Implementation and evaluation of a gravimetric i.v. workflow software system in an oncology ambulatory care pharmacy

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Purpose. The implementation and evaluation of a gravimetric i.v. workflow software system in an oncology ambulatory care pharmacy are described.

Summary. To estimate the risk involved in the sterile i.v. compounding process, a failure modes and effects analysis (FMEA) in the oncology ambulatory care pharmacy was performed. When a volumetric-based process was used to reconstitute vials, the actual concentration was unknown since an assumption must be made that the exact volume of diluent was used when reconstituting the drug. This gap in our process was discovered during the FMEA and was resolved with the implementation of an i.v. workflow software solution. The i.v. software system standardized preparation steps and documented each process step, enabling a systematic review of the metrics for safety, productivity, and drug waste. Over the study period, 15,843 doses were prepared utilizing the new technology, with a total of 1,126 errors (7%) detected by the workflow software during dose preparation. Barcode scanning detected 292 (26%) of the total errors, the gravimetric weighing step detected 797 (71%) deviation errors, and 37 (3%) errors were detected at the vial reconstitution step. All errors were detected during compounding, eliminating the need to correct errors after production. Technician production time decreased by 34%, and pharmacist checking time decreased by 37%.

Conclusion. Implementation of a gravimetric-based software system that used barcode verification and real-time alerts improved the detection of errors in the chemotherapy preparation process when compared with self-reporting. Standardized workflow processes and the elimination of time-consuming manual steps increased productivity while vial management decreased costs.

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System failures and human factors contributing to preventable errors in the healthcare system can be found in publications dating back to the early 1960s.[1] While much has transpired since those early days to improve the delivery of healthcare, medication errors continue to affect many patients every year.[2-4] Although nonpunitive programs are designed to increase reporting and recognition of safety concerns, there is much to be gained from developing stronger systems to prevent medication errors from reaching patients.

The i.v. route of medication administration can be particularly harmful due to its invasiveness and the fast onset of action of the drug. Over the past decade, the risks associated with the use of sterile i.v. preparations have led to a number of recommendations by safety groups and regulatory changes expressed by the United States Pharmacopeial Convention and state boards of pharmacy.[5,6] In 2013, the Institute for Safe Medication Practices (ISMP) published "Guidelines for Safe Preparation of Compounded Sterile Preparations" to identify and eliminate or reduce errors related to the use of such compounds.[7] Included in the published guidelines were recom-

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mendations to use technology such as barcode scanning for both the preparation and verification of compounded sterile products and to use i.v. workflow software to augment manual processes.

Unfortunately, many pharmacies have been slow to adopt these recommendations for best practices. In January 2015, ISMP revisited the topic, exploring five possible system and behavioral causes for the delay in progress to improve i.v. compounding programs.[8] ISMP also acknowledged that the original 2013 guidelines[5] provided valuable, peer-reviewed consensus statements for many processes but did not delve into specific tasks for checking sterile compounds. Similarly, the regulations of many state boards of pharmacy have provided detailed descriptions of the required conditions for i.v. preparation, though such regulations are nonspecific in describing the steps for verifying i.v. sterile compounded preparations.

Workflow software technologies are available for i.v. sterile compounded preparations and offer the ability to verify ingredients through barcode scanning. Many workflow software solutions rely on volumetric verification through visual inspection by a pharmacist or retrospective pharmacist review through digital images. Several disadvantages exist with image-based workflow solutions. First, the volumetric technique used with chemotherapy doses is highly variable.[9] Second, preparation is delayed if the technician relies on a pharmacist check before injecting the drug, and drug waste occurs if a dose is incorrectly prepared and later identified. Third, digital imaging for verification could lead to new types of errors. In a recent report, Moniz et al.[10] found that nearly 36% of errors detected during a performance evaluation of an i.v. compounding workflow management system were related to blurry or missing images. Lastly, some workflow systems require a printed bag label before dose preparation. There is a risk for errors if staff circumvent best-practice procedures by keeping several printed labels in the work area at the time of preparation.[11]

The gravimetric method uses an electronic balance and the density of a solution as quality-assurance checks to confirm the accuracy of volumes. Gravimetric solutions have primarily been reserved for use in total parenteral nutrition compounding systems and robotic technology. Technology has become available that integrates gravimetric verification as an adjunct to the human visual check. Technology that incorporates gravimetric verification of additives during i.v. sterile compounding could provide further risk reduction into the sterile compounding process over image-based volumetric workflow solutions. Given the need for process improvement in the i.v. room and the advancement of technology-assisted workflow software, M. D. Anderson Cancer Center evaluated a gravimetric i.v. workflow software solution in an oncology ambulatory care pharmacy.

KEY POINTS

- A gravimetric i.v. workflow software system can increase the detection of errors that may go unrecognized in a manual i.v. compounding process.
- FMEA is an important risk-assessment tool used to identify and address safety concerns in a complex process.
- Cost savings can be realized through the use of technology when processes are standardized and manual steps are eliminated.

Background

Existing chemotherapy i.v. preparation processes. The i.v. chemotherapy preparation process used at the oncology ambulatory care pharmacy consisted of many manual steps (Figure 1). The variability and inconsistency between how pharmacists and technicians performed these steps made the entire process prone to errors. A value-stream map was used to identify areas of waste and capture key metrics of the process, such as cycle time and costs.

Pharmacists printed, sorted, and timed labels according to the patient's infusion schedule and then matched labels with paper orders, which were filed after each infusion appointment. Once the dose was requested by a nurse, the i.v. compounding process began when a label was given to the i.v. technician, who gathered drug vials and supplies, calculated the amounts of required ingredients, prepared the dose, and labeled partial vials with the preparer's initials and the correct beyond-use date (BUD). As part of the gravimetric verification, the technician printed weight slips displaying final bag and drug weights and attached them to a production sticker, along with handwritten vial lot numbers for verification by the pharmacist. The i.v. pharmacist reviewed the order, calculated doses, verified ingredient selection, checked vial dating, calculated the BUD for the prepared bag, and finished verification by reviewing the product label.

Failure modes and effects analysis. To estimate the risk involved in the sterile i.v. compounding process, a failure modes and effects analysis (FMEA) in the oncology ambulatory care pharmacy was performed. The FMEA process was the standard risk-assessment tool used for performance-improvement projects within M. D. Anderson Cancer Center at the onset of the project. Compounding steps from all types of preparations totaled 97 unique steps. The failure modes, failure effects, causes, and current controls were determined for each step. The effects of the failures were identified in the FMEA and clas-

sified by a severity level, they ranged from a minor treatment delay to the administration an overdose or wrong drug that could severely harm the patient. A probability score was assigned based on the likelihood of an occurrence, and a detectability score was assigned for each control based on the likelihood the error would be discovered. The scoring guideline is shown in Table 1. Table 2 shows examples of the FMEA results for three steps of the i.v. preparation process. The proposed effects on failure modes after the implementation of workflow software are outlined in Table 3.

After severity, probability, and detectability scores were assigned for each failure mode, a risk priority number was calculated as the product of these scores. A total of 334 potential failure modes were identified in the processes, over 80 of which had a high severity ranking (8–10), implying potential direct harm to a patient. Available technologies could reduce the estimated risk by increasing the detectability of errors as well as reduce the probability of occurrence through features such as barcode scanning and label printing after dose preparation. Applying technology as an action in the FMEA process provided an opportunity to affect 52% of the process failure modes.

Although a gravimetric method was used when verifying drug doses as part of the existing workflow processes, only a volumetric process was in place to confirm the reconstitution diluent volume. When a volumetric-based process is used to reconstitute vials, the actual concentration is unknown since an assumption must be made that the exact volume of diluent is used when reconstituting the drug. This gap in our process was discovered during the FMEA and was resolved with the implementation of an i.v. workflow software solution.

Implementation of the i.v. workflow software system

An i.v. workflow software system (BD Cato, Becton, Dickinson and Company, Franklin Lakes, NJ) was pilot tested in October 2012 in one of the ambulatory treatment center pharmacies. This system consists of hardware components including a computer with a display screen, a barcode scanner, a balance, and a label printer. The process steps at the time of implementation are shown in Figure 2, including manual steps that were eliminated after the software pilot. The software component interfaces with the pharmacy information system to receive pharmacist-verified medication orders. The orders that are received can be prioritized through a dose queue management function and approved for preparation by the pharmacist. The software automatically calculates the amounts of ingredients required to achieve the prescribed dose and recommends drug vials and appropriate consumables from the perpetual electronic pharmacy inventory, including any available partial drug vials.

During dose preparation, a required scan of the manufacturer's barcode verifies that the drugs and

Figure 1. Preimplementation process steps in the pharmacy.

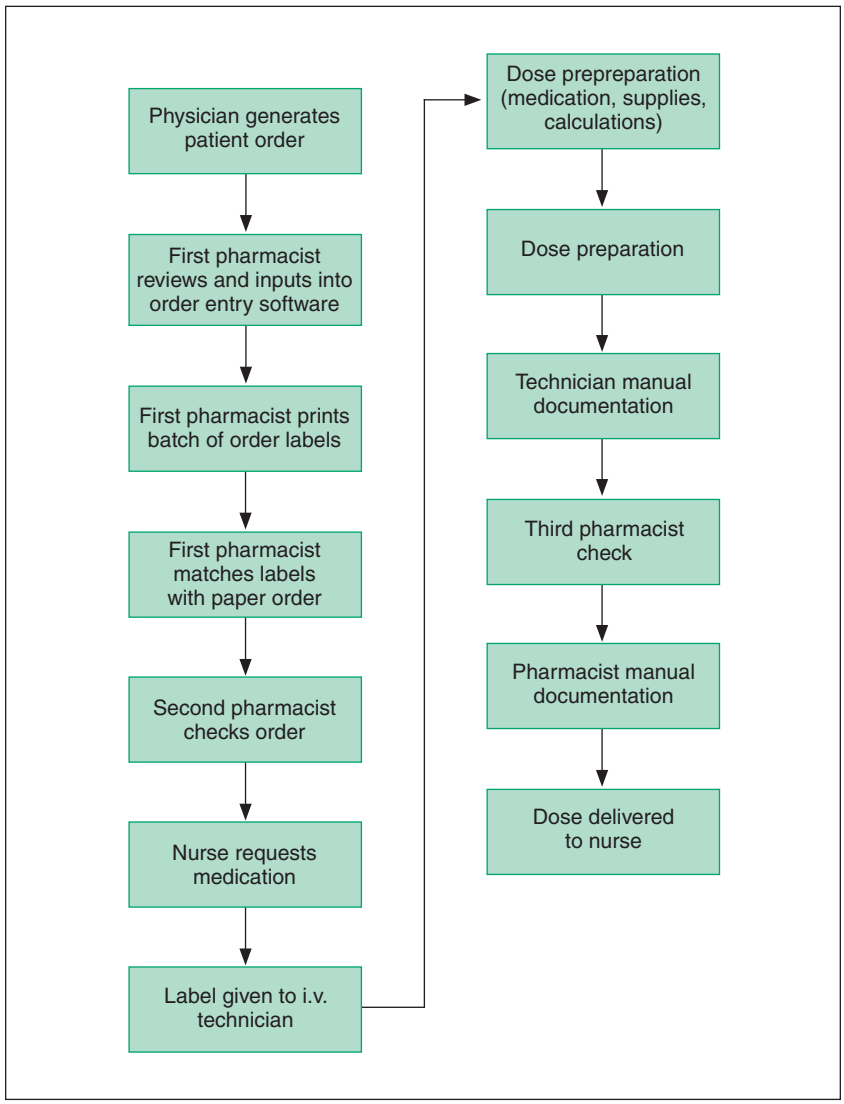


Table 1. Failure Modes and Effects Analysis Scoring Guidelines for I.V. Compounding Process

Score Type	Description
Severity	
1	Minor (no delay and no impact on patient care)
2 or 3	Low (low-to-moderate delay, low inconvenience to patient)
4–6	Moderate (moderate-to-high delay, high inconvenience to patient, treatment effectiveness slightly affected)
7 or 8	Major (patient treatment effectiveness considerably affected)
9 or 10	Catastrophic (patient may be significantly harmed)
Probability	
1	Remote (failure unlikely)
2–5	Uncommon (isolated failures exist)
6 or 7	Occasional (occasional failures but not in major proportions)
8 or 9	Frequent (failures often occur)
10	Routine (failures are inevitable)
Detection and control[a]	
1	Defect easy to detect; high control (technology error proofing, cannot physically continue next step)
2–5	Defect easy-to-moderate to detect; moderate-to-high control (high technology, good visual aids, some process restrictions, low-to-moderate fatigue)
6–8	Defect moderate-to-difficult to detect; low-to-moderate control (some technology, poor visual aids, limited process restrictions, moderate-to-high fatigue)
9	Defect difficult to detect; visual judgment only with limited aid (high fatigue)
10	Defect extremely difficult to detect; visual judgment only with no aid (very high fatigue)

[a]Likelihood of error being discovered before patient harm occurs.

fluids are correct. The software gives step-by-step guidance to the technician through the preparation process and gives a hard-stop alert to the technician when an error occurs. The gravimetric system uses a balance to weigh the product components and verifies accurate volumes based on the density of the drug. The technicians are also led through the vial reconstitution process, which includes barcode identification of the diluent, weighing of the diluent, and calculation and documentation of the actual vial concentration. The gravimetric-based software system weighs diluents and uses the active and inactive ingredients to calculate the exact vial concentration as opposed to using an assumed concentration. The system prints the patient-specific medication label with the BUD and accurate infusion rate only after the correct dose is prepared. Partial vials are weighed and labeled with a software-generated label that includes a barcode and BUD for future use and electronic management of drug inventory. When appropriate, waste is automatically recorded. Each step and each activity performed by the technician while using the software are documented in real time and made available for compliance and medication traceability. Finally, a product inspection for particulate matter and product integrity is completed by the pharmacist and documented through barcode scanning of the software-generated label.

The pilot study evaluating the processes with the new software system was conducted between November 2012 and November 2013. Three frequently ordered chemotherapy drugs—fluorouracil, cyclophosphamide, and gemcitabine—were the first to be prepared using the new software. Over the study period, the software was used when processing orders for 28 chemotherapy drugs; the process changes were implemented on a rolling schedule between October 2012 and September 2013. Preparation errors were collected using generated reports for barcode identification failures, tolerance deviations (defined as weights falling outside of established parameters) of the drug weight, and tolerance deviations of the reconstitution diluent weight.

Tolerance settings for the drug weight in the syringe before injection and the final weight of the bag after injection were set at ±4% and ±5%, respectively. A 5% final prepared dose tolerance was chosen based on recommendations from the *United States Pharmacopeia*.[5] The tolerance for drug weight in the syringe must be set at a lower value (±4%) in order to account for the loss of drug when injecting it into the bag and remain within the final tolerance. Volumes of <2 g are compounded using a linearly extrapolated extended tolerance. These extended tolerances are inversely proportional to the mass of the solution (the lower the solution mass, the higher the tolerance). Due to the difficulty of achieving a 4% tolerance with small volumes, extended tolerances were set at a maximum of 10% and excluded from the data.

A tolerance value for the weight of the reconstitution diluent was established at ±15%. Although the concentration deviates, the software

Table 2. Examples of Failure Modes and Effects Analysis Results

	Process Step		
Variable	**Obtain Fluid Bag**	**Consult Reconstitution Chart for Diluent Volume Needed to Dilute Powder Vial**	**Affix Label on Prepared Bag and Gravimetric Weight Slip Documentation**
Failure mode	Wrong fluid selected	Chart not consulted	Label affixed to wrong bag
Failure effects	Dose made with wrong fluid and administered	Wrong dose given to patient	Incorrect dose and drug given to patient
Severity score	9	9	10
Potential cause	Bags look alike	Technician relies on memory and does not consult chart	Multiple labels in hood due to batch preparation of same drug orders
Probability score	9	7	5
Current control	Technician and pharmacist perform visual check	Technician writes diluent type and amount on vial	Pharmacist verifies printed weight slip with prescribed dose on order
Detectability score	7	10	6
Risk priority number	567	630	300
Recommended action or countermeasure	Technology provides barcode scanning	Technology provides scanning of diluent and weighing of diluent to confirm volume	Technology requires final weight verification to complete dose and prints bag labels one at a time
New severity score	9	9	10
New probability score	4	2	3
New detectability score	3	1	1
New risk priority number	108	18	30

modifies the dose volume based on the actual vial concentration, which allows for the correct dose for the patient. We evaluated the gravimetric-based workflow software system for its potential impact on patient safety, pharmacy waste, and productivity.

Results after implementation

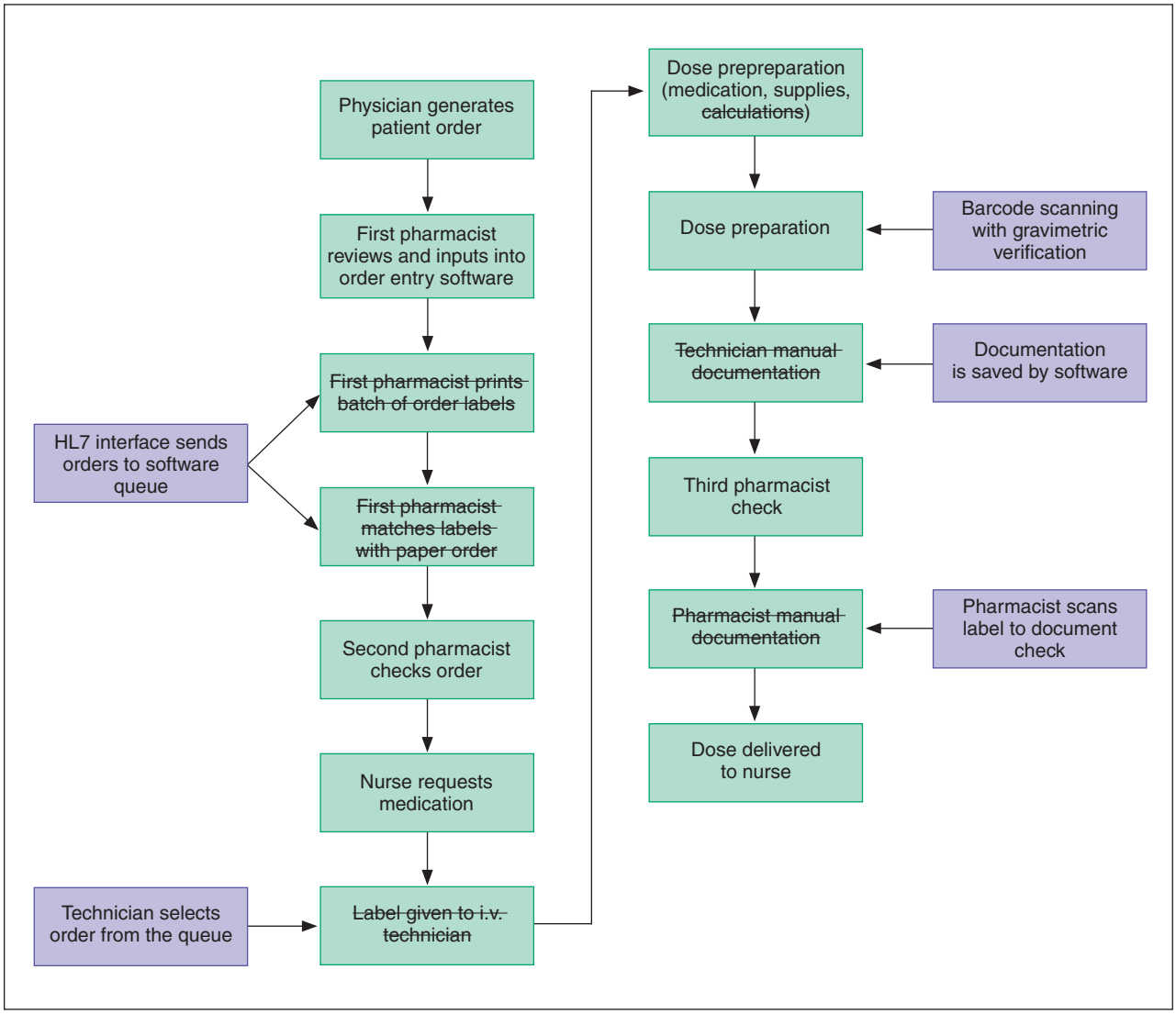
Over the study period, 15,843 doses were prepared using the workflow software system, with 1,126 preparation errors (7.1%) identified. The same pharmacy prepared an additional 51,037 chemotherapy doses without the workflow software system using the remaining 52 drugs awaiting inclusion into the software. The self-reported percentage of errors for those doses was 0.096% (49 errors)(Table 4). The errors detected for doses prepared without the use of the workflow software did not in-

Table 3. Proposed Effects on Failure Modes With Implementation of I.V. Workflow Software

	Before Implementation		
I.V. Process Category	**No. Steps per Category (*n* = 97)**	**No. Failure Modes (*n* = 334)**	**No. Failure Modes After Implementation (*n* = 175)**
Review label	4	19	16
Gather components	8	28	14
Preparation setup	8	24	20
Vehicle bag preparation	13	49	24
Vial preparation	23	106	25
Final product evaluation	12	58	44
Vinca alkaloids process[a]	15	19	13
Intrathecal process[a]	14	31	19

[a]Processes requiring additional steps.

Figure 2. Process steps in the pharmacy at the time of implementation of i.v. workflow software system, including manual steps that were eliminated after pilot testing. The process implemented after the pilot phase appears in purple. Manual steps that were eliminated by the use of the workflow software are struck through. HL7 = Health Level 7.



clude near misses, as self-reporting was limited to errors that were not corrected during preparation. Self-reported errors included errors in vehicle type and amount, drug and amount, bag material type, and reconstitution errors, all of which would have been detected by barcode scanning. The sound-alike drug clofarabine was used instead of cladrabine in one self-reported incident; in another report, oxaliplatin was used instead of cytarabine, most likely the result of similar product labels from the same manufacturer. Other errors detected without the workflow software were calculation errors, missing weight slip documentation, and expired drug vials.

Three steps in the i.v. compounding process where errors could be detected by the workflow software were barcode scanning, drug weighing, and vial reconstitution. Barcode scanning detected 292 (26%) of the 1,126 errors identified, including wrong vehicle, diluent, vehicle bag size or bag type, and drug. Three wrong-drug scanning errors were detected: vincristine sulfate was scanned for vinblastine sulfate, rituximab was scanned for cetuximab, and oxaliplatin was scanned for rituximab, probably due to sound-alike and look-alike drug names. During the study period, a total of 11,874 chemotherapy doses with volumes of ≥2 g were compounded using a ±4% drug withdrawal tolerance and ±5% final bag weight tolerance. Due to the variability in extended tolerances, doses with vol-

umes of <2 g were excluded from the deviation data. In the drug-weighing step, 797 deviations (71% of the total errors) before injection into the final bag were detected through the gravimetric analysis. No deviations were detected at the final weight verification step, which ensured that the correct amount of drug was accurately injected into the final bag. The mean percent difference between the prescribed dose and the final actual dose was –0.62% (range, –5.04% to 4.97%). The vial reconstitution step detected 37 dilution errors (3% of the total errors). Of the 5,317 vials reconstituted during the study, 12 were rejected because too much diluent was added to the vial and 25 were reworked because not enough diluent was added to the vial. The mean percent volume deviation for accepted reconstituted vials was –0.08% (range, –15% to 14.92%).

The preparation cycle time for dose preparation was measured starting when the technician received the patient label (preimplementation) or the order in the dose queue (postimplementation) and ending when the pharmacist verified (preimplementation) or scanned (postimplementation) the prepared product. The mean ± S.D. baseline preparation cycle time for a dose prepared by pharmacy technicians was reduced from 9.2 ± 6.9 minutes without the workflow software system to 6.0 ± 4.3 minutes using the workflow software system (a decrease of 34%) during the 12-month study period. Similarly, the mean baseline cycle time to verify each prepared dose by the pharmacist decreased from 3.17 minutes without the workflow software system to a mean ± S.D. cycle time of 2.00 ± 0.78 minutes (a decrease of 37%) when using the workflow software system.

Total labor cost savings was estimated to be $158,000 annually based on direct and indirect labor savings. Direct labor cost savings (decreased cycle time multiplied by salary) was estimated to be $110,628, though actual labor savings was not realized due to repurposing that time toward the current workflow. From the pre-pilot value-stream map, the potential nonvalue-added indirect labor cost savings of $47,430 per year was calculated by using time savings from the elimination of steps and a mean hourly pay rate for pharmacists and technicians. Greater than 66% of the indirect labor savings ($33,353) was attributed to the elimination of 12 hours of pharmacists' time assigned to batch label printing and the matching of labels to orders. Further, the workflow software provides stock reports, eliminating the need for manual inventory counts to determine drug supply, and waste reports, eliminating the need to document waste.

Furthermore, the prepared bags for the 49 self-reported errors had to be discarded and amounted to over $56,000 in waste. The 12 vials that were rejected during reconstitution using the workflow software system amounted to $12,398 in waste. The remaining 1,114 errors detected with the software were corrected before the final dose was completed and did not incur waste.

Table 4. Comparison of Errors Detected Before and After Implementation of I.V. Workflow Software

Type of Error	No. Errors (% of Total Errors)	
	Detected Without Software (*n* = 49)	Detected With Software (*n* = 1126)
Identification error[a]		
Wrong vehicle	6 (12.2)	111 (9.9)
Wrong vehicle bag (volume)	3 (6.1)	93 (8.3)
Wrong diluent	1 (2.0)	52 (4.6)
Wrong bag type	3 (6.1)	31 (2.8)
Wrong drug	4 (8.2)	5 (0.4)
Weighing deviation error		
Wrong amount of drug	7 (14.3)	797 (70.8)
Vial reconstitution error		
Wrong amount of diluent	4 (8.2)	37 (3.3)
Manual process error		
Expired drug vial	5 (10.2)	0
Missing printed weight slip	4 (8.2)	0
Calculation error	2 (4.1)	0
Unspecified mixing error	10 (20.4)	0

[a]Detected through barcode scanning.

Discussion

Use of the gravimetric workflow software system improved the accuracy of i.v. sterile compounded products and potentially improved patient safety due to the increased detection of preparation errors. The implementation of this workflow software system resulted in an over 74-fold increase in the detection of medication errors (49 self-reported errors [0.096%] compared with 1,126 errors [7%] while using the workflow software). All self-reported and software-detected errors in the study were identified before reaching the patient; however, the software barcode-scanning technology and gravimetric weighing step allowed the

errors to be corrected before completion of the dose.

Implementation of the workflow software also decreased the mean cycle and turnaround times for production and final-dose verification. We attribute this reduction to streamlined process steps created by the software, including a parts list with required vials and materials for the technician to preview before starting preparation. We were able to eliminate a standard concentration reference chart, used by the technicians to determine dilution volume and calculate vial concentration, as well as a reference weight chart and calculator. Because the information from these charts is incorporated in the software, the technician no longer needs to consult the reference chart for information, thereby reducing the risk of visual and judgment errors. The pharmacists can focus on a product quality check rather than visually checking each vial and bag, as the barcodes have already been scanned. The manual documentation of BUD on the vials and prepared bags is automatically calculated by the software and prints on the labels. The gravimetric-based workflow software system provides added risk reduction for the misapplication of labels by using a one-piece flow and prints a patient bag label only when the final product is prepared correctly. Overall, many nonvalue-added processes were eliminated from our workflow, including order label timing and sorting, waste management, and inventory counts.

The waste reduction can be attributed to the efficient management of partial vials through the tracking of usable remainders and assignment of vial BUD. Management of partial vials is beneficial in light of the oncology drug shortages, which have had clinical and financial effects on hospitals.[12] One other area of potential savings is waste associated with the preventable self-reported errors.

A few challenges were noted during software implementation. The Joint Commission warned that users must be aware of the technology-related adverse events that can occur when adopting new systems.[13] Interfacing the existing pharmacy order entry software with the workflow software required planning, software testing, and staff training. Because reluctance and hesitation to adopt workflow changes can hinder progress, staff were involved early in the process to ensure successful implementation of the new system. It is also important to note that when following proper procedures using the workflow software, any detected error must be corrected in order to complete the dose; however, if processes are circumvented, errors could be undetectable. Another challenge faced during the database build was collecting product densities from pharmaceutical manufacturers. The gravimetric method is relatively new in the United States compared with European countries, where it is common practice.

Limitations noted in the study should be considered when interpreting results. The pharmacy staff had been using a gravimetric method for all chemotherapy preparations before the implementation of the software, so the learning curve for the compounding process may have been reduced. The self-reported errors were extracted from pharmacy waste data collection and did not include near misses, which could result in a higher rate of detected errors than reported. Also, the software does not determine the cause of withdrawal deviations captured at the point of weighing the drug in the syringe. Thus, a deviation in the weighing process could result not only from using the incorrect amount of drug but any weighing discrepancy, such as a foreign object on the scale or an incorrect item placed on the scale.

Conclusion

Implementation of a gravimetric-based software system that used barcode verification and real-time alerts improved the detection of errors in the chemotherapy preparation process when compared with self-reporting. Standardized workflow processes and the elimination of time-consuming manual steps increased productivity while vial management decreased costs.

Disclosures

Dr. Reece has received an honorarium from Becton, Dickinson and Company, Franklin Lakes, NJ, for a speaking engagement. The authors have declared no other potential conflicts of interest.

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