails to check multiple patient identifiers RPN score: 210
22.2 Second nurse checks identifiers but fails to recognize an error RPN score: 210

Sequence: 23 Verify Line Placement
Accomplished by: Ambulatory infusion center nursing staff
Activities: 1. Flush with saline and verify blood return.

Sequence: 24 Administer Chemotherapy & Follow-up Treatment
Accomplished by: Ambulatory infusion center nursing staff
Story: The patient is monitored during the administration per the protocol. If the patient has an adverse drug reaction, the administration of the chemo is stopped, the reaction is treated, an ADR form is completed and delivered to the pharmacy, and the clinic is notified. The ambulatory infusion center nurse places a yellow caution sticker on the outside of the chart.
Potential failures identified from FMEA:
24.1 Medication administered by incorrect route of administration RPN score: 200
24.2 Failure of nurse to provide patient follow-up RPN score: 210

Sequence: 25 Complete Documentation
Accomplished by: Ambulatory infusion center nursing staff

Sequence: 26 Check Patient Out & Discharge
Accomplished by: Ambulatory infusion center nursing staff

Process Map Summary
Grant Chemo Pharmacy Dispensing Current State

Sequence: 1 Batch Print Labels
Accomplished by: Pharmacy
Story: Each afternoon, labels are printed for the orders scheduled for the next day. These labels may be for orders that were entered well in advance of the day the chemo is to be administered. After the labels are printed, they are matched with the order sheet.
Potential failures identified from FMEA:
1.1 Labels print on wrong date due to incorrect scheduling of treatment in pharmacy information system RPN score: 50
1.2 Equipment failure RPN score: 6

Sequence: 1.1 Review Daily PAR Level
Accomplished by: Pharmacy technician
Story: This step is performed each morning by the tech to ensure that an adequate inventory is maintained for each commonly used drug.

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Activities:
1. Reconstitute the appropriate amount of commonly used drugs.
2. Label the bottle with the current date, expiration date, and concentration.
3. Log the type and amount of drug reconstituted.

Potential failures identified from FMEA:

1.1.1 Inventory levels not reviewed, resulting in delay in preparation	RPN score: 30
1.1.2 Technician reconstitutes incorrect drug used in preparation	RPN score: 100
1.1.3 Technician reconstitutes correct drug at incorrect concentration	RPN score: 50
1.1.4 Technician reconstitutes correct drug with incorrect diluent	RPN score: 80

Sequence: 2 Review Order (1)
Accomplished by: Pharmacist
Story: Orders are pulled from the fax and reviewed.
Potential failures identified from FMEA:

2.1 Multiple copies of the same order(s) received via fax	RPN score: 50
2.2 Fax machine failure	RPN score: 6
2.3 Incorrect patient name on orders	RPN score: 420
2.4 Illegible order (either fax transmission or handwriting problems)	RPN score: 280
2.5 Incorrect labeling information	RPN score: 100

Sequence: 3 Search for Patient Profile
Accomplished by: Pharmacist
Story: Once the order is received, the pharmacist searches for the patient profile by using the patient's name or by entering the MRN in the pharmacy information system.
Potential failures identified from FMEA:

3.1 Incorrect patient search results by name or medical record number	RPN score: 112

Sequence: 4 Review Patient Profile
Accomplished by: Pharmacist
Story: The patient profile includes the patient's protocol information.

Sequence: 5 Ensure Protocol Compliance
Accomplished by: Pharmacist
Activities:
1. If the patient is not on the protocol in the pharmacy information system, the pharmacist contacts the clinic to get the correct information.

Sequence: 6 Review Roadmap
Accomplished by: Pharmacist
Story: The roadmap is reviewed to verify that the patient is on the correct cycle.
Activities:
1. Pull the protocol from the notebook.
2. Check doses on the roadmap.
3. Check in pharmacy information system to verify what week the patient is on by reviewing the comment line in pharmacy information system. The pharmacists are trained to type this information in the comment line along with dose and BSA. If there is a variance in the dose, the pharmacist will review the roadmap from the patient's chart or physician notes to clarify why there is a variance. If clarification cannot be obtained from these sources, then the clinic physician is called.

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Sequence: 7 Calculate Dosage(s)
Accomplished by: Pharmacist
Story: Dosages are calculated on drugs, IV fluids, etc. If an incorrect dosage calculation has been made, the pharmacist will call the clinic to confirm the correct dosage.

Sequence: 8 Enter Order(s)
Accomplished by: Pharmacist
Activities:
1. Search for drug and correct concentration from a predefined order list.
2. Check the correct route.
3. Search for the correct fluid.
4. Complete order details and review and OK the first screen.
5. On the second screen, enter the frequency, rate, time, start/stop date, and label comments.
6. Review the information on the computer screen versus what is on the faxed order.
7. OK the order after verifying all the information. This places the drug on a working list. Changes can still be made to the order if needed.
8. Accept the order by keying F8.
9. Stamp and initial the faxed order sheet.

Potential failures identified from FMEA:
8.1 Order entered for incorrect drug RPN score: 150
8.2 Order entered for incorrect route of administration RPN score: 28
8.3 Order entered with incorrect diluent RPN score: 144

Sequence: 9 Print Labels
Accomplished by: Pharmacy information system
Story: Labels are printed at the default location based on where the pharmacy is located that will be responsible for dispensing. Labels for same-day orders print immediately. For future orders, the labels will not be printed until the day before the order is due.
An alternative process is developing in the pharmacy in which the labels are printed to the location where the orders are entered and matched immediately with the order sheet. This allows the pharmacist to verify that the labels print correctly. After the labels are matched with the order sheet, they are forwarded to the appropriate location. If this alternative process is followed, sequences 10 and 11 are omitted.
Potential failures identified from FMEA:
9.1 Duplicate labels are printed leading to possibly two doses being prepared RPN score: 70

Sequence: 10 Fax Order Sheet
Accomplished by: Pharmacist or technician
Story: The order sheet is faxed to the pharmacy location where the labels printed.

Sequence: 11 Match Labels to Order Sheet
Accomplished by: harmacist or technician
Story: The labels and the faxed order sheet are matched and held until needed.

Sequence: 12 Review and Verify
Accomplished by: Pharmacist
Story: At this point in the process, a second pharmacist independently reviews the same information all the way back to ensure protocol compliance.

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Sequence: 13 Initial Label
Accomplished by: Pharmacist
Story: After the second pharmacist verifies all the information, he/she will sign their initials on the label. This is considered the second set of pharmacist's initials on the label; the first is printed on the label by the computer system at the time the label is printed.

Sequence: 14 Review Label
Accomplished by: Pharmacy technician
Activities:
1. The order is compared with the information on the label, matching the patient name, drug, and dose.
2. If discrepancies are noted between the order and the label, the pharmacist is notified.

Sequence: 15 Pull Drug from Inventory stock
Accomplished by: Pharmacy tech
Activities:
1. Make sure the dose matches the label verifying correct amount and correct drug.
2. Transport drug to the IV prep area.
3. Once in the prep area, double check the drug and drug concentration against the label.

Potential failures identified from FMEA:
15.1 Incorrect drug used for preparation (e.g., look-alike, sound-alike drug name) RPN score: 70
15.2 Drug supplies past their expiration date used in preparation. RPN score: 30
15.3 Incorrect concentration of drug used in preparation RPN score: 64
15.4 Incorrect bag size for IV fluid used in preparation RPN score: 60
15.5 Incorrect IV fluid used in preparation RPN score:100

Sequence: 16 Reconstitute the Drug if Necessary
Accomplished by: Pharmacy tech
Activities:
1. The tech reviews the appropriate reference for proper reconstitution volume.
2. The tech obtains the proper diluent and reconstitutes the drug.
3. The tech then pulls the syringe back to indicate to the pharmacist the volume of diluent used to reconstitute the drug.

Potential failures identified from FMEA:
16.1 Incorrect diluent used for reconstitution RPN score: 100
16.2 Incorrect volume of diluent used for reconstitution RPN score: 200

Sequence: 17 Prepare Medication
Accomplished by: Pharmacy tech
Activities: Draw up appropriate drug amount into a syringe.
Potential failures identified from FMEA:
17.1 Incorrect amount of drug drawn up into syringe RPN score: 105

Sequence: 18 Call Pharmacist to Verify Preparation
Accomplished by: Pharmacy tech

Sequence: 19 Verify Drug Preparation
Accomplished by: Pharmacist

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Story: The pharmacist verifies that the correct diluent and correct volume of diluent were used and the correct drug(s) was prepared in the correct volume and at the correct concentration.

Sequence: 20 Inject Med into Bag
Accomplished by: Pharmacy tech
Story: The med is injected into the bag, if an admixture, under the supervision of a pharmacist. The drug label is then affixed to the bag or syringe immediately by the pharmacy technician.
Potential failures identified from FMEA:
20.1 Incorrect medication injected into incorrect admixture bag, if multiple products are being prepared at same time RPN score: 224

Sequence: 21 Deliver Drug
Accomplished by: Pharmacy tech
Story: The pharmacy tech delivers the drug to the inpatient floors following activities 1 and 2. The pharmacist delivers the drug to the ambulatory infusion center, but no delivery receipt is prepared. Instead, the ambulatory infusion center nurse signs off on the daily scheduling report that the drug has been delivered.
Activities:
1. Prepare delivery receipt for inpatient drug deliveries.
2. Deliver chemo.

Potential failures identified from FMEA:
21.1 Deliver to incorrect patient location RPN score: 90

As described in the methods section, three options for ordering chemotherapy regimens electronically (two currently available, one to be available in the future) were presented to clinicians involved in the chemotherapy meds process. Option 1, individual order entry, was summarily dismissed due to the large number of orders associated with complex chemotherapy regimens and the time that would be required to generate large numbers of orders with all associated details on a one-by-one basis. Option 2, using first-generation electronic order sets, was deemed unacceptable due to a system constraint within each order requiring a specified date and time to be established and completed by the end user. Given that complex chemotherapy regimens often have upward of 10 to 20 individual component orders, which commonly must be specified to occur in a critically timed sequence or time relationship with a single key component, ordering clinicians determined that the risk of not accurately dating and timing each order individually in the regimen sequence was too high compared with the current paper-based process. The current paper system includes preprinted order sheets for which the requested date and time to begin a regimen is provided as a single reference point against which all subsequent orders are scheduled by nursing staff.

At this point in the project, each team attempted to analyze how an electronic medical record with clinician ordering of complex chemotherapy regimens electronically, automatic transfer of these orders into an integrated pharmacy information system, and eventual documentation of administration within an integrated electronic mediation administration record would affect the overall process as well as detailed subprocess steps. Unfortunately, a suitable computer testing system with all these components installed and completely developed to serve as a demonstration model for future processes was not available for the remaining portion of the grant period.

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Subsequently, the deficiencies in the electronic medical record to accomplish this complex chemotherapy process were shared and discussed with the vendor, Cerner Corporation. Some of these deficiencies had been previously recognized, and strategies were being developed to provide additional options to accomplish electronic order entry by clinicians within the electronic medical record system. An initial version of this additional strategy (PowerPlans®, Cerner Corporation) has been provided and installed in a testing domain.

To date, a few example chemotherapy regimens have been developed within the PowerPlans functionality for demonstration and proof-of-concept purposes. Initially, members of the project team have presented these example regimens to grant team members (physicians, physician assistants) to determine the overall acceptability and evaluation of PowerPlans using the same FMEA scoring process used during the current-state phase of the project. In this limited sampling strategy, PowerPlans have been well received. Potential failure points in the ordering process, such as illegible handwriting or inadequate or missing facsimile transmissions of orders, are eliminated entirely under the electronic future-state process. RPN scores for other potential failure points in the ordering process either remained the same or decreased compared with the current process.

Discussion

Although CPOE is supported philosophically by multiple groups that exert significant pressure to adopt CPOE throughout healthcare systems, such as the Leapfrog Group, whether or not CPOE will consistently result in improved patient safety remains to be determined. A recent (June 2005) symposium sponsored by the Institute for Safe Medication Practices, entitled “Is CPOE Still the Right Thing to Do?” provides a current example of how controversial this topic remains and the uncertainty it creates, even in forward-thinking organizations.

The more complex the area of medication usage, the more complex this decision becomes as to whether or not implementing CPOE is, as the symposium asks, the right thing to do. Improved patient safety is sometimes considered a foregone conclusion with the incorporation of CPOE into the medication use process and promoted without any formal comparison of patient safety compared with an organization’s current process.

Conclusions

With an especially high-risk medication process in use daily here at St. Jude, we attempted to accomplish a formal comparison of current versus future processes for chemotherapy treatment regimens in children with cancer specifically from a patient safety perspective using FMEA. Unfortunately, software development and installation delays between our site and our software vendor did not allow a sufficiently robust test system to be available during the grant period to fully ascertain the FMEA for the future electronic process. The software available at the time of this report appears to hold significant promise and, based on our initial analysis, we are proceeding with installation that should include chemotherapy orders during 2006. Individual potential failure points, such as illegible handwriting, can be eliminated entirely with an electronic ordering process, and automated checks, rules, and alerts appear promising. A final conclusion regarding an overall comparison of the safety of the current paper-based process to an analogous electronic one will require additional analysis at installation, which is planned.

No publications have resulted from this work to date.

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