Impact of Pre-mix Intravenous Medication In the Pharmacy

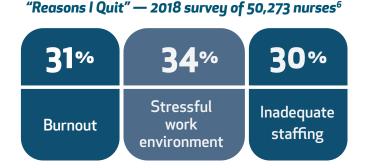


A recent study provides quantifiable evidence of the positive impact that pre-mix medication can have on pharmacy team members, including reduced stressors associated with sterile compounding.

Before the COVID-19 pandemic hit in 2020, health care workers were stretched thin. Burnout and a sense of work dissatisfaction were present and worsening among physicians, nurses, and clinical pharmacy workers alike.¹⁻³

Today's healthcare workers remain under serious strain in the workplace, due to high workloads, job-related stress, and time pressure.⁴ One national cross-functional survey of healthcare workers in 2020 indicated some level of work stress and burnout among clinical and non-clinical staff.⁵ Regardless of occupation, daily stress was scored as high or very high in 30% of all respondents (N=20,947).

Given the stressors that can lead to healthcare worker burnout and staff shortages, examining departmental workflows to identify areas of improvement may provide some relief for these issues.



Staff Perceptions From a Real-World Experience Study⁷

A recent study conducted among pharmacists and pharmacy technicians within a hospital setting has provided insights about the human impact related to IV compounding and the use of pre-mix IV products.

Results from the study, which included a user experience survey that examined pharmacy staff members' perceptions of workload, pharmacy processes, and the effects of supply chain issues, beg the question :

Could something as simple as increasing the use of pre-mix IV products provide some needed relief from work stressors to those working in hospital pharmacies?

Study Background⁷

This study was conducted in 2021 by Virginia Mason Institute (VMI), a consulting arm of Virginia Mason Franciscan Health who work with healthcare organizations globally to help them apply the Virginia Mason Production System® to achieve operational excellence. As part of their study, VMI conducted an extensive review of several processes within a busy urban acute care hospital (>300 beds) with a focus on workflows involving the hospital's robust inpatient pharmacy team.

The hospital has long applied lean production principles to meet its objectives of improving patient quality, team member experience, cost containment, and to meet the changing health care landscape. Within the pharmacy, pharmacists and pharmacy technicians work closely, operating "at the top of their license" to maximize their contributions to pharmacy processes. In general, while the hospital can be characterized as high functioning, its participation in this study was based on a desire to gain a deeper, comprehensive understanding of the processes, as well as the impact they have on personnel.

As part of the study, VMI collected information on hospital pharmacy practices, mapping workflows for batch compounding, single-item compounding, and pre-mix products.* Time elements related to various activities along with understanding staff perspectives were also documented and mapped. Additionally, investigators conducted analyses, ranging from a quality analysis of mistake-proofing processes within compounding and pre-mix usage, to total cost analysis.

* Chemotherapy medications, compounded and pre-mixed products used in the operating room satellite pharmacy, and all clinic-based/retail pharmaceutical processes were excluded from the study.

Study Results Highlights⁷

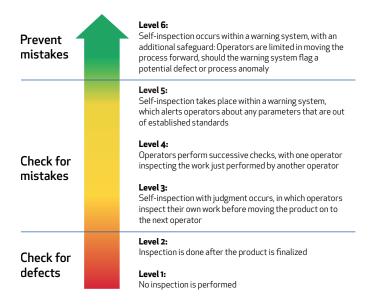
Sterile compounding processes were associated with lower mistake-proofing levels than pre-mix product usage

These analyses provided some useful insights regarding the differences between pre-mix management and compounding processes.

Reviews of quality and safety are based on a 6-tier set of mistakeproofing levels within a workflow process.

Figure 1.

Purposes and descriptions of mistake-proofing levels



In the analysis of mistake-proofing levels within this pharmacy, VMI investigators found that mistake proofing for batch or single-item compounding relied largely on self-inspection with judgment (Level 3). In the batch compounding process, the use of scanning technology to identify the correct medication and IV bag elevated mistake proofing to Level 5.

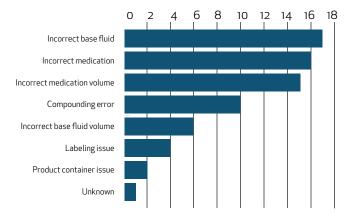
In contrast, pre-mix product usage typically involved mistake proofing with operator successive checks (Level 4); 6 out of 10 pre-mix related processes had mistake proofing performed at Level 5. Consequently, the mistake proofing for pre-mix usage provided a potentially higher level of safety than the mistake proofing for compounded products.

Mistake proofing for pre-mix usage provided a potentially higher level of safety than mistake proofing for compounded products.

A further quality and safety analysis of 71 compounded defective products was performed by VMI through the collection of retrospective data from August 2020 to June 2021.⁺ These products had an estimated defect rate between 0.1% and 0.5%, based on the number of compounded products during that time. Defects resulted from a variety of errors (see Figure 2).

Figure 2.

Analysis of compounded product defects



Other notable observations made during the study involved a review of compounded product expiration. In an analysis of products that had been batch compounded, 3,156 out of 42,471 products analyzed were wasted due to expiration—a 7.4% waste rate, a low number that may be due to the use of lean processes throughout the study organization. Through informal discussions with similar-sized organizations, VMI found that this waste rate due to product expiration was considered within the 90th to 95th percentile of expected results. Reasons for this waste were variable patient census, challenges associated with inventory predictive modeling, and shorter than expected lengths of hospital stays.

Experience Survey Background⁷

One of the more unique elements of this study involved data collected from an experience survey, which was administered over a 2-week period in late 2021 to inpatient pharmacy staff. Survey questions were constructed to examine the effects of pharmacy processes and workload on the staff.

Approximately 90% of pharmacy technicians and 100% of pharmacists provided feedback. Survey participants were instructed to focus on questions based on their operational experience, and to skip questions that did not reflect their frequent work experiences.

Survey results showed varying perceptions about the current staffing situation, as well as the direct impact of compounding processes and pre-mix product management on pharmacy team members.

* All of the products included in this analysis were identified as defective through mistake proofing performed within the compounding process before administration to patients could occur.

Staff shortages and training issues result in higher team burden

Of the 18 pharmacists and 18 pharmacy technicians (n=36) who responded to questions relating to staffing, 92% said their team was experiencing a staff shortage. Comments indicated that the impact of staff shortages was greater on pharmacy technicians than on pharmacists, although pharmacists were also negatively impacted by staff shortages.

These staffing issues resulted in workload imbalances among all shifts, as well as burnout and an increase in overall stress levels. Having insufficient numbers of fully trained pharmacy technicians able to perform IV compounding was another staffing challenge identified in the survey. Some potential causes related to this issue were the time required for training, as well as the higher physical workload demands.

As part of the survey, the pharmacists and pharmacy technicians who responded that they currently were experiencing a staff shortage were asked to detail the impact it had on them personally and professionally. The frustration and exhaustion was apparent in many of the responses (see callout to the right).

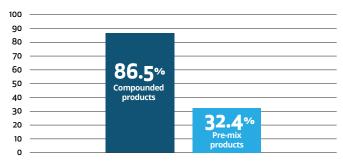
Supply chain issues have a greater impact on compounded products than on pre-mix

Responses from the 18 pharmacists and

19 pharmacy technicians who answered supply chain–related questions indicated that supply concerns caused a significant burden to pharmacists' and pharmacy technicians' ability to meet production needs within the hospital pharmacy.

Figure 3.

Supply chain effect on compounded and pre-mix products. Percentage of products affected by supply chain issues on a weekly basis over a 90-day period (n=37)



Notably, respondents felt that products requiring sterile compounding were more greatly affected by supply chain issues than pre-mix products. A reason for this difference may be the greater number of supplies required for compounding than for pre-mix products.

"We're always short-staffed. It's stressful and makes everyone not want to be here. Stress is bad for our health, too." — Pharmacist

"We have to take on the work of other people constantly. This results in burnout, lower quality of work, making mistakes, physical injury because of repetitive motion, and lower morale amongst all team members." — Pharmacy Technician

Pharmacy technicians experience physical discomfort from compounding

Study investigators who observed pharmacy technicians during single-item compounding noted certain ergonomic issues for pharmacy team members, some of whom also provided unsolicited input on this topic.



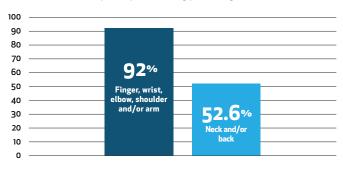
Informal discussions with pharmacy technicians during the study uncovered stories of physical discomfort related to working in the IV room, where single-item and batch compounding takes place. A high amount of wrist, hand, and elbow twisting was noted with compounding; hand cramps and discomfort were also noted by pharmacy technicians who had to push fluid through larger syringes. In addition, pharmacy team members who leaned into the hood to inspect the syringe and IV bag during single-item compounding experienced neck and back issues. Over time, this discomfort can cause medical concerns that result in taking time away from performing certain tasks, missing work, and the need to seek medical treatment.

Of the 19 pharmacy technicians who responded to questions regarding the physical impact of their work, 92% noted they have experienced discomfort in their fingers, wrists, elbow, shoulder and/or arms while working as a pharmacy technician (See Figure 4). Among these pharmacy technicians, 78.6% noted they had to pause their work to stretch or massage their areas of discomfort. Additionally, 28.6% of pharmacy technician respondents said they have seen a doctor to address their discomfort, while 64.3% said they have taken over-the-counter medications or prescription medications to manage their pain.

Similarly, work-related discomfort in the neck and/or back was noted by 52.6% of the 19 pharmacy technicians survey respondents.

Figure 4.

Work-related discomfort experienced by pharmacy technicians (n=19)



Pre-mix products generate more positive perceptions than compounded products

Survey participants were also asked to provide their thoughts on the differences between pre-mix and compounded products specifically, as they related to their workload and the ability of premix and compounded products to meet timeliness requirements for patient needs. Perceptions of pre-mix products tended to be more positive than perceptions of compounded products (see Tables 1 and 2 on the following page).



of the 38 pharmacists and pharmacy technicians interviewed on this topic said pre-mix products greatly reduced their workload

Of the remaining 8 survey respondents, 10.5% said there were no differences in workload observed when processing pre-mix or compounded products, while another 10.5% said pre-mix products reduced their workload slightly compared to compounding. No survey participant said that compounded products reduced their workload slightly or greatly (See Table 1).

When comparing your workload using pre-mix products and preparing compounded products, what statement below best represents your day-to-day experience?

	Pharmacy technician	Pharmacist	Combined (%)
Pre-mix products reduce my workload greatly	14 of 20	16 of 18	30 of 38 (79%)
Pre-mix products reduce my workload slightly	2 of 20	2 of 18	4 of 38 (10.5%)
No difference in workload	4 of 20	0 of 18	4 of 38 (10.5%)
Compounded products reduce my workload slightly	0 of 20	0 of 18	0 of 38 (0%)
Compounded products reduce my workload greatly	0 of 20	0 of 18	0 of 38 (0%)

Table 1.

Looking at products in terms of their ability to meet patient needs in a timely fashion, 39.5% ranked pre-mix and compounded products equally, while 55% stated a pre-mix product best allowed meeting the timeliness needs of patients. (See Table 2).

Table 2.

In your experience, which of the following best represents your ability to meet the timeliness requirements of our patients?				
	Pharmacy technician	Pharmacist	Combined (%)	
A compounded product best allows us to meet the timeliness needs of our patients	0 of 20	2 of 18	2 of 38 (5.2%)	
Both pre-mix and compounded products equally allow us to meet the timeliness needs of our patients	12 of 20	3 of 18	15 of 38 (39.5%)	
A pre-mix product best allows us to meet the timeliness needs of our patients	8 of 20	13 of 18	21 of 38 (55.3%)	

"We can't provide IV compounded product in a timely manner when there is too much IV compounding that spreads us thin." — Pharmacist

IV room assignments and batch compounding tasks elicit negative feelings among pharmacy technicians

Among the survey questions were several designed to evaluate points within pharmacy processes that correlated with high emotional reactions.

These questions asked pharmacy technicians about their feelings regarding assignments to a triage role and the IV room, where compounding takes place, as well as requests to prepare compounded products versus using pre-mix products. Pharmacists were asked about how they felt when receiving orders for a compounded or pre-mix product, when batch compounding was required, and their individual impact on the patient.

"Requests for batch compounding elicited an increase in negative feelings from technicians by more than 300% compared to requests for pre-mix products."

Both groups of pharmacy team members indicated some negative feelings in their responses. However, given their hands-on roles in compounding tasks, it is not surprising that pharmacy technicians (n=20) demonstrated a higher tendency toward negative feelings in specific and notable cases compared with pharmacists (n=18). For example, requests for batch compounding elicited an increase in negative feelings from technicians by 100% compared with requests for single-item compounding, and by more than 300% compared with requests for pre-mix products. More pharmacy technicians expressed negative feelings about an IV room assignment than about a triage role (22.7% vs 9.1%, respectively).

Pharmacists also showed greater negative feelings about requests for products requiring batch compounding (44.4%) compared with premix product requests (5.6%). A large majority (88.9%) had a neutral or positive feeling as it related to their overall impact on patient care.

Perceptions of how supply chain issues impact products for compounding and pre-mix products

When asked about the effects of supply chain issues on team members, both pharmacists and pharmacy technicians felt that these issues added a significant burden to their ability to meet production needs (see Tables 3 and 4 on the following page).

Table 3.

In the last 90 days, how often have supply chain issues impacted the medication and/or supply availability needed for compounding?			
	Pharmacy technician	Pharmacist	Combined (%)
Never	1 of 19	0 of 18	1 of 37 (2.7%)
Once or twice	2 of 19	2 of 18	4 of 37 (10.8%)
Weekly	9 of 19	7 of 18	16 of 37 (43.2%)
Daily	3 of 19	5 of 18	8 of 37 (21.6%)
Multiple times a day	4 of 19	4 of 18	8 of 37 (21.6%)

Table 4.

In the last 90 days, how often have supply chain issues impacted your ability to have pre-mixed products available?			
	Pharmacy technician	Pharmacist	Combined (%)
Never	3 of 19	1 of 18	4 of 37 (10.8%)
Once or twice	9 of 19	12 of 18	21 of 37 (56.8%)
Weekly	2 of 19	4 of 18	6 of 37 (16.2%)
Daily	2 of 19	0 of 18	2 of 37 (5.4%)
Multiple times a day	3 of 19	1 of 18	4 of 37 (10.8%)

Top challenges related to batch compounded and pre-mix products

Another portion of the survey was dedicated to asking pharmacists and pharmacy technicians what they consider their top challenges to be in relation to working with batch compounded and pre-mix products.

Challenges related to pre-mix products include unique issues — time required for thawing frozen pre-mix as well as a finite number of available strengths per product — while lack of trained IV technicians and short beyond-use dates are challenges seen with compounded products. Survey responses were categorized within several themes, including:

Challenges related to batch compounding

- The burden of supply chain and the impact on day-to-day workflows
- Meeting the timeliness needs of the patient due to increased work needed for compounding
- · Increased effort required for compounding
- Short beyond-use dates resulting in wasted products
- The lack of adequate staffing and/or trained staff to perform compounding
- The impact that compounding has on team member discomfort

Total Cost Analysis⁷

Beyond the experience survey, VMI conducted another analysis within the study—this one on the total cost to provide medication. This analysis was based on certain factors for which the consultant could provide reliable estimations, including human labor, IV room disposable supplies, the cost associated with adherence to an IV room safety protocol, and batch compounded product waste due to expiration.

Of the factors, the cost of human labor associated with single-item compounding was highest, followed by batch compounding, and then pre-mix products (see Table 5). It is worth noting that compounded products were found to have a 2- to 2.5-times higher cost associated with product preparation compared with pre-mix products. Additionally, compounded products have higher supply costs that must be accounted for in decision making, based on the many supplies needed in the sterile compounding process.

Non-medication-related costs associated with product readiness

Table 5.

and delivery			
Cost description	Pre-mixed product	Single-item compounded product	Batch compounded product
Estimated disposable supply cost	\$0.00	\$2.37	\$1.53
Estimated PPE* costs per IV room safety protocol	\$0.00	\$0.73	\$0.43
People Cost			
Pharmacy tech- product readiness	\$0.33	\$2.74	\$1.27
Pharmacist	\$1.28	\$1.33	\$2.19
Product delivery	\$1.98	\$1.98	\$1.98
Total Cost	\$3.59	\$9.15	\$7.40

* Personal Protective Equipment

Medication-related costs were excluded from the analysis.

Challenges related to pre-mix products

- · Supply chain challenges impacting product availability
- The additional time it takes to thaw frozen pre-mix products
- Limited strengths available for pre-mix products
- Management of automated replenishment levels in Automated Dispensing Cabinets (ADCs) and the potential for expired products

Study Limitations

This study centered on the preparation and use of pre-mix products, as well as those products prepared via single-item compounding, batch compounding. Certain processes and products were excluded from study assessment, including chemotherapy medications used in the oncology center; compounded and pre-mixed products made in the operating room satellite pharmacy; and all clinic-based/retail pharmacy medications. Any inpatient pharmacy medications outside of pre-mix, batch compounding, and single-item compounding were also excluded from the study, including pill, patch, and oral liquid medications.

Observations of processes within the study organization were affected by operational limitations, as well as the impact of COVID-19. Additionally, cost analyses were affected by a lack of inputs of costs related to the sterile compounding infrastructure; purchasing and stocking; product-specific training and education; and pharmacy team member discomfort.

Summary

Results from this study show the key differences that compounded products and pre-mix products can make to a hospital and its pharmacy team.

The information highlighted in the study illustrates how compounding can adversely impact workplace wellness, further straining teams who may already be understaffed and over-stressed on the edge of burnout.

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As noted in the survey responses, the burden of having insufficient staff to support the complex work of sterile compounding may result in additional burden to the team.

While compounded products will always remain necessary in hospital pharmacy, decision makers must also consider the potential negative effects that compounding can have on patient safety and treatment timeliness—and, as detailed in this study, on pharmacy team members' physical and emotional well-being.

In contrast, while pre-mix products may come at a premium cost and may not meet all medication needs within a hospital system, they can provide important benefits relevant to today's pharmacies. Not only can they alleviate pharmacy technician workload and supply chain challenges currently faced within the industry, but when compared with compounded products, they may also better meet the timeliness needs of patients, workforce wellness, and provide a potentially higher level of patient safety.

Results from this study demonstrate that many elements need to be considered when making decisions around products and processes used in the hospital pharmacy. Balancing these very human considerations with practical fiscal concerns is paramount.

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