A continuous-improvement approach for reducing the number of chemotherapy-related medication errors

BARRY R. GOLDSPIEL, ROBERT DECHRISTOFORO, AND CHARLES E. DANIELS

Abstract: A comprehensive, interdisciplinary approach for reducing the number of chemotherapy-related medication errors at the National Institutes of Health Clinical Center, where approximately 8500 doses of chemotherapy agents are dispensed annually, is described.

Heightened awareness of the seriousness of chemotherapy-related medication errors prompted formation of an interdisciplinary task force in June 1995 to analyze and improve the hospital's system for ordering, checking, processing, and administering cancer chemotherapy agents. Problems were analyzed and rectified in accordance with the hospital's plan-do-check-act performance-improvement model. Performance monitors for the improvements included a system to record and categorize all chemotherapy-related prescribing errors and a hospitalwide occurrence-reporting system. The task force identified seven major categories in which improvements were needed: protocol development, computer-system enhancements, dose verification, information access, education for health care practitioners, error follow-up, and infusion pumps. Despite the Clinical Center's good safety-net system, 23 modifications were made to the existing system through December 1999. These changes resulted in an overall 23% decrease in prescribing errors and a 53% decrease in serious prescribing errors. The task force membership was recently broadened to include representatives of additional departments where chemotherapy agents are used, and this group recommended more than 20 additional system changes. The changes are being implemented, and their effect on reducing the number of chemotherapy-related errors will be measured.

The continuous-improvement process used prospectively by the task force helps ensure that safe chemotherapy practices are instituted uniformly throughout the hospital.

Index terms: Administration; Antineoplastic agents; Costs; Devices; Dosage; Drug information; Education; Errors, medication; Pharmaceutical services; Pharmacy, institutional, hospital; Physicians; Prescribing; Quality assurance; Reports; Toxicity

Am J Health-Syst Pharm. 2000; 57(Suppl 4):S4-9

Chemotherapy-related medication errors can have serious and sometimes fatal consequences, and news stories about chemotherapy-related medication errors at some hospitals heightened our awareness of that potential.[1-3] The pharmacy department at the National Institutes of Health (NIH) Clinical Center initiated a performance-improvement project using an interdisciplinary task force to analyze and improve our current multilevel, interdisciplinary system for ordering, checking, processing, and administering cancer chemotherapy agents. Although there was no perception that we had a problem with chemotherapy-related medication errors, we initiated a prospective program to determine whether our system could be improved.

This project aligns with our hospital's mission to initiate and support the clinical research sponsored by the individual institutes that make up NIH. It is also consistent

BARRY R. GOLDSPIEL, PHARM.D., FASHP, is Oncology Clinical Pharmacy Specialist; ROBERT DECHRISTOFORO, M.S., is Deputy Chief; and CHARLES E. DANIELS, PH.D., FASHP, is Chief, Pharmacy Department, National Institutes of Health Clinical Center, Bethesda, MD.

Address reprint requests to Dr. Goldspiel at the National Institutes of Health Clinical Center, Pharmacy Department, Bldg. 10, Room 1N-257, MSC 1196, Bethesda, MD 20892-1196 (bgoldspiel@cc.nih.gov).

The assistance of members of the Chemotherapy Error Reduction Task Force is acknowledged: Elaine Ferguson, M.S., Laurence Green, Pharm.D., David Kohler, Pharm.D., and Judith Smith, Pharm.D., from the pharmacy department; David Henderson, M.D., and Laura Lee from the Office of the Director; Laura Chisholm, Priscilla Rivera, and Barbara Summers, Ph.D., from nursing; Linda Berry, Lillian Butler, Greg Hinson, and Thomas Lewis, M.D., Ph.D., from the information systems department; and Frank Balis, M.D., Greg Curt, M.D., and Wyndham Wilson, M.D., Ph.D., from the National Cancer Institute.

Based on the proceedings of the ASHP Best Practices in Health-System Pharmacy Management Award Symposium held June 6, 2000, during the ASHP Annual Meeting in Philadelphia, PA, and supported by an educational grant from Pfizer Inc. The NIH Clinical Center received a monetary award from Pfizer as part of the recognition associated with the Best Practices program.

with the hospital's current goals to provide

- Quality patient care (reduce possibility of unexpected adverse effects from toxic chemotherapy and administer correct dose 100% of the time),
- Excellence in clinical research (provide protocol quality assurance and reduce protocol violations), and
- Cost-effectiveness and efficiency (provide patients with an appropriate supply of expensive medications and ensure correct drug supply).

Our suggested changes were directed at eliminating the possibility of a chemotherapy-related medication error to ensure that the patient will always receive appropriate chemotherapy as directed by the protocol.

Description of the program

The NIH Clinical Center is the intramural hospital for NIH research. Patients are referred to the Clinical Center for assignment to research protocols. The hospital complex has 325 beds, 15 outpatient units, and 7 extended-care outpatient units. Cancer patients' medications represent approximately 40% of the pharmacy's workload. We dispense approximately 8500 doses of chemotherapy agents per year and use the Eclipsys Medical Information System (MIS) for direct prescriber order entry. Pharmacy department personnel create protocol-specific ordering screens.

An interdisciplinary task force composed of members from the pharmacy department, nursing department, National Cancer Institute intramural program, information systems department (ISD), and hospital administration met in June 1995 to identify and prioritize a list of system problems and possible enhancements. Personnel resources came from existing full-time-equivalent staff within the departments that participated on the task force. Consultants from Eclipsys helped develop some of the computer enhancements.

The task force began by mapping the sequence of events from the time the prescriber enters the order until the patient actually receives the chemotherapy agent. We then identified the weak points in our safety net using prospective failure mode and effects analysis.[4] Solutions to these problems and methods for implementing the enhancements were developed and designed in accordance with our hospital's PDCA (plan-do-check-act) performance-improvement model. Deadlines for each subproject were established.

The group defined major elements that form the overall "plan" and elements under each of these categories. Individual projects or subplans for each of these major categories were then designed. To accomplish the "do" aspect of the model, the task force then formed subcommittees to carry out the subplans.

Our performance monitors ("check") include a system to record and categorize all chemotherapy-related prescribing errors, which we call chemo-checks, and a hospital-wide occurrence-reporting system.[5] Orders are considered incorrect if they cannot be dispensed exactly as written. Order-entry errors are not routinely reported through the hospital occurrence-reporting system; rather, a pharmacist intervenes as appropriate on these orders to correct them before they are prepared by the pharmacy. The incorrect orders are classified as class I (serious adverse effects likely to occur), class II (temporary or medically reversible effects likely to occur), or class III (adverse effects unlikely) and then subcategorized as to the problem with the order.

This classification system allows us to analyze commonly occurring prescribing errors so that we can suggest system changes to correct the problem. Each order-entry error ("near miss") is treated seriously even though the overwhelming majority of these prescribing errors are detected before preparation.

Medication errors that affect patients are reported through an occurrence-reporting system. These errors are then classified into order entry, preparation or dispensing, and administration errors.

Additional improvements to the system that are identified throughout the process constitute the "act" part of the performance-improvement cycle.

Experience with the program

As shown in Table 1, the task force identified seven major categories in which improvements were needed: protocol development, computer-system enhancements, dose verification, information access, education for health care practitioners, error follow-up, and infusion pumps. Although the Clinical Center had what we considered a good safety-net system, as of December 1999 23 modifications have been made to the existing system since the task force began meeting in June 1995.

Because we are a research institution, we believed that research protocols are the initial source of prescribing errors if the language that describes the dosage regimen is not clear and unambiguous. Therefore, we created standardized language to be used when describing chemotherapy regimens within protocols and when chemotherapy orders are written. This language has been adopted by the NCI institutional review board and subsequently by the NCI extramural program.[6]

We focused heavily on simplifying and improving the ordering process through our MIS direct prescriber order-entry system because a correct order ensures that other system safeguards, such as an automatic nursing care plan with drug ad-

Table 1.

Summary of Task Force Recommendations and Implementation Strategies

Plan	Do	Collaborations	Check	Act
Protocol development	Develop standardized nomenclature for chemotherapy prescribing	Pharmacy, NCI,[a] nursing	Chemo-checks, occurrence reports, pharmacy review at IRB[b]	
Computer-system enhancements	Automated dose calculation in computer system	Pharmacy, ISD[c]	Chemo-checks, occurrence reports	Automated dose calculations for pediatric protocols, establish automatic dose limits, automatic date and time generation, chemo "quick peek,"[d] and automatic dose-modification calculations
	Route restriction (e.g., vincristine)	Pharmacy, ISD		
	Order-entry simplification	Pharmacy, ISD		
	Protocol-specific lab parameters automatically added to computer-generated order	Pharmacy, ISD		
Dose preparation and administration verification	Pharmacy preparation-card checklists	Pharmacy	Chemo-checks, occurrence reports	Computerized preparation-card processing system
	Pharmacy product checklists	Pharmacy		
	Nursing administration checklists	Nursing		
	Nursing detailed, protocol-specific drug administration sheets	Nursing, pharmacy		
	New standard of practice for administering cytotoxic agents	Nursing, pharmacy		
Information access	Provide drug information via intranet "clinical desktop"	ISD	Chemo-checks, occurrence reports	Provide protocol schema on intranet
	Provide drug fact sheets on intranet	Pharmacy, ISD		
Education for health care practitioners	MIS chemotherapy-ordering specific training	NCI, ISD, pharmacy	Chemo-checks, occurrence reports	
	Lecture on chemotherapy errors and lecture for nursing chemo-certification course	Pharmacy, nursing		
	Lecture on chemotherapy errors for all new prescribers	Pharmacy		
	Error summaries presented at medical group meetings	Pharmacy, NCI		
Error follow-up	Serious prescribing errors reported in full detail to branch chiefs; all other errors summarized for branch chiefs	Pharmacy, NCI	Chemo-checks, occurrence reports	
	Errors discussed at branch chief and protocol group meetings	Pharmacy, NCI		
	Errors summarized for P&T committee meeting	Pharmacy, OD[e]		
	Develop intranet database for occurrence reporting	ISD, pharmacy, nursing		
Infusion pump issues	Standardize portable pumps used throughout hospital	Pharmacy, nursing, OD	Pump-related occurrence reports	
	Develop policy and procedure for standardizing overfill for infusion pump preparations	Pharmacy, nursing		

[a]NCI = National Cancer Institute.
[b]IRB = Institutional Review Board.
[c]ISD = Information Services Department.
[d]A chemo "quick peek" is a computerized way for physicians, pharmacists, and nurses to review just the last cycle of chemotherapy ordered (excluding other medications).
[e]Office of the Director.

ministration times and automatic stop dates, will function properly. One of the major enhancements to our computer system was to create a method whereby doses were automatically calculated on the basis of height and weight values entered into the patient's record. This calculation is shown directly on the ordering screen (Figure 1). Implementing this change required some creative programming efforts within the ISD to use the existing hospital computer system. Other MIS changes included creating ordering screens that restrict the route by which a drug like vincristine is given, thereby making it virtually impossible to order the drug by any other, possibly fatal, route.

Both pharmacy and nursing revised their procedures for checking chemotherapy before preparation and administration. In addition to developing a new nursing department standard of practice for administering cytotoxic agents, checklists were developed to guide individuals through product preparation and the process for checking drug products.[7] The concept of these checklists is similar to that used by the airline industry to ensure safety and quality.

In collaboration with ISD, a clinical desktop was created that allows instant access to drug information from any computer terminal throughout the hospital. In addition, investigational drug sheets, which detail how investigational drugs are used in our protocols, are now accessible via the hospital's intranet.

In an effort to provide practitioners with educational programs, the group recommended that all physicians who prescribe chemotherapy complete a chemotherapy-specific training module before obtaining credentials. In addition, to heighten awareness about errors, all hospital personnel who prescribe, prepare, or administer chemotherapy now attend an orientation lecture covering the potentially serious nature of chemotherapy medication errors.

Figure 1. Example of a dose-calculation ordering screen.

```
   LEE H MD
   17463          95-C-0055              Q4A

  CYTOXAN(750MG/MSQ) CALC DOSE 1395 MG
  CYCLOPHOSPHAMIDE INJ  ____MG  IV
   IN 100ML 5% DEXTROSE/WATER(D5W)
   ADMINISTER IN CLINIC  INFUSE OVER
   15MIN  AT ___M  X1DOSE ON __/__


  1 HOUR AFTER CYTOXAN
  TAXOL(250MG/MSQ) CALC DOSE 465 MG
  PACLITAXEL INJ  ___MG  IV
   IN 1000ML 0.9% NACL (NS)
   ADMINISTER IN CLINIC  AT ___M  X1DOSE
   ON __/__  INFUSE OVER 24HRS
   VIA PORTABLE INFUSION PUMP
 HT: 166CM   WT: 78KG    BSA  1.860


 ◇BACK  ◇NEXT
   RETURN                MASTER    REVIEW
 ERR        TYPE     RETRIEVE
```

Class I errors are reported to the prescriber's supervisor, using the form shown in Figure 2, soon after the error is detected. These potential errors are taken seriously and often trigger changes in the ordering screens. Actual administration errors that occur are discussed at multidisciplinary meetings to analyze the error and to determine whether a system change is necessary.

Medication errors related to portable infusion pumps were corrected by standardizing the pumps used within the hospital.

Overall, these changes over the last four and a half years have resulted in a 23% decrease in prescribing errors and a 53% decrease in serious prescribing errors. Table 2 summarizes all elements of our current system used to prevent chemotherapy errors.

Discussion

When we compared our current practices against those recommended in articles describing systems for preventing chemotherapy-related medication errors,[7-9] we found that our system met or exceeded all published benchmarks with few exceptions. The current system relies heavily on independent dose verification and education about the safety process for everyone involved, including prescribers, nurses, pharmacists, technicians, and patients.

We believe that monitoring the overall trends in prescribing errors and actual occurrences before and after implementation of changes recommended by the task force is a valid measure of the success of our efforts. In some cases it was possible to measure the effect of an individual change, but we believed it was more important to look at how all

Figure 2. Example of a class I error-reporting form.

R.Ph. Name:
Month/Year:_____

Protocol-Check Error: Category I Outcome Documentation Form

DOSE	**SCHEDULE**	**ADMIN METHOD**	
❑ Differs by ≥**25%***	❑ Dosing interval	❑ Route	
❑ Incorrect # of doses	❑ Drug sequence	❑ Wrong diluent	
	❑ Start/stop date	❑ Quantity of diluent	PASTE LABEL HERE
	❑ Infusion duration	❑ Dosage form	
MISSING INFO	**PROTOCOL**	**MISCELLANEOUS**	
❑ Dose	❑ Wrong protocol #	❑ Wrong quantity drug	
❑ Start/stop time	❑ Pt not registered	❑ Unnecessary reorder	
❑ Therapy duration	❑ Pt not eligible	❑ MIS screen problem	
❑ Name	❑ All labs not available	❑ Wrong drug ordered	
❑ Directions	❑ Labs not satisfactory	❑ Wrong patient	
❑ Dosing interval			
	MIS Order Set ❑Y ❑N	**Non-Protocol** ❑	

*Dose errors of 10 to 25% may be considered class I depending on protocol modification specifications.

Table 2.
Elements of Comprehensive Chemotherapy Error-Reduction Program

Process Level	Systems Used To Reduce Number of Errors	System Monitors for Improvement
Prescribing	Prescriber education about error prevention Patient education about chemotherapy regimen orally and through informed consent Standardized nomenclature for dosage expression in protocol Standardized nomenclature for order Protocol-specific, physician direct order entry Automated dose calculations Pharmacist checks order against protocol Dose verification independent from prescriber (i.e., dose checked with principal investigator or study chairperson)	Prescribing errors classified by potential error severity Class I prescribing errors reported with full details to branch chiefs Quarterly summaries and analysis provided for Class II and III errors Hospital occurrence-reporting system
Preparation and dispensing	Education about error prevention Product preparation card checked by two pharmacists assisted by a checklist Technician checks calculations before preparing Pharmacist checks product assisted by a checklist Patient education when dispensing oral chemotherapy medications	Hospital occurrence-reporting system
Administration	Education about error prevention Computer-generated care plan Dose verification independent from prescriber (i.e., dose checked with principal investigator or study chairperson) Nurse checks order against protocol and second nurse verifies Nurse checks product label against order and second nurse verifies Two nurses verify infusion pump settings Patient education about chemotherapy regimen orally and through informed consent	Hospital occurrence-reporting system

these changes worked synergistically toward our overall goal of reducing the number of chemotherapy-related medication errors at our hospital. Overall, these changes have directly resulted in fewer prescribing errors, especially those considered very harmful to patients if they had received the drugs from the orders as written.

The task force met again in June 2000. The membership of the group was expanded to include representatives of additional departments where chemotherapy is used. Our goal is to ensure that all safe chemotherapy practices are instituted uniformly throughout the hospital.

The new task force identified over 20 additional recommendations for improvement. For example, until recently, no prescribing errors were recorded on protocols where dose-calculation screens were available. The new task force recommended that the capability for maximum dose checks be added to the ordering screens. We are currently working with ISD to implement this and several other recommendations related to enhancing the computer system even more. We know, however, that our present computer system has limited capabilities and cannot perform some of the desired functions identified by the task force. For example, we want orders to be linked automatically so that if the time is changed on one order, the times are changed on all related orders. Fortunately, we are in the process of procuring a new hospital computer system, and these capabilities will be part of the functional requirements for the new system.

Conclusion

We have developed a comprehensive, interdisciplinary approach for reducing the number of chemotherapy-related medication errors at our institution. We expect that the recommendations of the task force, which now includes broader representation of departments, will result in additional system enhancements that will help ensure that safe chemotherapy practices are instituted uniformly throughout the hospital.

References

1. Knox RA. Doctor's orders killed cancer patient: Dana-Farber admits drug overdose caused death of Globe columnist, damage to second woman. *Boston Globe.* 1995; Mar 23:Metro1.
2. Rousch W. Dana-Farber death sends a warning to research hospitals. *Science.* 1995; 269:295-6.
3. Cancer patient in Chicago dies after chemotherapy overdose. *NY Times.* 1995; Jun 18:A17.
4. Fletcher CE. Failure mode and effects analysis: an interdisciplinary way to analyze and reduce medication errors. *J Nurs Adm.* 1997; 27(12):19-26.
5. Chapman MM, Goldspiel BR, DeChristoforo RD et al. Reporting and classifying prescribing errors found while checking protocol orders. Abstract presented at the ASHP Midyear Clinical Meeting, New Orleans, LA; 1991 Dec 8-12.
6. Kohler DR, Montello MJ, Green L et al. Standardizing the expression and nomenclature of cancer treatment regimens. *Am J Health-Syst Pharm.* 1998; 55:137-44.
7. Fischer DS, Alfano S, Knopf MT et al. Improving the cancer chemotherapy use process. *J Clin Oncol.* 1996; 14: 3148-55.
8. Cohen MR, Anderson RW, Attilo RM et al. Preventing medication errors in cancer chemotherapy. *Am J Health-Syst Pharm.* 1996; 53:737-46.
9. Attilo RM. Caring enough to understand: the road to oncology medication error prevention. *Hosp Pharm.* 1996; 31:17-26.