The Impact of Intravenous Push Lacosamide on Efficiency in Provision of Patient Care

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Abstract

The health care industry has long been focused on providing both efficient and safe patient care. However, since the beginning of the COVID-19 pandemic, a heavier burden has been placed on health care workers due to staffing shortages. Many facilities are at maximum patient capacity based on reduced nursing staff availability, and inpatient pharmacies have been significantly impacted by staffing strains as well. From these challenges, it has become clear that developing and implementing efficiency boosting processes is critical to ensuring that the health care industry can continue to provide safe and timely patient care.

Epilepsy, which can result in seizures among other symptoms, affects numerous individuals in the United States. Lacosamide is an antiepileptic to be administered intravenously over 30 to 60 minutes. Once diluted with an appropriate intravenous (IV) fluid to create an IV piggyback (IVPB), lacosamide has an extremely short beyond-use-date. Additionally, lacosamide is a schedule V controlled substance, requiring the incorporation of numerous steps to track the medication through the compounding and dispensing process. The combination of these two factors makes it logistically challenging to stock lacosamide on the patient care unit for easy access and administration by nursing staff. Previous data have demonstrated that administering lacosamide as an IV push (IVP) rather than an IVPB can reduce time from order verification to administration with a similar safety profile. Switching to IVP administration greatly reduces the number of steps required in the dispensing process and may have a significant impact on the workflows of both pharmacy and nursing staff. The Allegheny Health Network implemented a

policy change to administer lacosamide via IVP instead of IVPB. The purpose of this study was to describe the steps required to implement this policy and to elucidate the effect of this change on both efficiency and safety.

This project is relevant to public health as it highlights the impact that process changes can have on the provision of safe and timely patient care and on maintaining efficient workflows during critical staffing shortages.

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1.0 Background

Lacosamide is an FDA approved medication that can be used to treat epilepsy, a disorder that causes seizures and affects over three million individuals in the United States.³ While not a typical first-line agent for maintenance therapy, lacosamide can be used in patients requiring additional seizure control, especially those with treatment-resistant epilepsy.⁷ Lacosamide can be administered orally or intravenously. Solution for intravenous (IV) injection is supplied as a vial with a concentration of 200 mg per 20 milliliters (mL) and can be diluted with an appropriate fluid, such as 0.9% sodium chloride. Administration can take place diluted or undiluted, though dilution results in an IV piggyback (IVPB) product that should not be stored for more than 4 hours at room temperature per package insert.⁴ This short beyond-use-date makes it operationally challenging to stock lacosamide for IVPB administration on the nursing unit. Typical maintenance doses range from 50 to 200 mg twice daily; for quicker effect, which may be used in cases of emergent seizures, a single dose of 200 to 400 mg may be appropriate.⁸ Per manufacturer labeling, IV administration should take place over 30 to 60 minutes. However, administration via rapid infusion over 15 minutes is recommended in the Neurocritical Care Society's Guidelines for Status Epilepticus (SE).⁹ SE is a state of uninterrupted seizing, a critical situation that puts patients at substantial risk of morbidity and mortality if appropriate therapies are not administered quickly enough.

Lacosamide is a schedule V Controlled Substance, requiring lengthy tracking practices during the dispensing and administration process to meet requirements set by the Drug Enforcement Administration (DEA). At the study institution, Allegheny Health Network (AHN), this included the following steps: 1) order is verified by the pharmacist, 2) order is received in the IV room, 3) IV room pharmacist pulls vial from a controlled substance cabinet, 4) IVPB is compounded by the pharmacy technician, 5) dose is verified by the pharmacist, 6) dose is written up on a tracking sheet, 7) dose is delivered to the unit automated dispensing cabinet (ADC), 8) drug is removed from the ADC by the nurse, and, finally, 9) the dose is administered to the patient over 60 minutes. As summarized in Figure 1a, the dispensing and preparation of this medication as an IVPB may involve the work of six staff members.

The inability to stock lacosamide on the nursing unit for administration due to the beyonduse-date and extended process necessary to track lacosamide as a controlled substance is one of two major barriers to ensuring the safe and efficient provision of this medication. The second barrier is a relatively common issue with all patient-specific medications: loss or misplacement. Patient-specific medications are those not routinely stocked in the ADC for nurse-driven removal, typically due to the limited amount of space available for medication storage. There are often unavoidable, though uncommon, workflow issues that may result in a medication not being readily available to the nursing staff.¹⁰ An example of one such circumstance may be when an ADC is down for maintenance but there is a lack of communication regarding where medications will be stored in the meantime.

The combination of these two barriers can significantly delay the administration of lacosamide, which can be used in emergent situations such as SE. They also result in processes that add substantial steps and time to both the pharmacy and nursing workflow. Given the severity of health care staffing shortages over the last year, streamlining workflows is critical to ensuring safe and efficient patient care.^{1,2}

Historically, other medications have been administered via IV push (IVP) instead of IVPB in an effort to mitigate these issues. IVP administration occurs by the nurse drawing the medication into a syringe then slowly "pushing" the medication into the patient's IV line.¹¹ Other medications

that are administered by IVP include many pain medications and antibiotics.¹² Previous studies have provided evidence for the administration of lacosamide via IVP at rates of 40 to 80 mg/min, allowing for higher doses to be administered more quickly. For example, 400 mg would be given over approximately 5 minutes compared to this study institution's standard 60-minute infusion. Davidson and colleagues demonstrated that this administration method decreased the median time from verification to administration from 109 minutes to 35 minutes. Data found no significant difference in adverse event rates such as hypotension, bradycardia, or PR prolongation, which are known side effects of IV lacosamide administration.^{5,6} The ability to administer lacosamide via IVP greatly reduces the steps required for the dispensing and preparation process. As depicted in Figure 1b, there are five fewer steps and three fewer staff members involved in the IVP process at the study institution.

Given the previously published data regarding safety, the primary objective of this study was to describe the steps required to implement a health system wide IVP lacosamide policy; similar implementation studies are not frequently published so the goal of this project was to expand this area of literature. The efficiency secondary objective was a measure of time from order verification to administration. Safety secondary objectives included a safety composite and the incidence of PR prolongation.

Figure 1a: IVPB la	acosamide dispensing and preparation process
Provider	Order entry
Pharmacist 1	Order verification
Electronic	Order sent to IV room
Pharmacist 2	IV room pharmacist pulls medication from secured stock
Technician 1	IV room technician compounds IVPB
Pharmacist 2	[IVPB verified by IV room pharmacist and paperwork is completed]
Technician 2	Technician delivers medication to dispensing cabinet on nursing unit
Nurse 1	Nurse removes medication from dispensing cabinet
Nurse 1	Nurse administers IVPB over 60 minutes
Тес	hnician and pharmacist complete tracking process upon delivery
Figure 1b: IVP lac	osamide dispensing and preparation process
Provider	Order entry
Pharmacist 1	Order verification
Electronic	Order sent to dispensing cabinet on nursing unit
Nurse 1	Nurse removes vial from dispensing cabinet
Nurse 1	Nurse draws up dose in syringe and administers to patient at 80 mg/min (over approx, 2-5 minutes)
Vials w	yould be refilled by pharmacy staff as needed based on usage

Figure 1: Summary of differences between the IVPB and IVP dispensing processes

2.0 Methods

This study was completed across a health system network including ten acute care hospitals and received AHN IRB approval as exempt. This study was completed in two parts, the first being a prospective description of the process for implementing a lacosamide IVP policy. After the IVP policy go-live date, all included orders at all sites defaulted to IVP unless a provider requested IVBP administration to be entered by the pharmacy staff. The second part consisted of a retrospective cohort analysis between patients who received lacosamide via IVPB and those who received lacosamide via IVP. An electronic health record (EHR) report identified all patients who received lacosamide, by either administration method, from the time frames of August 2021 to October 2021 (pre-implementation) and December 2021 to February 2022 (post-implementation). Patients were excluded if they were younger than 18 years of age or if they were pregnant or incarcerated. The EHR was utilized to collect data including, but not limited to, demographic characteristics, medical history, vital signs, and lacosamide order details.

The efficiency measure was time (in minutes) from verification to administration for new orders. In the inpatient setting, the term order is similar to the outpatient term prescription: a medication to be given at a defined dose, frequency, and duration of time. Multiple administrations can be completed under one order, all authorized at the time of order verification. Time of order verification was defined as the time of pharmacist verification and time of administration was defined as the time when the dose was charted to be given. Both were collected by reviewing the order history in the EHR.

The safety composite measure captured the occurrence of one of the following within 2 hours of administration completion: 1) hypotension requiring intervention or 2) bradycardia

requiring intervention. Hypotension was defined as a systolic blood pressure (SBP) of less than 90 mmHg or a reduction in SBP of 30% or greater within two hours of administration. Bradycardia was defined as a heart rate (HR) of less than 60 bpm or a reduction in HR of 30% or greater within two hours of administration. Applicable interventions can be found in Figure 2. Time from administration was based on the time at which lacosamide administration was complete. Percent change was calculated using the lowest SBP or HR within 2 hours before administration as a baseline. PR prolongation was defined as a PR interval of greater than 200 msec, as measured and reported from an EKG collected within 48 hours after the end of lacosamide administration. If vital sign readings were not recorded in the EHR, that administration was not included in analysis of the applicable safety endpoint. This data may be missing as all values were collected in a manner according to provision of patient care; for example, if a patient was on a low acuity floor and only required vital signs to be taken twice a day, these readings may not have been taken within the defined window of 2 hours.

Hypotension requiring	intervention
Within 2 hours of	• the administration of a fluid bolus, the initiation of a new vasopressor or inotropic
lacosamide	agent, or a reduction or discontinuation of a continuous infusion of an
administration:	antihypertensive, diuretic, or afterload reducing agent, or
	 the reduction in lacosamide dose or lacosamide discontinuation.
Within 1 dosing	• the reduction or discontinuation of an intermittently dosed antihypertensive, diuretic,
interval:	or afterload reducing agent
Bradycardia requiring	intervention
Within 2 hours of	• the administration of a fluid bolus, the initiation of a new vasopressor or inotropic
lacosamide	agent, a reduction or discontinuation of a continuous infusion of an antihypertensive,
administration:	diuretic, or afterload reducing agent, or the administration of atropine, or
	• the reduction in lacosamide dose or lacosamide discontinuation
Within 1 dosing	• the reduction or discontinuation of an intermittently dosed beta blocker, calcium
interval:	channel blocker, or other agent linked with bradycardia

Figure 2: Description of interventions for hypotension or bradycardia

To compare the efficiency and safety outcomes between IVPB and IVP administrations, data was analyzed using Stata. Categorical data was analyzed using χ^2 tests. Continuous data that was normally distributed was analyzed with a two-sample t-test and reported utilizing means and standard deviations. Continuous data with a non-normal distribution was analyzed with the Wilcoxon rank-sum test to generate medians and interquartile ranges.

3.0 Results

3.1 Primary Outcome: Description of Implementation

To implement this project, it was critical to develop an implementation timeline (Figure 3). One of the first steps was to obtain approval from the pharmacy and therapeutics (P&T) committee. To gain approval, an existing policy had to be updated: the IVP policy that provides a list of medications that can be administered via IVP at AHN facilities. Approximately six months prior to the go-live date, the addition of lacosamide to this list was first approved by the applicable subcommittee for patients aged 17 years or older for doses of 400 mg or less to be administered via IVP at a rate of 80 mg/min. Doses greater than 400 mg lack data for IVP administration and were excluded and would continue be administered as an IVPB over 15 minutes (Figure 4). As there is no data for administering lacosamide as IVP in the pediatric population, patients under the age of 17 were also excluded and dosed at 1 to 5 mg/kg as an IVPB over 60 minutes with a max dose of 200 mg. The IVP medication profile was then built within the EHR to include the appropriate route and administration instructions.

&T Subcommittee pproval & EHR Build	Pharmacy Education Refill level analysis	Order switching Education
6 months prior	2-4 weeks prior	Go-live date
1.5 months prior	1 week prior	After go-live
Network P&T Approval	Nursing Education Vial Loading	On-going analysis Troubleshooting Continuing education Inventory management

Figure 3: Implementation timeline

Age	\geq 17 years	< 17 years	
Dogo	\leq 400 mg IVP at 80 mg/min	1-5 mg/kg IVPB over 60 minutes	
Dose	> 400 mg IVPB over 15 minutes	Max dose: 200 mg	

Figure 4: Age and dosing guidelines for IVP lacosamide policy

Approximately three months prior to the go-live date, preparation for presentation at the network-level P&T committee began. The addition of lacosamide to the IVP policy was approved approximately six weeks prior to the go-live. During this time, critical stakeholders were identified to be the pharmacy staff and the nursing staff as these two populations would be most greatly impacted by the change in workflow (Figure 5). Ordering providers were also identified as internal stakeholders, though they would not be as affected by the operational change. Other internal stakeholders included the P&T committee and hospital administrators. Patients, though they played no role in the implementation process, were critical stakeholders as they would be directly affected by the improvements in delivery of care and the assurance of safe medication administration.

Group	Communication provided about workflow changes	
Critical stakeholders: intimately affected by workflow changes		
Nursing staff	Customized emails, in-person huddles, signage on ADCs	
Pharmacy staff	Customized emails, in-person huddles	
Stakeholders: not intimately affected by workflow changes		
Providers	Generalized email	
P&T and hospital administrators	P&T presentation, generalized email	
Other stakeholders: not impacted by workflow changes		
Patients	No communication	

Figure 5: Stakeholder description

One month prior to go-live, the implementation team engaged in providing education to one of the key stakeholders: the pharmacy staff, including pharmacists and pharmacy technicians. Pharmacy education was distributed via emails and in-person announcements, and staff members were given the opportunity to ask questions, voice concerns, or make recommendations.

A medication use analysis was completed to evaluate the use of lacosamide based on location within the hospitals. This information was used to decide where lacosamide vials would be loaded throughout the facilities and at what number.

One week prior to the go-live date, members of the pharmacy team provided in-person education to nursing staff working in high utilization units. Education was also provided via email communications and signage posted on the ADCs (Figure 6). During this week, the vials were loaded into the applicable ADCs. On the day of go-live, an EHR update occurred at all sites to activate changes to the ordering process. Additionally, education was again provided to the pharmacy staff and all active orders that met criteria were manually changed from IVPB to IVP. After the go-live date, a continuous process of analysis, troubleshooting, inventory management, and education have been completed.



Figure 6: Example signage that was displayed on nursing unit

3.2 Secondary Outcomes: Efficiency and Safety

112 patient profiles were initially screened, ten of which were excluded (Figure 7). 56 patients received lacosamide via IVBP and 49 received IVP; three patients received both administration methods during the study time periods and were included in both analysis groups. Data was collected for a total of 869 individual administrations. Patient demographics were similar between the two cohorts, including prior history of epilepsy or cardiovascular disease (Table 1).

Exclusions: Incarceratio No administ	n: 2 patients rations: 8 patients	dy periods: tients
	Patients meeting 102 pa	inclusion criteria ttients
		•
(3 patients received both treatments)	Patients who received IVPB 56 patients	Patients who received IVP 49 patients
Number of Administrations	519 administrations	350 administrations
Safety Outcome: Safety Composi	Total Orders: 111 STAT Orders: 26	Total Orders: 95 STAT Orders: 15
		237 administrations
BP or HR readings within 2 hours after completion	372 administrations	
BP or HR readings within 2 hours after completion Subanalysis: Hypotension	372 administrations	
Unit of Measure: Administrations with BP or HR readings within 2 hours after completion Subanalysis: Hypotension Unit of Measure: Administrations with BP readings within 2 hours after completion	312 administrations	178 administrations
Unit of Measure: Administrations with BP or HR readings within 2 hours after completion Unit of Measure: Administrations with BP readings within 2 hours after completion Subanalysis: Bradycardia	312 administrations	178 administrations
Unit of Measure: Administrations with BP or HR readings within 2 hours after completion Subanalysis: Hypotension Unit of Measure: Administrations with BP readings within 2 hours after completion Subanalysis: Bradycardia Unit of Measure: Administrations with HR readings within 2 hours after completion	319 administrations 364 administrations	178 administrations
Unit of Measure: Administrations with BP or HR readings within 2 hours after completion Subanalysis: Hypotension Unit of Measure: Administrations with BP readings within 2 hours after completion Subanalysis: Bradycardia Unit of Measure: Administrations with HR readings within 2 hours after completion Safety Outcome: PR Prolongation	319 administrations 364 administrations	178 administrations

Figure 7: Flowchart of included patients, along with applicable sample size for each analysis

Table 1: Baseline characteristics

	IVPB ($n = 56$ patients)	IVP ($n = 49$ patients)	p-value
Age (years) – mean (SD)	56.6 (19.6)	56.6 (17.8)	0.999
Female sex	31 (55.4%)	22 (44.9%)	0.285
Weight (kg) – mean (SD)	78.5 (24.3)	74.1 (23.1)	0.349
History of Epilepsy	38 (67.9%)	35 (71.4%)	0.692
Cardiovascular History	9 (16.1%)	7 (14.3%)	0.799
Dose (mg) – mean (SD)	148.3 (65.6)	152.8 (74.4)	0.359

For the efficiency endpoint of time from verification to administration, there were 111 IVPB orders and 95 IVP orders assessed (Table 2). The mean time from verification to administration in the IVPB group was 258.5 minutes compared to 227.5 minutes in the IVP group (P = 0.404). A subgroup analysis was completed on those orders which were placed as STAT, which included 26 IVPB orders and 15 IVP orders. When comparing this subgroup, ordered STAT to indicate that the dose was critically or urgently needed, the median time from verification to administration was 84.5 (IQR 55 – 159) minutes for IVPB and 31 (IQR 16 – 58) minutes for IVP (P < 0.001).

	IVPB (n = 111 orders)	IVP ($n = 95$ orders)	p-value
Time from verification to	258 5 (252 5)	227 5 (280 7)	0.404
administration in minutes – mean (SD)	230.3 (232.3)	227.3 (200.7)	0.404
Orders entered as $STAT - n$ (%)	26 (23.4%)	15 (15.8%)	
Time from verification to			
administration for STAT orders in	84.5 (55-159)	31 (16-58)	< 0.001
minutes – median (IQR)			

Table 2: Time from verification to administration

For the safety composite score based on hypotension or bradycardia requiring intervention, all administrations that had at least one BP or HR reading within 2 hours after administration were included: 372 in the IVPB group and 237 in the IVP group (Table 3). Each treatment group had five administrations which required intervention for hypotension or bradycardia (1.3% vs. 2.1%,

P = 0.522). Interventions included the reduction, holding, or discontinuation of a concomitant medication, administration of a fluid bolus, or initiation of a vasopressor agent.

 Table 3: Safety composite incidence

Administrations with BP or HR reading within 2 hours of administration	IVPB (n = 372)	IVP (n = 237)	p-value
Administrations that required intervention – n (%)	5 (1.3%)	5 (2.1%)	0.522

To further assess the risk of bradycardia and hypotension, each adverse effect was analyzed individually in subanalysis groups (Table 4). 319 individual IVPB administrations and 178 IVP administrations had BP readings within 2 hours of administration completion. Among these administrations, 12 in the IVPB group experienced hypotension compared to 8 in the IVP group (3.8% vs. 4.5%, P = 0.69). Hypotension requiring intervention among IVPB and IVP administrations did not differ (0.9% vs. 0.6%, P = 1). 364 individual IVPB administrations and 232 IVP administrations had HR readings within 2 hours of administration completion. Among these, 21 in the IVPB group and 26 in the IVP group experienced bradycardia (5.8% vs. 11.2%, P = 0.01). Bradycardia which required intervention did not differ between the two groups (0.5% vs. 1.7%, P = 0.215).

Administrations with BP reading within 2 hours of administration	IVPB (n = 319)	IVP (n = 178)	p-value
Administrations with hypotension – n (%)	12 (3.8%)	8 (4.5%)	0.69
Requiring intervention – n (%)	2 (0.9%)	1 (0.6%)	1
Administrations with HR reading within 2 hours of administration	IVPB (n = 364)	IVP (n = 232)	p-value
Administrations with bradycardia – n (%)	21 (5.8%)	26 (11.2%)	0.01
Requiring intervention – n (%)	2 (0.5%)	4 (1.7%)	0.215

Table 4: Subanalysis of hypotension and bradycardia

6 IVPB administrations and 18 IVP administrations had an EKG reading to assess PR prolongation within 48 hours of administration (Table 5). Zero administrations in the IVPB group had recorded PR prolongation compared to four administrations in the IVP group (0% vs. 22.2%, P = 0.539). No bradycardic findings were associated with these recorded PR prolongations.

Administrations with EKG reading within 48 hours of administration	IVPB $(n = 6)$	IVP (n = 18)	p-value
With PR prolongation – n (%)	0 (0%)	4 (22.2%)	0.539

4.0 Discussion

This study described the successful implementation of a health system wide policy to administer lacosamide via IVP and generated appropriate data endpoints. The results of this study can be analyzed and discussed for its impact at the individual, institutional, and community level. As further described below, the individual patients were impacted most by the decrease in time to administration during emergent situations, without any unexpected increases in adverse effects. While the institution, AHN, is concerned with these individual outcomes, another focus is on the logistic and operational implications of this policy change. Finally, the pharmacy, medical, and public health community can also benefit from the results described in this study.

4.1 Individual Level: Patient Impact

The overall time from verification to administration did not decrease when comparing all new orders for lacosamide via IVPB and IVP. It is theorized that this is due to an ordering practice that involves ordering the loading dose and the maintenance dose at the same time. For example, a 300 mg bolus dose may be ordered as STAT and administered within the hour. However, a maintenance dose order of 100 mg every 12 hours may have been ordered and verified at the same time, though its administration would not occur until 12 hours post-bolus. Thus, a subgroup analysis was conducted on those new orders placed as STAT, where a statistically significant reduction in time from verification to administration was demonstrated. This indicates that those doses needed emergently are reaching patients more quickly, nearly an hour faster for IVP

administrations compared to IVPB, a finding that confirms previously published data.⁵ Currently, there is no evidence that a shorter time to administration results in better clinical outcomes for the patient; however, at least in emergent situations, it may be theorized that quicker administration would lead to earlier seizure control and improved morbidity and mortality. Research measuring the clinical impact of such an operational change should be completed in the future to more fully elucidate this possible benefit.

The safety composite comprised of hypotension or bradycardia requiring intervention did not statistically differ, suggesting that lacosamide administered via IVP had a similar rate of adverse events that required intervention compared to IVPB administration. While a larger proportion of patients in the IVP group experienced bradycardia based on vital sign monitoring alone, there was no difference in rate of bradycardia requiring intervention. Overall, this data is consistent with previous studies that have demonstrated no clinically significant difference in safety profiles.^{5,6} Only a small number of administrations had associated EKG readings that could be analyzed for PR prolongation. Nearly a quarter of those with readings in the IVP group experienced PR prolongation of greater than 200 msec. However, patients did not experience associated bradycardia. Given the limited number of patients, it is difficult to draw any conclusions regarding the impact of lacosamide administration via IVP on PR interval and further research is recommended.

The overall individual benefit of this operational change, from the patient's perspective, is the improvement in time from verification to administration in emergent situations without an increase in adverse events requiring additional intervention. Other individual stakeholders may also recognize the benefit of this operational change; nurses no longer have to wait for the medication to be dispensed through a lengthy process and the pharmacist or pharmacy technician would also benefit from this streamlined workflow.

4.2 Institutional Level: Hospital and Health System Impact

The primary concern for the institution is the safety of patients during the provision of care. The second is maintaining positive clinical outcomes while improving the efficiency of care delivery. As discussed in the previous section, results from this study indicate that this policy change resulted in an efficiency improvement while maintaining safety, though the link to improved clinical outcomes has not been studied.

However, at the institutional level, not only is efficiency in direct patient care critical, simplicity of these processes is also of utmost importance. The impact of improved efficiency will be discussed from the perspective of one key population: the nursing staff. In an emergent situation, a nurse is likely highly aware of the need for urgent receipt of a lacosamide dose and may spend considerable time and cognitive energy on waiting for the medication's delivery. From this study, the median wait time for STAT orders was reduced from 85 minutes to 31 minutes. That is one hour less of the nurse's day in which they are worrying about a medication arriving in time to be administered as needed. The nurse also definitively knows where the medication can be removed from; they do not have to concern themselves with delivery or storage. In non-emergent situations, which are more common, this serves to simplify one aspect of patient care compared to the complexities of IVPB administration. This is especially important to nursing staff because they may be internally benchmarked based on medications being administered within a certain window of the scheduled time. Medication not being available at the correct time may also directly interfere

with the care of other patients. This is especially critical during a time of nursing shortages, as data indicates that one nurse may be caring for as many as nine patients at a time.¹³ Additionally, nurses spend approximately 15% to 25% of their time on tasks related to medication administration, indicating that medications are a point of critical impact on their workflows.^{14,15}

These improvements in efficiency also apply to pharmacy staff. At the institutional level, efficiency across and between departments is vital to financial stability. Time saved on lower-level clinical tasks (such as medication preparation, dispensing, and administration) is additional time that nursing and pharmacy staff can utilize for higher-level clinical activities, such as providing patient education. Improved workflows also result in improved employee satisfaction.¹⁶

4.3 Community Level: Pharmacy, Medical, and Public Health Impact

This study demonstrated that the implementation of a health system wide policy to administer lacosamide via IVP is accomplishable within six months. Policy changes are often rapidly implemented in the health care setting; however, the implementation processes described in this study may provide a beneficial outline for thoughtful and timely policy modification.

Key components to success included implementation, education, and operationalization. Implementation included the creation of an updated IVP policy and the process of gaining P&T approval, as well as the development of EHR medication profiles. Education focused on nursing and pharmacy staff as it was proposed that these two groups would be most impacted by logistical and operational workflow changes. Tools utilized to provide education included the posting of signage on ADCs on the patient care units, the distribution of communication via email, and the provision of in-person education delivered at huddles. Education at nursing and pharmacy huddles also provided the opportunity for questions and concerns to be addressed. Recognizing the importance of interdisciplinary initiatives, concepts from public health intervention development were utilized, including the identification of key stakeholders and relationship building to garner buy-in and ensure that a meaningful intervention was being produced. This study demonstrates that public health tools can be extremely useful in the clinical pharmacy and medical setting.

4.4 General Discussion

This study has several limitations including the method of retrospective chart review, which limits the ability to draw causation conclusions. For example, it cannot be guaranteed that additional adverse events did not occur but were missing documentation in the EHR. Interventions were assumed to have been a result of adverse events related to administration but there could have been other clinical reasons for these interventions. No analysis was completed on the reason for the patient's hospital admission nor the acuity of their overall clinical status, both of which may have influenced the frequency of vital sign monitoring and the vital signs themselves. Analysis was also not completed on the indication for lacosamide administration; adverse event profiles may be different for those receiving lacosamide for an active seizure compared to those continuing therapy. Finally, it should be acknowledged that, for the most part, the comparison groups occurred during different time periods; there was no analysis to measure other aspects, such as institutional staffing trends, that may have impacted the efficiency or safety measures.

Sample size was also a limitation, especially when trying to analyze a rare event. Additionally, there was a descriptive difference in EKG monitoring between the two groups, which was completed in 6 IVPB and 18 IVP administrations. The reason for more patients in the IVP group receiving monitoring is unknown, partially due to the lack of controlling for disease state or acuity as described above. It is possible that providers, aware that IVP was a newer practice for AHN facilities, were more apt to order EKGs for closer monitoring. Due to these inconclusive findings, it has been agreed upon by the P&T committee and the pharmacy department that additional safety follow-up will be completed in the near future.

Despite these limitations, this study provides guidance to successfully implementing a change in administration of lacosamide from IVPB to IVP. Importantly, it also provides evidence that administration of lacosamide via IVP can significantly reduce time from verification to administration in situations that may require urgent therapy. There was an overall reduction in the workflow required for both pharmacy and nursing staff, which is critical during this time of extreme staffing shortages. This study also adds to previously published data with regards to the safety profile of lacosamide administration via IVP. Guidance from this study could be utilized by other institutions to implement similar IVP policies for lacosamide or other intravenous medications. Further studies are required to elucidate the clinical implications of IVP lacosamide on outcomes such as time to seizure cessation.

5.0 Conclusion

This study provides guidance on the process for successfully implementing and operationalizing a transition from IVPB lacosamide to IVP lacosamide within 6 months. While this study indicates a reduction in time from verification to administration, the clinical implications of this reduction have not been measured and should be the focus of future research. Importantly, this demonstrates the public health value that can be gained from the implementation of a pharmacy policy through its impact on the provision of health care in a safe and timely manner at the individual, institutional, and community level.

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