Supplement

Safe and Successful Implementation of CPOE for Chemotherapy at a Children's Cancer Center

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Key Words

Computerized prescriber order entry, clinical decision support, electronic health records, chemotherapy, patient safety, electronic prescribing, medication error prevention and control, medication systems

Abstract

Computerized prescriber order entry (CPOE) for medications has been implemented in only approximately 1 in 6 United States hospitals, with CPOE for chemotherapy lagging behind that for nonchemotherapy medications. The high risks associated with chemotherapy combined with other aspects of cancer care present unique challenges for the safe and appropriate use of CPOE. This article describes the process for safe and successful implementation of CPOE for chemotherapy at a children's cancer center. A core principle throughout the development and implementation of this system was that it must be as safe (and eventually safer) as existing paper systems and processes. The history of requiring standardized, regimen-specific, preprinted paper order forms served as the foundation for safe implementation of CPOE for chemotherapy. Extensive use of electronic order sets with advanced functionality; formal process redesign and system analysis; automated clinical decision support; and a phased implementation approach were essential strategies for safe implementation of CPOE. With careful planning and adequate resources, CPOE for chemotherapy can be safely implemented. (*JNCCN* 2011;9[Suppl 3]:S36–S50)

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Patient safety and other benefits of health information technology, especially electronic health records (EHR) and computerized prescriber order entry (CPOE), have been touted by numerous entities. Despite widespread optimism and regular promotion, the adoption of EHRs and CPOE is minimal in most United States hospitals. Recent surveys indicate that fewer than 9% of United States hospitals have a comprehensive EHR, and CPOE for medications has been implemented in only approximately 1 of 6.[1–3] Various programs are ongoing to promote the implementation of EHRs and CPOE, including federal incentives that will become available in 2011.[4]

Specific data on the use of CPOE for chemotherapy are limited, but CPOE for chemotherapy seems to lag behind its use for other medications. Communications with peer hospitals and the authors' EHR vendor indicated that many organizations defer using CPOE for chemotherapy even though the system is in place for all other medications and order types. A 2007 survey found that only 31% of hospitals with CPOE entered all medication orders into the system, and among the hospitals that did not enter all medication orders, more than 70% did not enter chemotherapy orders.[4] Therefore, a very small percentage of United States hospitals seem to successfully use CPOE for complex chemotherapy regimens, and even fewer do so within well-integrated EHR systems.

Deferring implementation of CPOE for chemotherapy may be an appropriate strategy in many situations. There is an increasing understanding of the challenges, unintended consequences, and risks for new errors associated with any CPOE implementation.[5–10] These general risks are magnified for the use of CPOE for chemotherapy, which in nearly all cases is considered a therapy at risk for error and patient harm. In one recent study

of medication administration to cancer patients, a medication error occurred in 7% of adult and 19% of pediatric clinic visits.[11] The high-risk nature of chemotherapy combined with many other aspects cancer care lead to unique challenges for the safe and appropriate use of CPOE for chemotherapy (Table 1). This article describes the process for implementing CPOE for chemotherapy at St. Jude Children's Research Hospital (SJCRH) with the intent of providing physicians, pharmacists, nurses, and other health care professionals general direction and insights into possible methods for safely implementing CPOE for chemotherapy.

Background

St. Jude Children's Research Hospital

SJCRH's mission is "to advance cures, and means of prevention, for pediatric catastrophic diseases through research and treatment."[12] Approximately 5700 patients are treated at SJCRH each year and more than 25,000 doses of chemotherapy are administered. Research is focused mainly on childhood cancers, acquired and inherited immunodeficiencies, infectious diseases, sickle cell disease, and genetic disorders. SJCRH is designated as a Comprehensive Cancer Center by the NCI.

Clinical Informatics at SJCRH and Organizational Commitment

SJCRH has dedicated substantial resources to converting from a paper-based to an electronic-based medical record system. Led by the Chief Medical Information Officer (CMIO), the Clinical Informatics Division of the Information Sciences Department is responsible for implementing an EHR system under the overall direction of the Chief Information Officer and Clinical Medical Director. Clinical Informatics consists of approximately 40 staff, many of whom have clinical backgrounds (2 physicians, 2 pharmacists, and several nurses, dietitians, and medical technologists). This clinical background is essential for staff to facilitate integration of computer systems into clinical operations. Clinical Informatics also includes staff members with more technical backgrounds (e.g., software programmers, process redesign engineer).

Groups within Clinical Informatics focus on particular clinical needs, such as documentation, orders, scheduling, process redesign, training, programming, and various ancillary operations. Small informatics groups are also present within the departments of pharmacy, pathology, radiology, and nursing to meet specific departmental informatics needs. One critical function of the CMIO is to facilitate interdepartmental and clinical service communication and collaboration. The Clinical Informatics Division includes the Health Information Management Systems (HIMS) service, which supports the paper record and International Classification of Diseases, Ninth Revision, Clinical Modification (ICD9-CM) coding. The CMIO and Clinical Informatics Directors are therefore positioned to coordinate the transition from a paper to an electronic system and to consider HIMS regulations and requirements for coding when developing an EHR. During the transition, HIMS was merged into Clinical Informatics.

Support for the safe conversion to electronic medical records, including CPOE for complex chemotherapy, extended beyond the Clinical Informatics Division. The effort required collaboration among physicians, physician assistants, nurse practitioners, nurses, pharmacists, and others involved in patient care. Furthermore, the project has been steadfastly and strongly supported by the hospital CEO and the SJCRH Board of Governors.

Chemotherapy Safety Systems Before CPOE

Medications used in cancer care often combine the risks associated with a narrow therapeutic window and the high risks of administration based on exceedingly complex treatment regimens, with little or no tolerance for error. These regimens also include multiple concomitant medications to prevent or ameliorate adverse effects of chemotherapy (e.g., antiemetics, hemorrhagic cystitis inhibitors, antihistamines, corticosteroids), which may require specific timing of administration in relation to chemotherapy doses. Also, as outcomes have improved with combination therapy, the past 3 decades has seen a trend toward steadily increasing complexity of chemotherapy regimens.

For many years, SJCRH has recognized that errors associated with chemotherapy regimens are among the greatest risk points for patient harm. A strong patient safety culture has focused on evaluating and improving processes and systems. SJCRH is keenly aware that systems of care are dynamic and require constant vigilance and modification to maintain and enhance patient safety. Safety of the

Table 1 Special Considerations for the Development, Implementation, and Use of CPOE for Complex Chemotherapy Regimens

Chemotherapy Treatment Features		Examples
Use of complex multidrug regimens that often consist of drugs with narrow therapeutic indices and/or substantial risk of toxicity is critical to a successful outcome	Drugs within regimens may need to be given in precise timing and relation to each other or ancillary/supportive care medications	Drugs such as cyclophosphamide and ifosfamide must be administered in coordination with intravenous hydration fluids and uroprotectants (e.g., mesna)
	Regimens may need to be repeated over days, weeks, months, or even years	Typical remission maintenance treatment for a patient with acute lymphoblastic leukemia occurs weekly over 2 years
	Some chemotherapy may be infused as mixtures of 2 or more drugs	Ifosfamide plus mesna diluted in dextrose 5% or cisplatin plus mannitol diluted in sodium chloride–containing solutions
	Regimens may include biological agents with unique administration and record keeping requirements	Lot number must be recorded for some biological products
	Essential that various routes of administration be used or avoided depending on regimen/drug	Methotrexate: intravenous, intramuscular, intrathecal Cytarabine: intravenous, subcutaneous, intrathecal Vincristine: intravenous only (specifically hide or disable intrathecal route)
	Frequent complex and important drug interactions	Methotrexate and voriconazole
Complex dose calculations and adjustments are often required	Body surface area dosing used for most chemotherapy	Accurate height and weight required to calculate body surface area
	Frequent use of pharmacokinetics, pharmacogenetics, and renal function to dose medications	Glomerular filtration rate required to calculate the dose of carboplatin
	Lifetime cumulative dose needs to be tracked for some agents	Patients can only receive a certain dose of anthracyclines in their lifetime to reduce the risk of cardiac dysfunction
	Frequent dose adjustments based on various clinical parameters are necessary	Absolute neutrophil count and renal, cardiac, and hepatic function
Unique documentation requirements	Treatment regimens often span inpatient and outpatient management, sometimes at different institutions, and must be integrated within the CPOE system and the EHR documentation	A patient with acute lymphoblastic leukemia receives most chemotherapy as an outpatient, but throughout therapy must be admitted several times for high-dose methotrexate
	Because of risk of toxicity and implications of error, additional and redundant reviews based on role are required, which must be facilitated and documented as part of the CPOE process	Chemotherapy is independently checked by 2 pharmacists and 2 nurses
	Must manage and track progress and changes in the regimen over time; these changes are also documented in the chemotherapy summary sheets, often referred to as the treatment *roadmap*	When a dose adjustment is made because of toxicity in a previous cycle of therapy, the goal is often to adjust all future doses accordingly Skip versus delay a treatment regimen/cycle

Abbreviations: CPOE, computerized prescriber order entry; EHR, electronic health record.

chemotherapy use process has been analyzed and improved on multiple occasions. Examples of standard procedures for chemotherapy safety that have been in place since the 1990s are listed in Table 2. These safety practices are similar to the recommendations of major professional organizations for safe use of chemotherapy.[13,14]

SJCRH's extensive use of standardized, regimen-specific, preprinted paper order forms is particularly relevant to our regimen-specific approach to CPOE. Use of these forms had been required for all complex chemotherapy regimens since the early 1990s. Complex chemotherapy regimens were defined as treatment with more than 3 drugs, a regimen that included drug treatment on multiple days, and all transplant conditioning regimens. The preprinted forms for chemotherapy carefully detailed all chemotherapy, supportive care, laboratory tests, and other relevant information, and the forms were specific to the day or course of treatment within a clinical trial or treatment plan. If a clinical trial included various strata according to age, risk classification, or other factors, separate forms were created for each stratum of the protocol.

Preprinted chemotherapy forms were carefully prepared and double checked during the development process to standardize chemotherapy ordering and prevent errors. Order forms for chemotherapy administered as part of a clinical trial were developed by nurses, pharmacists, and study staff as part of the clinical trial activation process. All clinical trial chemotherapy order forms were approved by the principal investigator before the protocol was opened for enrollment. After these forms were produced, the forms were strictly controlled by the hospital's central protocol office and only released to a patient's medical record when enrollment on the clinical trial was confirmed.

When patients could not be treated on a clinical trial, the chemotherapy order form was generated through a different process. First, the patient's primary attending physician was required to develop and document a treatment plan for the individual patient within the paper-based medical record. The

Table 2 Examples of Established Safety Systems for Chemotherapy at St. Jude Children's Research Hospital Using Paper Processes

Safety System	Example
Formal and required training programs	New nurse practitioners, physician assistants, oncology fellows, and others who write chemotherapy orders must complete a formal training program
Limits on who can order chemotherapy	Medical residents not authorized to generate chemotherapy orders Chemotherapy orders written by nurse practitioners, physician assistants, and oncology fellows require verification by an attending physician
Standardization and clear documentation of plan for chemotherapy use	All chemotherapy use is per protocol within the context of a clinical trial or written treatment plans, which are standardized, carefully reviewed, and generated for individual patients when enrollment on a study is not available
Standardized, regimen-specific preprinted order forms required for all complex chemotherapy regimens	Order forms for protocols controlled by central protocol office and only released once patient enrollment is confirmed Order forms for nonprotocol patients developed in collaboration with and approved by a clinical pharmacist and the patient's oncologist
Elimination of abbreviations, acronyms, and brand names for chemotherapy	Orders must be written for "methotrexate" not "MTX," and for "vincristine" not "VCR" or "Oncovin"
Various redundant checks in chemotherapy ordering, preparation, and administration process	The "OK to Give" process: an additional patient assessment and order indicating that the intended chemotherapy is "OK to give" must be written by an attending oncologist before chemotherapy orders will be carried out by pharmacy and nursing staff. This order is separate and distinct from the chemotherapy orders themselves and is only valid within 72 hours before chemotherapy administration Orders and doses reviewed independently by at least 2 pharmacists Orders and doses reviewed independently by at least 2 nurses
Additional safety measures for specific therapies	Doses of chemotherapy for intrathecal administration include additional special labeling, and administration area is separate and distinct from the standard chemotherapy infusion center

oncologist then forwarded the treatment plan to a clinical pharmacist for independent review and assistance in generating the preprinted orders. After the clinical pharmacists developed the nonprotocol order forms, these were approved for use by that patient's oncologist.

Substantial resources were required to develop and maintain the preprinted chemotherapy order forms. However, the standardization and patient safety benefits made the investment of resources worthwhile. Beyond obvious improvements in legibility, the forms guided the process for the prescriber, enabling orders to be made easily and correctly, and provided a clear reference point for everyone involved in the chemotherapy use process. Figure 1 provides examples of complex chemotherapy orders at SJCRH before and after the use of preprinted orders.

Given SJCRH's refinement of chemotherapy safety systems over many years, the core principle throughout the development and implementation of the CPOE system for chemotherapy was that it must be as safe as (and eventually safer than) existing paper chemotherapy systems and processes. Therefore, the leaders of this effort established and maintained an excellent understanding of existing paper safety systems for chemotherapy. Safety of the CPOE and paper systems was formally compared on 2 occasions using the proactive risk assessment technique Failure Mode and Effects Analysis (FMEA).

Planning

Initial Planning and Vendor Selection

In the mid-1990s, SJCRH developed the vision of an electronic medical record that would be interactive and based on discrete data capture. Previous unfavorable experiences with a system developed in-house discouraged consideration of building this system from the ground up. Therefore, the institution considered 2 approaches to achieve this goal: 1) the "best of breed" approach, in which the best information system to meet a specific patient care or departmental need is purchased and interfaced with other systems, and 2) an integrated single system designed to share key data elements within departmental software applications that were, in turn, designed to work together as a whole.[15,16] To achieve the high degree of integration sought, SJCRH chose the single integrated system approach. Several vendors were considered. The primary considerations

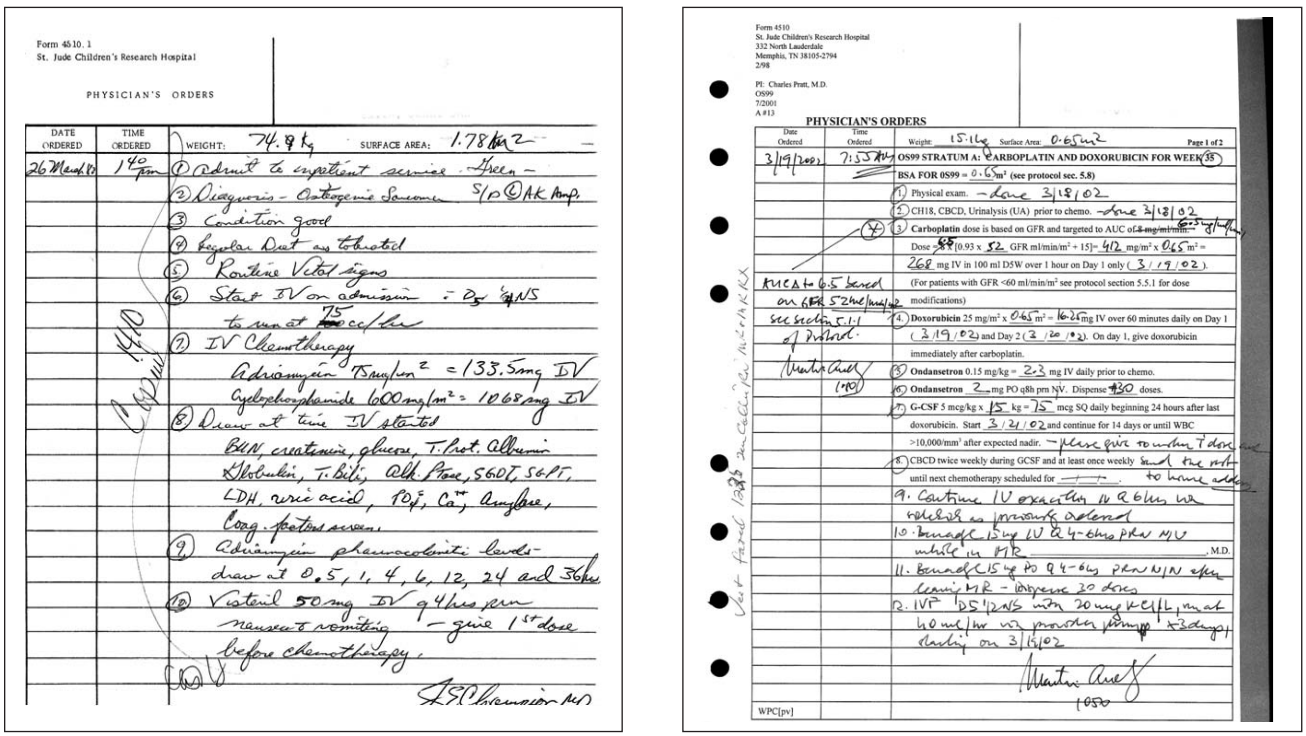

Figure 1 Examples of chemotherapy orders before and after preprinted orders were required.

for vendor selection at that time were 1) the overall current performance of the system; 2) the vision of the vendor for future development; 3) the current and future predicted viability of the vendor; 4) the nonintegrated systems in use at that time; and 5) the overall cost of the system. In 1997, SJCRH contracted with Cerner Corporation to provide a highly integrated electronic medical record with decision support and populated with discrete data through their Millennium system. For example, the software is integrated so that a medication order is shared among the ordering module, the pharmacy module, and finally the electronic medication administration record (eMAR) without needing to transcribe the original order into the pharmacy information system or eMAR. The first segment of the EHR, which provided access to view laboratory results, was installed on April 1, 1999.

Implementation of the system has taken much longer than the 3 years originally envisioned. Although progress has been steady, a stepwise implementation has been necessary to achieve clinician acceptance and maintain the desired level of patient safety. Notably, many institutions that have performed "big bang" implementations that often exclude oncology because of perceived patient safety concerns. Figure 2 provides a timeline of the implementation, including key milestones in both EHR and CPOE implementation efforts. Due to important improvements in the vendor's software, safely implementing CPOE for chemotherapy should not require as much time were it performed now. However, as is explained throughout this article, a careful, stepwise approach is essential to safe implementation of CPOE for chemotherapy.

Process Redesign as the Foundation for System Design, Build, and Implementation

Formal process redesign and system analysis served as the foundation for the design, build, training, implementation, and support of this CPOE system for chemotherapy.[17] Current and future state process flow maps were created for each segment of the CPOE implementation. In addition, 2 separate FMEAs of the entire chemotherapy processes were conducted. The process redesign approach and the results of the first FMEA of the chemotherapy ordering process with CPOE were previously described.[18] The importance of considering workflow implications of CPOE implementation of chemotherapy is highlighted throughout the ASCO principles of safe use of oncology EHR.[19,20]

The process redesign efforts were led by individuals with specific expertise in process redesign. For each phase of implementation, a team of individuals directly involved in ordering, dispensing, and administering chemotherapy were assembled to document their processes associated with chemotherapy. Process flow maps were created to detail each step in a process, the role or resource that accomplished each step, and any links between processes. Separate process flow maps were created based on the current state with paper and the expected future state once the electronic system was implemented. The comparison of current and future process flow maps

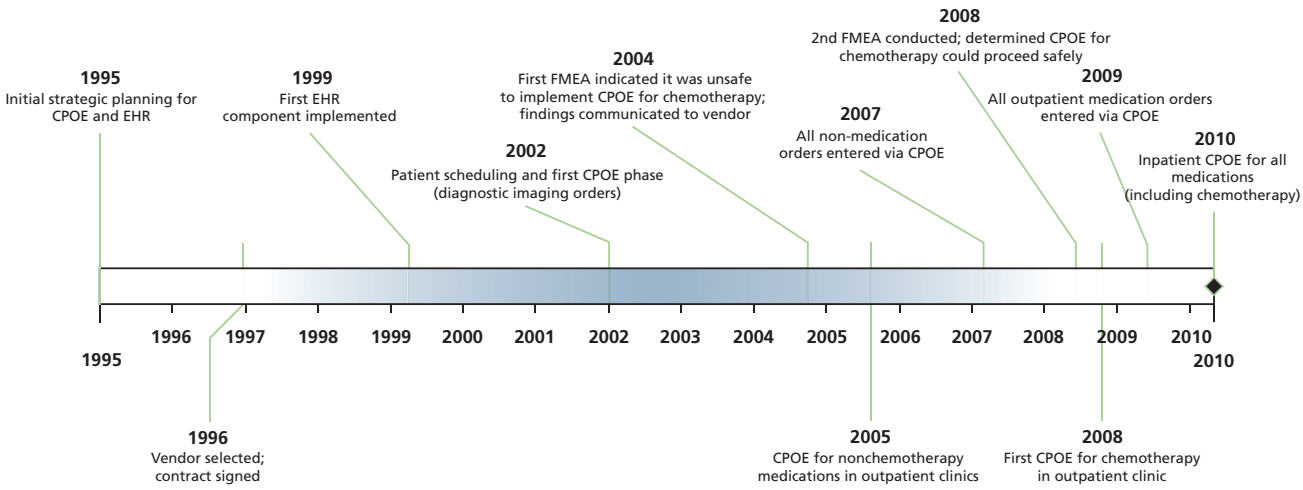

Figure 2 A timeline of computerized prescriber order entry implementation.
Abbreviations: CPOE, computerized prescriber order entry; EHR, electronic health records; FMEA, Failure Mode and Effects Analysis.

identified and clarified changes in practices that would occur as CPOE was implemented. Dozens of process flow maps were created to support the CPOE implementation. This approach yielded extensive information on potential barriers and challenges to implementation, which were then mitigated through modification or creation of new policies and procedures, changes in the computer system, focused training, and other means.

Besides process flow maps, 2 FMEAs of the chemotherapy process were conducted. FMEA was used to formally assess how individual components of the chemotherapy ordering process could fail, how likely failure was, and the consequences of any failure. The FMEA efforts built on the various process flow maps and focused on the entire chemotherapy process. Occasionally the process flow maps became very focused on individual aspects or locations within the hospital, and therefore the FMEA provided a more global view of the chemotherapy process. Because of the broad perspective, larger teams were used to conduct the FMEAs, and expertise of specific individuals was sought for certain aspects of the process. Because FMEA provides numeric values of the potential for harm (risk priority number [RPN]), the authors were able to quantify any increased patient risk from using CPOE for chemotherapy, and FMEA proved essential in reaching the goal that CPOE for chemotherapy would be as safe as (and eventually safer than) existing paper chemotherapy systems and processes.

The first FMEA of the chemotherapy process, conducted in 2004, identified significant limitations of CPOE for chemotherapy, postponing its implementation. Several ordering options were considered. Individually generating each electronic order for chemotherapy and associated medications was immediately dismissed as too time-consuming and unsafe. Simple order sets failed to maintain the context of the regimen once executed. Fortunately, advanced ordering functions had recently become available (PowerPlans, Cerner), and the new ordering functions mimicked many features of paper order sets. However, the team identified several important limitations of the new ordering functions, including integration across components of the system, various aspects of clinician ordering, and availability of medication frequencies. Some chemotherapy orders did not fully match between the ordering and pharmacy components of the system, which was unacceptable because this limited the pharmacist's ability to properly review and check chemotherapy. The system did not allow for some orders essential to the safe use of chemotherapy, such as corresponding intravenous fluids and interval frequencies commonly used for chemotherapy. All of these findings were communicated to the vendor before further implementation for chemotherapy, and the vendor worked with SJCRH to improve the software functionality.

After receiving a significant number of software enhancements, a similar approach was used for a second FMEA conducted in 2008, which focused on the potential use of CPOE for chemotherapy in a pediatric neuro-oncology ambulatory clinic setting with administration of chemotherapy in the hospital's outpatient infusion center. This was also an extensive effort that included 15 meetings with at least 17 people from various areas and disciplines. Because the previous FMEA had characterized the paper process, the second FMEA focused entirely on proposed electronic processes. The team identified more than 100 individual steps in the chemotherapy process, and each step received an RPN.

Although some risk existed for each point in the process, it was clearly concentrated in a small number of steps. The areas of greatest risk were grouped into 2 general areas, on which risk mitigation and error prevention efforts were focused. Initiating and selecting the correct electronic order set was the area of risk rated highest. Because electronic order sets were central to the entire CPOE process for chemotherapy and thousands of order sets were created, selecting the wrong order set was believed to be relatively easy (e.g., unintentional selection of an order set above or below the desired set). This posed the risk that an error initiated from an incorrect order set could be carried forward through one or more doses of the chemotherapy regimen.

The second general area of risk was properly transferring data from the order set to the pharmacy system. Most importantly, the FMEA indicated that CPOE brought fundamental changes in the way prescriber and pharmacist communicate regarding details of an order, especially for complex chemotherapy. For example, results showed that a prescriber may provide special information, such as longer infusion time, but the pharmacy system would unintentionally overwrite these instructions with default information associated with the drug. Furthermore, the

prescribing module did not allow individual ordering of multidrug component intravenous solutions that contained a frequency (e.g., ifosfamide plus mesna diluted in dextrose 5% intravenous every 24 hours for 5 doses) while the pharmacy information system did contain this functionality. These medication order types are commonly used for complex chemotherapy regimens. Risk mitigation strategies were developed, including careful review and removal of default information in selected cases, creation of special fields to guide prescribers, and continued collaboration with the vendor to improve software functionality based on the FMEA findings until the FMEA team concluded that the electronic CPOE process for chemotherapy was safe enough.

Approval of Chemotherapy Administration by an Attending Oncologist

One critically important improvisation in the implementation of CPOE for chemotherapy was to embed an electronic order detail in each chemotherapy order that was defaulted to "Not OK to Give." This detail could only be accessed by an attending oncologist with chemotherapy ordering privileges, who must reset this detail to "OK to Give" for each chemotherapy order within 72 hours of administration as a prerequisite for the drug to be dispensed by the pharmacist or administered by the nurse. This process assures that every chemotherapy order undergoes final review by the responsible attending oncologist during the critical step of therapy initiation.

Planning for Clinical Decision Support

Clinical decision support (CDS) consists of functions that provide clinicians and others with knowledge and person-specific information, intelligently filtered or presented at appropriate times to enhance health and health care. It is frequently cited as a compelling benefit of CPOE and EHR.[21,22] Types of decision support available in the SJCRH CPOE system include drug–drug interaction, drug–food interaction, duplicate therapy, allergy checking, and rule-based alerts (i.e., customized and advanced decision support); retrieval and display of time-relevant clinical parameters (e.g., most recent absolute neutrophil count within past 72 hours must be > 500); and presentation of the predetermined intended dosing regimen within the context of electronic order sets to prescribers. More advanced and customized decision support functions that bring together various discrete elements of the medical record are also possible.

Despite evidence establishing the benefit of CDS through CPOE, many implementation challenges exist for both basic and advanced decision support. Basic decision support for medications is often not useful to clinicians, and therefore is ineffective in improving patient care.[23,24] "Alert fatigue," in which clinicians see several alerts and fail to differentiate those with critically relevant information from the less-informative warnings, is a common problem in the application of CDS. A systematic review of 17 published studies of drug safety alerts in CPOE found that clinicians override alerts 49% to 96% of the time.[25] Alert fatigue and poor design are pervasive challenges in basic CDS, and are even greater challenges in more advanced decision support for complex patients.

The authors recognized both the opportunities and the challenges with CDS, and were able to plan proactively. During CPOE implementation, they focused primarily on basic decision support functions for medications, but in select situations also developed and applied more advanced decision support functions. A multidisciplinary group of clinicians prospectively determined basic decision support functions for medications within CPOE, including drug allergy checking, drug–drug interactions, and duplicate therapy alerts. A primary goal of the group was to decrease the likelihood of alert fatigue so that the decision aids were targeted and useful. Given the intense and complex therapy the patients at SJCRH chronically receive, the following decisions were made:

- Duplicate therapy alerts were disabled because a high percentage of these alerts lacked clinical value (e.g., prescribing 2 pain medications or 2 antibiotics prompted an alert).
- Vendor-supplied drug–drug interaction alerts were set to warn only at the highest of 3 available severity levels (minor, moderate, severe).
- Clinicians were required to document a reason for overriding alerts, including drug allergy alerts. The override reason became a mandatory field and a short list of reasons was developed.

In an effort to continually refine the alerts that remained in the CPOE system, an alert review process was established. Clinicians are encouraged to suggest specific alerts to be considered for modifi-

cation or turned off if believed to lack clinical relevance. Requests for alert changes are reviewed by the Medication Safety Officer, CDS Officer, CMIO, and other staff when applicable (e.g., nursing, laboratory). Alert modifications are quickly implemented based on patient safety implications and benefit/risk assessment. In most cases, alerts have been turned off because clinicians explained that the alert added little clinical value, and the review process confirmed that assessment. However, in several important cases, alerts were raised to a level that would trigger a warning because the drug–drug interactions were especially applicable to the patient population. Alert modifications that involve medications are reviewed by the Pharmacy and Therapeutics Committee, and the alert modification decision is reconsidered if any concerns are identified.

Implementation Process

Approach

SJCRH's extensive use of standardized, regimen-specific preprinted paper order forms for chemotherapy served as a foundation for safe implementation of CPOE for chemotherapy and served as the basis for developing electronic order sets. The vendor refers to their electronic order set functionality as PowerPlans, which have special features of particular importance for chemotherapy regimens, such as the ability to time medications from an anchor order, link 2 orders together, and allow the physician to enter a single start date and time that will be applied to all orders within the plan. Multidisciplinary teams worked with clinical informatics staff to develop electronic order sets for all protocols. For useful and safe order sets, it proved essential to have broad involvement in the development process; therefore, physicians, pharmacists, nurses, nurse practitioners, and physician assistants were all involved. The final version of the electronic order set was approved by the principal investigator of each protocol. By the end of implementation, more than 3000 order sets were developed. Figure 3 provides an example of an electronic order set. Of note, "TALLman" lettering (e.g., CARBOplatin to differentiate from CISplatin) is used throughout the order sets to help prevent errors from drug name confusion.

The pros and cons of "big bang" versus incremental implementations were considered. The challenge with the "big bang" approach, especially for chemotherapy, was that 100% of the chemotherapy regimens would have to be available on day 1 of "go-live" before moving forward. An analysis of the work effort needed to convert all preprinted order sheets to electronic order sets and have these order sets reviewed and approved by oncology attending staff indicated that it would have taken almost 2 years of constant effort. In addition, the process redesign efforts for multiple areas and medical services were extensive.

Because of those concerns, SJCRH pursued a phased implementation of CPOE. Electronic orders other than medications (e.g., laboratory tests, diagnostic imaging) were implemented first to allow clinicians to become familiar with the system and the complexity of the electronic order sets. Medication orders were then implemented on a clinic-by-clinic basis (e.g., leukemia clinic, solid tumor clinic, neuro-oncology clinic) in 2 phases. First, nonchemotherapy medication orders were entered, such as infusions in the outpatient area and outpatient prescriptions. Later, each clinic used CPOE to order chemotherapy. The final increment was the inpatient unit, by which time all of the oncologists were relatively proficient using the system from their experience in the outpatient clinics. CPOE for chemotherapy was able to be implemented concurrently in the entire inpatient unit, but would have been difficult if the staff were not comfortable with CPOE from their outpatient experience.

Training and Support

Training was required and provided to all staff members involved in generating or carrying out chemotherapy orders before each defined go-live date with each incremental implementation. Members of the training team (4) joined process redesign groups during their final meetings so that they could obtain a clear understanding of the process flow maps, understand remaining gaps and key decisions, and make contact with personnel who helped form the necessary training strategies and materials. Because of their unique perspective, training staff were also adept at identifying gaps before implementation.

Various training methods were used. Interactive computer-based training modules were created to walk users through common, agreed-upon, role-based scenarios. Instructor-led classroom training was provided after core competencies had been es-

tablished through the computer-based training modules to educate staff members on process changes and demonstrate particularly challenging patient care scenarios (e.g., change in patient venue midway through a multiday chemotherapy regimen). Over 550 physicians, physician assistants, nurse practitioners, nurses, pharmacists, and others underwent training. When necessary, individualized one-on-

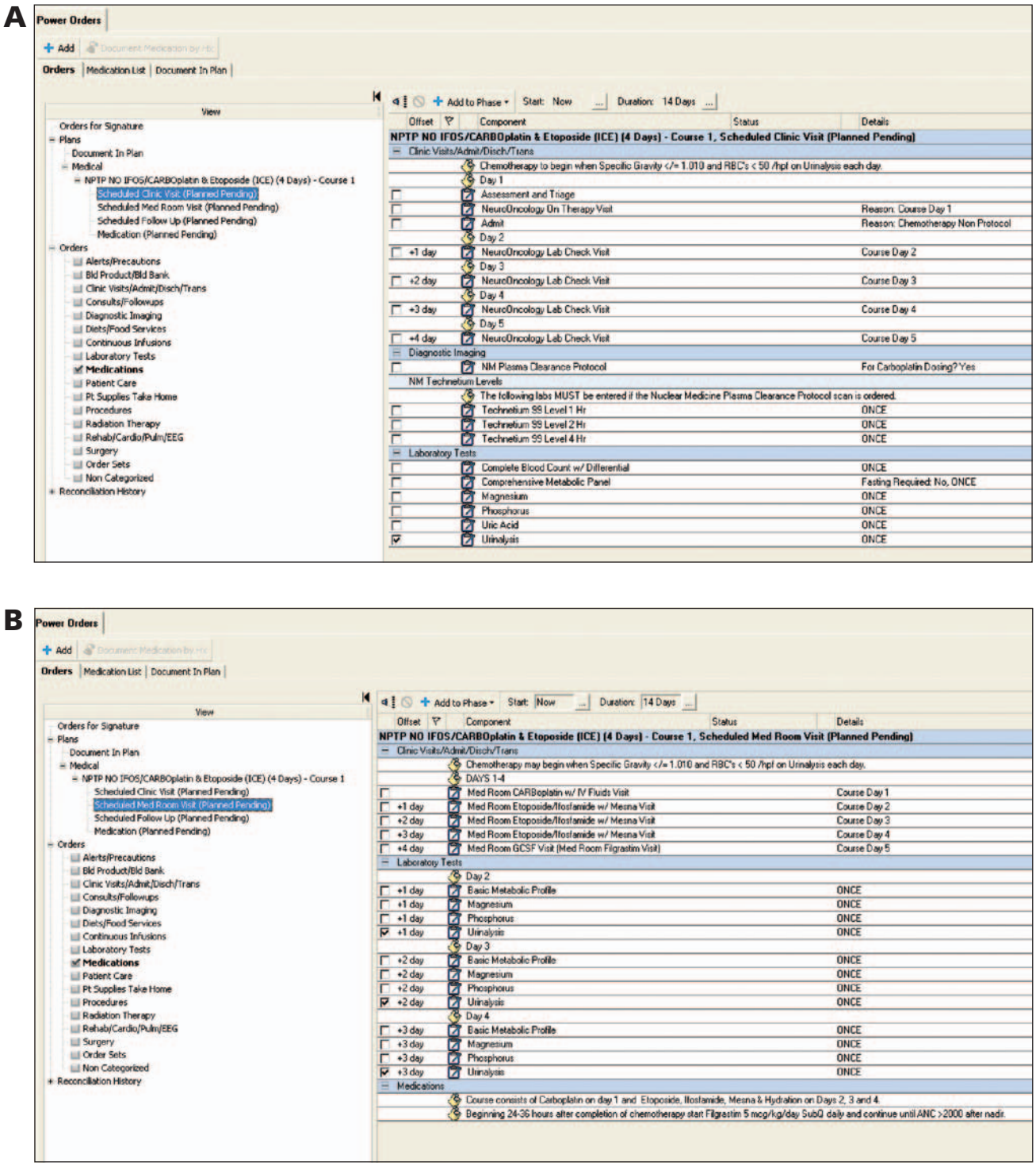

Figure 3 Electronic order sets (PowerPlans) – each plan has multiple sections. (A) Section 1: scheduled clinic visits and laboratory test. (B) Section 2: infusion center appointments and laboratory work due on subsequent days of treatment.

C

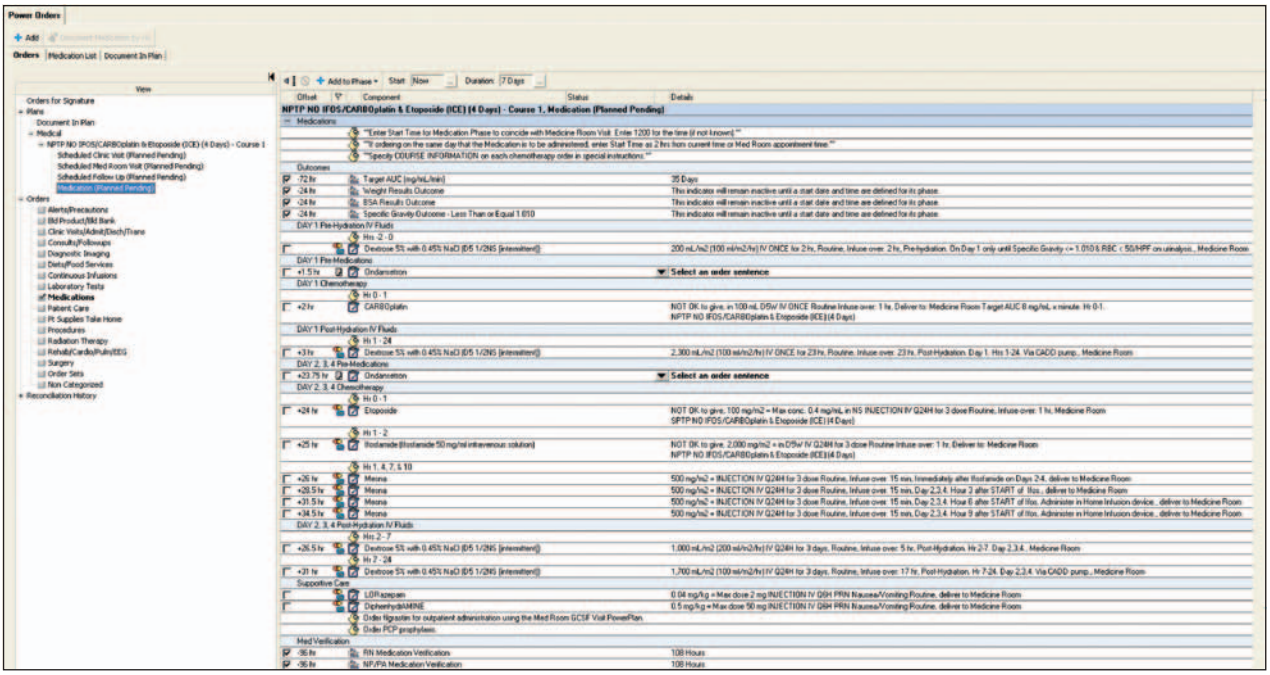

Figure 3 (Cont.) Electronic order sets (PowerPlans) – each plan has multiple sections. (C) Chemotherapy section.

one training sessions were also provided. Printed materials (posters, pocket guides) were distributed during training sessions or on the go-live date to serve as easy-to-use references. Access to the computer system was denied or rescinded if an individual did not attend required training sessions. Super users were usually identified through role and location during implementations. These individuals had often been directly involved in the process redesign meetings and had a deeper understanding of the processes involved, a more thorough understanding of the software, and attended more in-depth training sessions than the standard user.

During each implementation phase, clinical informatics staff was continuously available to provide support, and efforts were made to identify ongoing opportunities for improvement. Informatics staff remained available in the area being implemented, and clinicians could call a single cell phone number anytime to receive help. The electronic event reporting system was also essential to identify CPOE-related errors and improvements. Staff members were reminded to report to the system, and there was a heightened awareness and reporting of errors during CPOE implementation, especially inpatient implementation. Frequent multidisciplinary meetings were held to quickly identify and resolve challenges that arose during each implementation. Numerous small and large changes were made throughout each implementation phase.

Outcome and Discussion

All chemotherapy orders at SJCRH for inpatient and outpatient care are now entered through CPOE. Implementation was started in outpatient clinics in 2008 and was completed in all areas in May 2010. Physicians, physician assistants, nurse practitioners, pharmacists, and nurses have accepted and, in many cases, embraced the system during and after a gradual implementation strategy. During the implementation process, the safety level that had been achieved through decades of developing a highly safe paper-based system was successfully maintained. During inpatient implementation, which was believed to be the period of greatest risk, special emphasis was placed on reporting of patient safety events related to CPOE with special diligence. After review by a multidisciplinary team that included pharmacists, nurses, physicians, and informatics personnel, no medication events attributed specifically to CPOE caused patient harm. Importantly, the near-miss and no-harm events reported were valuable for identifying necessary improvements in the system. Although CPOE-related event reports that cause harm is a somewhat crude measure of success, this experience

stands in sharp contrast to other pediatric CPOE implementation experiences.[9] Additional analysis of CPOE-related event reports is ongoing. Further, acceptance of the CPOE system for chemotherapy by the involved health care staff has been positive. This is also in distinction to CPOE implementation failures related to physician complaints and refusals to work in the system, which have occurred at other organizations.[26]

Lessons Learned

Keys to successful implementation of CPOE for chemotherapy are listed in Table 3. Facilitating collaboration across departments and services before taking the system live is important. Clinically orientated staff familiar with how the organization operates and active involvement of key leaders is also of paramount importance during implementation. An overarching lesson of this experience is that the resources required to safely implement CPOE for chemotherapy are extensive and require significant clinical experience to be most effective. To provide comprehensive orders and order sets to administer chemotherapy safely and successfully, more resources may be required for oncology than all other order categories combined in institutions with comprehensive cancer programs.

One example of the resources required for CPOE for chemotherapy is order set development. SJCRH developed more than 3000 advanced function order sets (PowerPlans) to support its oncology protocols, whereas other larger children's hospitals have needed only a fraction of this number to support all of their clinical operations excluding oncology. Moreover, treatment protocols for oncology tend to evolve more quickly and globally than, for example, a standard management plan for asthma. Thus, 2 to 3 dedicated staff may be needed to support continuously evolving and new cancer protocols. Staff must also be available to develop custom advanced order sets for individual use, sometimes on an urgent basis.

Table 3 Keys to Successful Implementation of Computerized Prescriber Order Entry for Chemotherapy

Category	Keys to Success
Organizational commitment and leadership	Organizational and departmental leadership and staff commitment to patient safety as first priority; perspective was that computerized prescriber order entry must be made as safe or safer than existing paper processes, with recognition of some safety risks due to the window of unfamiliarity at implementation
	Appropriate resources for safe implementation, including process redesign efforts and adequate support to respond to questions and issues promptly
	Engagement and collaboration from all disciplines involved (physicians, nurse practitioners, physician assistants, nurses, pharmacists, informatics staff)
Implementation approach	Intense, formal process redesign with extensive involvement across all disciplines/areas
	Use of proactive risk assessment tools (e.g., Failure Modes and Effects Analysis)
	Sequential implementation of logical units that can be adequately supported (as opposed to an all-at-once or "big bang" approach)
Implementation techniques	Use of existing paper-based order sets to structure and standardize electronic versions of protocol and nonprotocol chemotherapy regimens
	Electronic order sets developed by a multidisciplinary team with final approval by the principal investigator and/or senior attending physicians
Software considerations and functions	Advanced software functionality to allow continuous review of the order set and regimen even after completion of the orders, and to sequence orders based on an anchoring order
	Some flexibility in software so that the process does not always have to adjust to the software, but rather the software can adjust to the process
Training and support	Inclusion of the training staff in the process redesign and development phases
	Extensive, in-hospital, around-the-clock support after go-live until the staff is comfortable (24 hours a day and 7 days a week, continuing until most of the staff have rotated through new process)
	Appropriate downtime processes (e.g., patient information saved on laptops and flash drives that can be deployed during downtimes, including complete network outages)

However, successful implementation goes beyond simply having the right electronic order set available. The initial process redesign work, risk assessment, and appropriate training before implementation are all crucial for the optimal appropriate use of the order set.

Patient safety and efficiency of operations for chemotherapy CPOE is highly dependent on thoughtful CDS. The authors estimated that if all of the alerts generated by the electronic medical record system were allowed to be displayed, each inpatient attending oncologist would have approximately 150 alerts per day. We carefully reviewed and filtered alerts in an attempt to interrupt clinician workflow only when truly necessary. In addition to disabling some alerts and because of the unique setting, the authors increased the severity rating of certain drug–drug interaction pairs that the vendor classified as moderate risk to the severe category so that automated warnings would interrupt the order entry process when detected. Increasingly, SJCRH is developing customized alerts that make the system safer.

Among the most innovative CDS SJCRH has in place is the ability to integrate information from the central protocol office, clinical trial application, and the ordering process. For example, when study-specific supplies of investigational medications are ordered, a custom rule determines if the patient for whom the order is being generated is enrolled on the corresponding clinical trial as recorded within the EHR. When an investigational drug is entered, the rule compares the drug entry to the listing of clinical trial enrollments in the EHR. This rule is accomplished by building specific entries for each investigational drug and documenting individual enrollment on clinical trials (Figure 4).

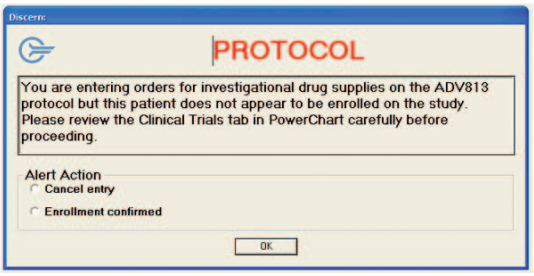

Figure 4. An example of an alert that warns when investigational drug orders do not match clinical trial enrollment.

Future Directions

Because implementation of CPOE is complete, SJCRH's full attention is now focused on completing electronic documentation and further refining all aspects of CPOE and EHR. As fewer resources are devoted to implementation, more resources will become available to focus on refining existing CDS and developing new CDS functions. Beyond the standard processes to continually monitor and refine existing CDS, priorities for new CDS include functions focused on the chemotherapy order sets and the organization of chemotherapy information in the EHR. In general, SJCRH's approach to CDS will place less emphasis on building new alerts that will be presented to clinicians. Instead, their CDS efforts will gravitate toward filtering and directing clinicians to the right information.

For protocol patients, CDS functions for electronic order sets will be developed to limit access to relevant order sets based on clinical trial enrollment and to increase usability of order sets. Currently, an order set can be used for any patient at any time, and incorrect selection of an order set is a key failure point. Therefore, a future priority is to filter chemotherapy order sets for clinical trials so that the clinician can only view orders for the protocols on which a patient is enrolled. Furthermore, because order sets are used sequentially (e.g., week 1, week 2), previously used sets will no longer be available for an individual patient. These new electronic functions will be analogous to the formerly used paper process, through which it was difficult to inadvertently reorder chemotherapy on an old order form, and preprinted order forms only became available in a patient's chart after confirmation of protocol enrollment.

New functions will make the electronic order sets more dynamic based on discrete clinical variables. After key clinical information such as age, gender, or protocol stratum is entered, the system will automatically eliminate sections of the order set that are not relevant. For example, if special drug dosing requirements exist for patients younger than 2 years and the patient for whom orders are generated is 12 months old, only the defaulted dosing regimen (for patients younger than 2) is shown. The dosing regimen for patients 2 years and older will automatically be eliminated from view by the system.

The vendor continues to increase capabilities to produce custom views, which SJCRH plans to develop for various functions and disciplines within the chemotherapy use process. Because locating all the relevant information necessary to order chemotherapy can be challenging, SJCRH has worked with the vendor to create an oncology flowsheet and summary page, which will be implemented in early 2011. These views will allow clinicians to quickly see the most recent chemotherapy administered, key laboratory values, and other information. The vendor recently made available a new approach that allows individual institutions to develop their own front-end interfaces and functionalities that operate seamlessly as if they were a vendor-supported application. This new functionality offers great promise to enhance patient safety and ease of use, but the extensive number of hours of programming time required to develop and test these applications may be a significant barrier to their use.

Conclusions

With careful planning, CPOE for chemotherapy can be safely implemented. Extensive use of electronic order sets, formal process redesign and system analysis, careful and strategic use of clinical decision support, and a phased implementation approach were essential for safe implementation of CPOE for chemotherapy at SJCRH. Collaboration and feedback with software providers is essential to achieve a safe and usable CPOE system for chemotherapy. Improvements in the vendor's software and experience gained during this implementation would enable chemotherapy orders to be implemented safely and successfully in a more condensed timeframe were the process to be undertaken today. The hope is that the lessons learned from this experience will allow other institutions to achieve safety and success as efficiently as possible.

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