**IMPROVING QUALITY OF INTRAVENOUS (IV) PRODUCTS THROUGH THE USE OF TECHNOLOGY-ASSISTED WORKFLOW SYSTEMS (TAWF)**

by

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**ABSTRACT**

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The intravenous (IV) room is a high risk area where sterile compounding errors can occur. Technology-assisted workflow (TAWF) systems were developed for use in the IV room to improve patient safety. Through the use of barcode scanning technology, TAWF systems intercept errors before the pharmacist verifies the final drug product. The technology also prioritizes the production of doses based on administration due time allowing for increased efficiency and reduction in waste volume. This project was designed to evaluate the errors, waste, and workflow efficiency at a tertiary care hospital pre-implementation of a TAWF system and post-implementation of a TAWF.

David Finegold, MD

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In order to measure the TAWF system’s effect in preventing and reducing medication errors, medication occurrences from 2009, 2010, and 2011 were analyzed. To measure IV product waste, data from four quarterly two week audits that were conducted before the implementation of the TAWF and four quarterly two week audits that were conducted post implementation were analyzed. The staffing model was analyzed prior to the implementation of the TAWF and after the implementation todetermine workflow efficiency.

There was a 93% decrease in errors associated with IV production post-implementation of the TAWF. Comparing the pre and post TAWF implementation data, there was a decrease of 10,836 IVs wasted per year equating to a decrease of 0.31 full-time equivalents (FTEs). Due to the increased efficiency of automation and the decreased FTEs needed to staff the IV room, only one full-time pharmacist and two full-time technicians on both the day and evening shifts were needed as opposed to two and three, respectively.

**Conclusion/Public Health Significance**: Sterile compounding is a significant component of pharmacy practice that is in need of improvement. There are a variety of factors that have led to fatal errors including lack of standardization of practice, inadequate IV room training, and a lax safety culture. To counteract the errors that can occur during sterile compounding, TAWF can be utilized and have shown to have a benefit in safety, waste reduction, and efficiency.

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 preface

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# Introduction

Pharmacy technologies in the hospital are changing how medications are dispensed, prepared, and administered. These technologies impact patient safety, institutional cost savings, and pharmacy workflow.1 The intravenous (IV) room is an area where technology and automation implementation is needed due to the high risk errors that can occur while preparing sterile products.2,3 Sterile product compounding is susceptible to the same general error-prone processes as all other medications. However, these products are associated with additional risk factors that make them more subject to error.4 For example, IV products can be particularly harmful due to its direct access to the blood stream and fast onset of action. The Institute for Safe Medication Practices (ISMP) identifies and refers to medications as “high-alert” if they have a great risk of causing significant patient harm when they are used in error.5 Most high alert medications are sterile compounded products.4 There are an array of reasons for why sterile compounding mistakes happen such as dose miscalculations, reconstitution errors, selection of the wrong medication or diluent, poor training, and fatigue.6 Because of the manual process of preparing an IV, it may be difficult for pharmacists to know what ingredients and products were used by a technician during the production stage.7 Due to the complexity of the IV process and the high-risk errors that could result during the preparation process, it is important for hospitals to evaluate the use of automation, such as technology-assisted workflow (TAWF) systems to improve patient safety. In this essay I will explain the public health concern of sterile compounding errors and how TAWF systems have the ability to counteract these errors, thereby, improving patient safety, reducing waste, and enhancing workflow efficiency.

## Sterile compounding errors

Unsafe and even fatal sterile compounding errors have occurred when preparing intravenous (IV) products in the pharmacy.8 The FDA found that 90% of the 150 compounding centers inspected had safety and sanitary problems.9 Between 1990 and 2005, there have been at least 12 incidents of contaminated pharmacy-prepared sterile compounds reported nationally, involving over 19,000 patients and resulting in at least 15 deaths.10 In 2012, 64 people died due a meningitis outbreak from contaminated epidural solutions prepared by the New England Compounding Center (NECC).11 In 2014, contaminated products at Specialty Compounding in Texas resulted in two deaths and several patients becoming sick. This occurred even after the FDA had inspected the facility and had identified many significant quality problems five months prior to the event.9, 12

Serious compounding errors besides infectious contamination have also been reported. In 2009, a patient event involving a compounding error occurred in 30% of surveyed hospitals within the past 5 years.3  From 2005 to 2011, it was found that serious sterile compounding errors could be attributed to the wrong concentration or strength of the product dispensed,[13](https://www-ncbi-nlm-nih-gov.pitt.idm.oclc.org/pmc/articles/PMC3839457/#r13)-[17](https://www-ncbi-nlm-nih-gov.pitt.idm.oclc.org/pmc/articles/PMC3839457/#r17) wrong product or diluent used in compounding,[18](https://www-ncbi-nlm-nih-gov.pitt.idm.oclc.org/pmc/articles/PMC3839457/#r18),[19](https://www-ncbi-nlm-nih-gov.pitt.idm.oclc.org/pmc/articles/PMC3839457/#r19) or product mislabeling by the pharmacy.20 For example, an accidental chemotherapy compounding error due to the wrong concentration of sodium chloride claimed the life of 2 year old Emily Jerry in 2006. More recently in December 2014, a 65 year old woman died due to a compounding error in which a rocuronium infusion was prepared and dispensed instead of a fosphenytoin infusion.11

In an effort to decrease sterile compounding errors, the United States Pharmacopeial Convention, a not-for-profit scientific organization focused on providing the public with quality standards regarding drugs, excipients, and supplements, released the United States Pharmacopoeia (USP) chapter <797>in 2004.21 This chapter is on “Pharmaceutical Compounding-Sterile Preparations”, and it was intended to become the standard of practice, reduce the risk of infectious contamination of pharmacy-prepared sterile products, and be enforced by federal and/or state laws and regulations. However, a recent survey revealed that only 18 states directly require compliance with this standard.22 Additionally, it was found that only 65.2% of hospitals follow USP <797> requirements for clean rooms,23 and less than 17% of hospitals adhere to all USP <797> requirements.24

### Why is the IV Room Overlooked?

Despite the IV room being a high risk area, there has been slow adoption of technology and other error-reduction strategies. In other areas of the hospital, there have been great advancements in the adoption of medication-related technologies. For example, 98% of hospitals use automated dispensing cabinets in some capacity, bar coded medication administration is up to 94%, and computerized prescriber order entry is up to 88%. However, in the IV room, barcode verification during sterile compounding is used in 20% of hospitals, robotic compounding devices are used in 2.8% of hospitals for sterile preparation and 0.3% for chemotherapy preparations, and a mere 6.5% use sterile workflow technology.25 The following are five possible systems and behavioral causes that result in the IV room being overlooked in terms of safety: 1) diminishing perceived importance of sterile compounding technique, 2) variability around best sterile compounding practices, 3) lack of standardized training, 4) acceptance and tolerance of practice deviations, and 5) a disinclination to learn from mistakes.11

***Diminishing Perceived Importance of Sterile Compounding Technique***

The practice of pharmacy has transformed greatly during the last few decades. There is a greater focus on clinical pharmacy and roles in antibiotic stewardship, anticoagulation management, and disease state management. Practices such as sterile compounding and dispensing, although a core part of the profession, do not receive as much attention. As pharmacists have been transitioning to a more clinically augmented role, many tasks that were once performed by pharmacists are now performed by technicians. However, these tasks are performed with minimal oversight by a pharmacist.11

***Variability around Best Sterile Compounding Practice****s*

The Institute for Safe Medication Practices (ISMP) on-site risk assessments and medication error reports submitted to the ISMP national medication error reporting program (ISMP-MERP) demonstrate that pharmacies vary greatly with respect to how they conduct sterile compounding practices. This may be partly due to the lack of specific practice guidelines related to product preparation checks.[26](https://www-ncbi-nlm-nih-gov.pitt.idm.oclc.org/pmc/articles/PMC3839457/#r26)While the USP<797> provides guidance on the sterility and quality components of the process, there is a discrepancy between the standards and what is practiced in pharmacies. In general, there have been limited resources on sterile preparation safety. In 2013, ISMP published a set of guidelines for safe preparation of sterile compounds to offer pharmacists and technicians a credible, peer reviewed resource on IV sterile compounding safety. While the guidelines provide consensus statements for many sterile compounding process steps, there are specific tasks, including the required components of an effective sterile compounding checking process, which do not have details outlined. Due to the lack of standardization of best practices, there is wide variability in completing sterile compounding tasks.11

***Lack of Standardized Training***

Some schools of pharmacy typically do not focus on teaching students robust principles of sterile compounding. Despite the lack of standardized training, new graduates are often immediately responsible for verifying compounded sterile preparations and overseeing processes that they may or may not have performed themselves. Many times sterile compounding procedures are handed down from one pharmacist to another, which leads to variability in training. Variability in training may lead to staff not understanding the rationale for certain steps that help ensure sterility and safety. Without a standardized training approach, practice change and long-term compliance with sterility and safety measures are unlikely.11

***Acceptance and Tolerance of Practice Deviations***

In the hospital pharmacy environment, there is pressure to get the compounded sterile preparation to the patient in a timely manner. This pressure can lead to preparation shortcuts that can eventually develop into unsafe practice habits. Overtime, deviations from a safe, sterile compounding preparation process could be accepted by staff. Since there is limited knowledge regarding best practices in sterile product preparation, the workplace culture can become tolerant of the practice deviations, which can lead to adverse patient outcomes.11

***Disinclination to Learn from Mistakes***

Even after the high-profile sterile compounding events in the past decade, healthcare practitioners are often disinclined to learn from the mistakes of others. Often times, if a serious adverse event has not happened as result of unsafe practices, there is little motivation to change that behavior or practice. In pharmacies, there should be a culture to have pharmacists and technicians objectively assess their own sterile compounding processes to see if there are gaps in terms of safety and sterility. As a profession, pharmacy practitioners must first acknowledge that the way they have been compounding sterile preparations can be improved before they can learn from the mistakes of others and identify vulnerabilities in their own processes.11

## the role of technology-assisted workflow systems

Technology-assisted workflow (TAWF) systems have been developed for the IV room to improve patient safety by reducing compounding errors through barcode scanning and verification.4,27 Through utilization of bar code scanning technology, technology-assisted workflow systems allow for technicians to scan the medication and diluent needed to ensure they are correct. By introducing checkpoints at each stage of IV preparation, they are able to reduce the opportunities for medication preparation errors and improve overall efficiency by managing workflow for non-sterile and sterile dose preparation. IV room automation technologies can also be used to analyze volume of waste and time of IV preparation. The reports that can be generated are useful for quality improvement purposes.7 ISMP supports the use of IV technology stating, “Given that IV production errors can result in serious medication errors, new IV robotic preparation systems and commercially available workflow management systems are highly welcomed technologies.”27 The American Society of Health-System Pharmacists (ASHP) is also in favor of barcode scanning technology for the preparation of sterile products.28

Despite the benefit and best practice of using this technology, the use of automation and technology in sterile compounding is not typical of hospital pharmacies.4 Many hospitals may not have implemented the automation due to cost; however, the technology can provide a return on investment by reducing the cost of IV errors that occur and the health care costs associated with these errors. In addition, labor costs and waste are reduced as IV preparation becomes more efficient with automation.7

There are studies that have shown the benefit of utilizing technology-assisted workflow systems. In 2010, one hospital was able to reduce the number of sterile medications prepared manually to 4.3% by implementing sterile processing automation. This significantly improved the accuracy of medication preparation.29 According to the project by Speth et al, after the implementation of a TAWF at a hospital pharmacy, 75% of the errors were intercepted due to barcode scanning, and the remainder of the errors were caught during the pharmacist verification process. The implementation of the TAWF also improved efficiency by decreasing medication turnaround times and also decreased the amount of waste.30 Deng et al found that the automated workflow management system intercepted 72.27% of the identified errors, which were mainly errors involving incorrect drug or diluent. The remaining 27.73% were intercepted by a pharmacist.31 Moniz et al detected preparation or documentation errors affecting 2,900 doses of the 425,683 doses reviewed. It was found that 23% of those errors would not have been detectable before the IV workflow management system, concluding that the implementation of an IV workflow management system led to a reduction of errors in the sterile product compounding process.32 Reece et al implemented and evaluated a gravimetric IV workflow software system in an ambulatory care pharmacy. Over the study period, 15,843 doses were prepared utilizing the new technology. A total of 1,126 errors (7%) were detected by the workflow software during dose preparation. These errors were caught before the production of the dose, reducing waste. The system also improved efficiency by decreasing technician production time and pharmacist checking time by more than 30%.33

# evaluation of errors, waste, and efficiency with a technology-assisted workflow system at a tertiary care hospital

Although the benefits of utilizing TAWF systems are apparent, it is important that institutions evaluate their error rates, waste volume, and workflow efficiency to improve patient safety and to reduce cost. Prior to 2010, Allegheny General Hospital, a 631 licensed bed hospital, was not utilizing a TAWF system. In order to improve the quality of intravenous products compounded, the IV room started utilizing a robust TAWF system called *DoseEdge.* *DoseEdge* has features such as photo capability and certain workflow efficiencies. The purpose of this project was to determine the error rate, waste volume, and workflow efficiencies prior to the implementation of a TAWF and after the implementation of a TAWF. It was hypothesized that the implementation of a TAWF would decrease error rates, reduce waste volume, and enhance workflow efficiency.

## methods

In order to measure *DoseEdge*’s effect in preventing and reducing medication errors, medication occurrences from 2009, 2010, and 2011 were analyzed and categorized into two groups: errors that could potentially be prevented by the use of the software’s safety features and errors that would not be impacted by *DoseEdge*.

To measure the effect of *DoseEdge* on IV product waste, data from four quarterly two week audits that were conducted before the implementation of *DoseEdge* and four quarterly two week audits that were conducted post implementation were analyzed. Waste was defined as patient specific IV preparations with short stabilities that are prepared, sent to the floor or unit and subsequently are not given to the patient due to a change in therapy or patient discharge. These products cannot be re-used and are discarded because of the product-limited stabilities. Documentation for each audit was extrapolated over a year. The four audit points, pre and post, were averaged for the purpose of comparing IVs wasted pre and post implementation. Information supplied from an IV preparation time study was applied to determine the difference in FTE commitment in making products that were ultimately wasted.

A more recent error and waste evaluation was conducted in 2015. TAWF reports were generated for November 1st-30th, 2015 to determine the frequency of errors and the number of IV bags wasted. The types of errors made were described, the cost associated with the waste was calculated, and the types of products wasted were characterized.

In order to determine efficiency, the staffing model was analyzed prior to the implementation of *DoseEdge* and after the implementation of *DoseEdge*. Efficiency was defined as the ability to reallocate pharmacy staff from the IV room to other areas in the hospital where pharmacy staff was needed.

## results

***Reducing Errors***

In 2009, prior to *DoseEdge* implementation, 69 medication occurrences were reported which could be attributed to medication preparation, verification, or dispensing. Analysis of those errors showed that 15 could have been prevented by use of the safety features of the *DoseEdge* software. In 2010, post *DoseEdge* implementation, 39 occurrences were reviewed. Six of those occurrences should have been prevented by use of the software’s safety features, but these errors still occurred. Further analysis of these errors was attributed to inexperience with using *DoseEdge* or bypassing the software’s safety features. Overall, the implementation of *DoseEdge* represented a 60% decrease in errors associated with IV production in 2010. In 2011, 35 errors were reviewed and only one error occurred, representing a 93% decrease in errors associated with IV production. This one error was a result of a staff member bypassing *DoseEdge’s* safety features.

The survey period in 2015 showed that the hospital prepared 34,284 doses, which if annualized was about 411,408 doses in a year. During that one month time frame, 267 errors (0.78%) were found. Two hundred thirty seven (89%) of the errors were intercepted by *DoseEdge* prior to the pharmacist verifying the dose. One hundred sixty one (68%) of the intercepted dose errors were because the technician scanned the wrong diluent or drug into the *DoseEdge* system. Other errors intercepted by *DoseEdge* included using expired product or having a wrong concentration. Of the 267 errors found, 30 (11%) of them were rejected during the pharmacist’s final verification, which shows that the majority of errors were caught by *DoseEdge* prior to pharmacist verification. The most common type of error that resulted in the pharmacist rejecting the dose was wrong drug concentration (Figure 1).

|  |  |  |
| --- | --- | --- |
| **Error Type** | **Errors intercepted (n=237)** | **Errors rejected (n=30)** |
| **Wrong drug or diluent, n (%)** | 161 (68%) | 2 (7%) |
| **Expiration, n (%)** | 7 (3%) | 10 (33%) |
| **Wrong concentration, n (%)** | 55 (23%) | 12 (40%) |
| **Other, n (%)** | 14 (6%) | 6 (20%) |

Figure . Results for Types of Errors

***Decreasing Waste***

There was continuous improvement in terms of waste as a result of the implementation of *DoseEdge*. Using time management studies, 217 seconds were applied as the average preparation time of each IV prepared. Average census per day pre-implementation was 412 inpatients compared to 448 inpatients per day post implementation. The overall results of the audits showed that on average 22,060 IVs were wasted per year before *DoseEdge* was implemented accounting for 1,330 hours in preparation time or a 0.64 FTE commitment compared to 11,224 IVs wasted on average per year after the implementation of *DoseEdge*, accounting for 677 hours in preparation time or a 0.33 FTE commitment (Figure 2). Comparing the pre and post *DoseEdge* implementation data, there was a decrease of 10,836 IVs wasted per year equating to a decrease of 0.31 FTEs.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Pre** | **Post** |
|  *Avg # of Wasted/year* | 22,060 | 11,224 |
| *Seconds to Prepare* | 4,787,020 | 2,435,554 |
| *Minutes to Prepare* | 79,784 | 40,593 |
| *Hrs to Prepare* | 1,330 | 677 |
| *FTE's Utilized* | 0.64 | 0.33 |

Figure . Pre and Post Workflow Management System

The waste audit performed in 2015 showed the pharmacy wasted 446 products during the survey period. This accounted for $16,669 in losses. The waste annualized would amount to 5,352 doses, resulting in about $200,000 in losses. The waste was classified for further quality improvement purposes and to determine if future action should be taken on costly wasted products (Figure 3).

|  |  |  |
| --- | --- | --- |
| Drug Class | Quantity | Total Cost |
| Immunosuppressant | 1 | $4,843 |
| Vasopressor | 65 | $4,197 |
| Anti-hypertensive | 5 | $1,912 |
| Antibiotic\* | 105 | $1,180 |
| Fibrinolytic | 1 | $998 |

\*Most wasted product at the institution

Figure . Results for Top Five Most Costly Wasted Drug Categories

***Enhancing Efficiency***

Prior to the implementation of *DoseEdge*, two full-time pharmacists and three full-time technicians on day and evening shift were scheduled to staff in the IV room. With the implementation of *DoseEdge*, and its ability to allow remote verification of IV preparations, one of the pharmacists was able to be moved out of the IV room and into a unit based position on an intensive care unit in the hospital. The workflow standardization allowed for one of the technicians to be moved out of the IV room and be used in an expanded role to enhance medication safety programs. Due to the decrease in the amount of FTEs needed to produce IV products, the IV room is now staffed with one full-time pharmacist and two full-time technicians on both the day and evening shifts as opposed to two and three, respectively.

## DISCUSSION

Although the technology reduced the number of errors, pharmacist judgement is still needed since all errors were not intercepted by the TAWF before reaching the pharmacist. There were some errors that still occurred despite utilizing the TAWF. As with any new system implemented, there was a learning curve. Errors that *DoseEdge* could have prevented but were not was a result of user inexperience. As these errors occurred when utilizing the new system, staff members were educated as to proper workflow, including when it is appropriate to bypass *DoseEdge’s* safety features (barcode will not scan, non-formulary medication). In addition, photography techniques were reviewed and standardized with the staff.

The TAWF system has allowed the hospital to reduce waste in different ways. For example, the stock of medications on the drug shortage list is able to be conserved. This is done by diverting the medications on the drug shortage list to the “wait/hold” queue upon verification. The senior technicians or pharmacists are instructed to call the patient’s nurse prior to preparing these medication. This process helps eliminate the mixing of backordered medications that are subsequently not administered to the patient and returned to the pharmacy. This workflow strategy is also instituted for high cost medications to avoid waste. Another way waste was decreased is due to *DoseEdge’s* tracking functionality, which allows pharmacists and technicians to see if a medication has been delivered to the unit or to determine what stage of the compounding process the preparation is in. This function has improved communication between pharmacy and nursing and has helped decrease waste by locating missing doses. Additionally, all technicians are required to follow the standardized workflow prompted by the software. The software prevents the preparation of doses more than four hours prior to the administration of a dose. This feature allows for discontinued or modified doses to be automatically pulled from the queue prior to compounding, avoiding re-work and possible waste.

In addition to reducing waste within the sterile products compounding process, efficiency was also enhanced. Since remote verification is possible with the *DoseEdge* software, pharmacists with internet access and appropriate workflow software on their computer could verify an IV preparation from anywhere, inside or outside the facility. This feature allowed for flexibility during busy periods and allowed multiple pharmacists to log onto the system to help verify IV preparations. The standardized workflow and *DoseEdge* functionalities has made the IV room more efficient when preparing sterile products for patients and has enabled the pharmacy to reallocate a pharmacist and a technician from the IV room to another area.

*Public Health Significance*

Due to the high risk nature of these medications, intravenous compounding errors are likely to cause patient harm. Recent events in the media have shown the harmful or fatal compounding errors that have occurred, devastating patients, families, and health care practitioners involved. As demonstrated by this evaluation as well as others in the literature, TAWF systems have a beneficial impact on public health by improving the quality of IV products. Although the technology does not replace aseptic technique and an experienced pharmacist review, the TAWF can be used as a tool to catch errors before it gets to a pharmacist for review. Considering that the technology reduces errors, decreases waste, and improves efficiency, pharmacies should evaluate their department’s need to implement TAWF for the safety of their patients.

# Conclusion

Sterile compounding is a high risk but core pharmacy process in need of improvement. Variability in practices, a failure to identify and teach best practices, and a host of cultural issues associated with routine practice deviations and tolerance of risks have led to harmful and fatal errors. The recent sterile compounding errors should serve as a catalyst to take measures to improve this practice. TAWF systems improve safety in health care settings through barcode scanning and provide benefit to pharmacy departments through documentation of IV errors and waste for ongoing quality assurance evaluations. They allow for error reports to be generated so that workflow changes can be implemented; the pharmacy automation system intercepts in order to stop the same errors from reoccurring. The technology allows for standardized preparation steps and documents each process step, enabling a systematic review of the metrics for safety, productivity, and drug waste.

In order to improve, it is important to understand the current IV error rate, waste volume, and IV room workflow at an institution. It is also important to determine what strategies can be implemented to decrease errors, reduce waste, and enhance efficiency. The evaluation performed at a tertiary care hospital confirmed the benefit of utilizing a TAWF to improve quality of IV products. It also identified future projects that need to be implemented, such as reducing antibiotic waste, preventing the wrong drug or diluent from being selected to prepare an IV, and optimizing the TAWF system to intercept more errors.

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