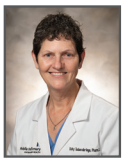
CASE STUDY

MOBILE INFIRMARY PILOTS INNOVATIVE CONCENTRATED NOREPINEPHRINE VIALS

Study Design and Findings — An Overview

Mobile Infirmary
INFIRMARY HEALTH

Nathan Browning, Pharm.D.
I.V. Room Supervisor
~ Mobile Infirmary



Vicky Vega, Pharm.D.
Pharmacy Education Coordinator
~ Mobile Infirmary

Roland Naseman, R.Ph.
Director of Pharmacy
~ Mobile Infirmary

PARTNERING TO ENHANCE WORKFLOW EFFICIENCY TO HELP CREATE BETTER PATIENT OUTCOMES

Infirmary Health is the largest non-governmental, non-profit healthcare system in Alabama. Serving southern Alabama, the organization's network of award-winning hospitals, physician practices, and affiliates makes it a top healthcare system on the Gulf Coast. This includes Mobile Infirmary — Infirmary Health's flagship hospital, which is among the leading hospitals in the state for surgical volume. The hospital houses a comprehensive cardiovascular program with a hybrid OR/cath lab, the region's only Bariatric Center of Excellence, a CARF-accredited rehabilitation hospital, a renowned cancer program, a thrombectomy-capable stroke center, and a freestanding emergency department.

It's no surprise that Mobile Infirmary's doctors and nurses keep the I.V. room pharmacists and technicians very busy. To help alleviate the stress and strain, Leiters, an FDA-registered 503B outsourcing provider of compounded sterile preparations, reached out to the hospital about participating in a workflow study for its new concentrated vials — Vicky Vega, Pharm.D., says they were very interested. "We always want to be involved in anything that promotes change and advancement," says Vega. "Especially where that means achieving better patient outcomes."

READY-TO-DILUTE, CONCENTRATED, PRE-FILLED VIALS

Leiters' concentrated vials are ready-to-dilute, pre-filled vials of highly used compounded sterile preparations that are not commercially available. Norepinephrine Bitartrate (Norepi) was selected for this workflow study.

"We prepare a good many Norepi bags in all milligram strengths — 4 mg, 8 mg, and 16 mg," says Vega. "We could see how having something readily available in concentrated vials could get medication to patients faster, so we wanted to take part."

Leiters.

CASE STUDY

Leiters
Concentrated Vials

Benefits at a Glance

- Compliant with all I.V. workflow and I.V. compounding software and all vial docking technologies.
- The concentrated vial sterile preparations are in solution, making them easier to dilute with no waiting for reconstitution of a lyophilized powder.
- Inventory space is reduced, waste minimized, and inventory turns increased.
- In the forward positions, vials can be stored in automated dispensing machines (ADMs) for rapid retrieval, dose tracking, and administration based on the hospital's specific vial-to-bag adapter and activation processes.
- Pre-labeled vials and boxes include TALLman lettering, barcodes, and color-coding for drug/strength differentiation to help reduce medication errors.

WORKFLOW STUDY: DESIGN

Nathan Browning, Pharm.D., was responsible for designing and tracking the workflow study for Mobile Infirmary. "Vicky and I decided to break the study down into three phases," he explains.

- In Phase 1, Browning and his team gathered data on the I.V. room's traditional manual compounding processes.
- In Phase 2, they switched to using Leiters' precise dosage Norepi vials for manual compounding.
- In Phase 3, they used the concentrated vials of Norepi from Leiters that use the vial docking technology so require no compounding.

"In each phase, we tracked the number of bags prepared, the staging time, the compounding time, the pharmacist check time, and the time to administration," says Browning. "We then used that information to calculate the cost per bag in each phase, which included product and supply costs as well as labor expenses." The study measured 8 mg and 16 mg vials across three and a half weeks.

Leiters was supportive through the entire process. "The team was very responsive and answered my questions or helped me find a solution quickly no matter the challenge," says Browning. "At one point, we ran out of some of the study drug, and Leiters sent us what we needed overnight so it was there by 7 a.m. the next morning."

WORKFLOW STUDY: TOPLINE FINDINGS

8 mg Norepi	Phase 1	Phase 2	Phase 3
Number of Bags	23	24	N/A
Staging Time	56 seconds	85.3 seconds	N/A
Compounding Time	2.48 minutes	1.58 minutes	N/A
Pharmacist Check Time	26.6 seconds	15.3 seconds	9.6 seconds
Time to Administration	174.3 minutes	152 minutes	61.4 minutes
Cost Per Bag	$17.52	$16.49	$17.93

16 mg Norepi	Phase 1	Phase 2	Phase 3
Number of Bags	38	66	N/A
Staging Time	47.8 seconds	31.9 seconds	N/A
Compounding Time	3.8 minutes	1.34 minutes	N/A
Pharmacist Check Time	27.7 seconds	13.6 seconds	9.6 seconds
Time to Administration	246.4 minutes	161.4 minutes	59.2 minutes
Cost Per Bag	$31.05	$18.31	$19.89

CASE STUDY

"The process saved a lot of time, which got medication to patients faster and freed up our I.V. room to handle other urgent tasks."

Nathan Browning, Pharm.D.
I.V. Room Supervisor
~ Mobile Infirmary

TIME SAVED GETS MEDICATION TO PATIENTS SOONER

"For us, the crux of the study was to see if we could reduce the time it took to hang a bag on the patient," says Browning. "Obviously, with the concentrated vials, there's no compounding time since they're ready to use, but we found that even when we spiked them under a hood, the relative prep time was something like 10 seconds compared to two or three minutes or more for compounding." That's because the concentrated vials require a simple aseptic technique where the top is popped, swabbed, and spiked. "The process saved a lot of time, which got medication to patients faster and freed up our I.V. room to handle other urgent tasks."

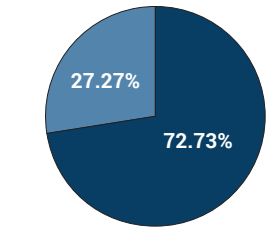
The nurses also liked the concentrated vials because they helped eliminate delays in care for their patients. "Requesting a bag, waiting for it to get made, and then eventually sent up all takes time," says Browning. Based on Phase 1 data, that was an average of 264 minutes from request to administration for the 16 mg bags.

"With the concentrated vials, when nurses needed a bag — they could just go to the ADM, pull out what they needed, dock it with vial docking technology and activate and hang it," Browning explains. In Phase 3 of the workflow study, Mobile Infirmary found that Norepi infusion began significantly faster, in 59.2 minutes on average for 16 mg bags.

The result? 100% of nurses answering an internal survey said having the concentrated vials in an ADM made it either a great deal or a lot faster to administer the first dose compared to waiting for the I.V. room to compound the product.

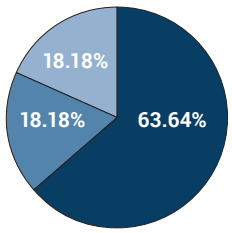
KEY NURSING SURVEY RESULTS

In your unit having the concentrated vials in your automated dispensing machine (ADM), was it quicker to administer the first dose rather than waiting on the pharmacy?



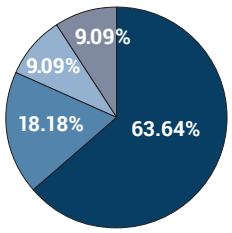
- A Great Deal
- A Lot
- A Moderate Amount
- A Little
- None at All

How likely would you support the pharmacy to continue to use the norepinephrine bitartrate in this format?



- Very Likely
- Likely
- Neither Likely, Nor Unlikely
- Unlikely
- Very Unlikely

How likely would you request pharmacy to add additional critically needed drugs in this vial format?



- Very Likely
- Likely
- Neither Likely, Nor Unlikely
- Unlikely
- Very Unlikely

Over 80% of nursing respondents stated that they would 'very likely or likely' support the pharmacy's continued use of the Norepi concentrated vial, as well as support other critically needed drugs in the same format. According to Browning, the concentrated vial was also supported by the I.V. room staff. Leiters provides compounded sterile preparations in several different volumes and precise milligrams — Norepi comes in 4 mg, 8 mg, and 16 mg single-use vials. "With our previous product, the vials only came in

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"With our previous product, the vials only came in 4 mg, so if we needed a 16 mg bag, we'd have to pull four vials. With Leiters, it's just one."

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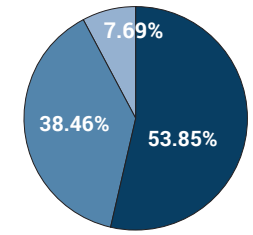
4 mg, so if we needed a 16 mg bag, we'd have to pull four vials. With Leiters, it's just one," says Browning. This seamless process just adds an extra layer of confidence in the final compounded product, he adds.

That's one of the reasons more than 90% of pharmacists and technicians surveyed internally said the concentrated vials were easy to use, took less time to complete a dose compared to a manual compounding processes, and would recommend the format to leadership.

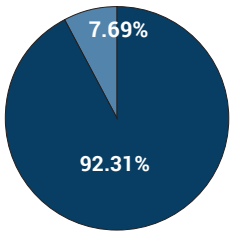
KEY PHARMACY SURVEY RESULTS

Were the concentrated vials easy to use?



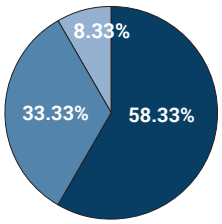
Very Likely
Likely
Neither Likely, Nor Unlikely
Unlikely
Very Unlikely

Did the concentrated vials take less time to complete a dose than the manual compounding process?



Yes
No

How likely would you recommend to your leadership on continuing to use the concentrated vials to save time, make compounding easier and more accurate?



Very Likely
Likely
Neither Likely, Nor Unlikely
Unlikely
Very Unlikely

WHY CONCENTRATED VIALS?

ASHP reports that health system pharmacies are faced with significant staffing shortages – particularly among pharmacy technicians. Reasons cited in a recent survey conducted by the organization include workload, work schedules and pay. Regardless of why, the simple fact is that pharmacy managers are continually looking for ways to do more with fewer resources by adding efficiency.[1]

Leiters concentrated vials add a lot of efficiency to pharmacy processes. Concentrated vials reduce the time to compound medications by reducing manual steps. For example, manually compounding a 16 mg/250 mL dose of Norepi diluent with commercially available vials takes 34 steps from staging to pharmacist check. With the concentrated vials, this is reduced to just nine steps.

ABOUT LEITERS

Leiters is an FDA-registered 503B outsourcing provider of compounded sterile preparations and pharmacy services. Their team of experts in sterile pharmaceutical manufacturing, compounding, and pharmacy provide a sophisticated understanding of what it takes to elevate quality and consistency of supply in pharmaceutical outsourcing. They combine a deeply experienced team, with robust processes, in a state-of-the-art facility, to ensure delivery of the highest quality medicines.

[1] "Hospitals and Health Systems Experiencing Severe Shortage of Pharmacy Technicians," ASHP, March 15, 2022: https://www.ashp.org/news/20 22/03/15/hospitals-and-health-systems-experiencing-severe-shortage-of-pharmacy-technicians