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ORIGINAL RESEARCH ARTICLE

A Multi-hospital Before–After Observational Study Using a Point-Prevalence Approach with an Infusion Safety Intervention Bundle to Reduce Intravenous Medication Administration Errors

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Abstract

Introduction We previously found a high rate of errors in the administration of intravenous medications using smart infusion pumps.

Objectives/Design An infusion safety intervention bundle was developed in response to the high rate of identified errors. A before–after observational study with a prospective point-prevalence approach was conducted in nine hospitals to measure the preliminary effects of the intervention.

Main Outcome Measures Primary outcome measures were overall errors and medication errors, with the secondary outcome defined as potentially harmful error rates.

Results We assessed a total of 418 patients with 972 medication administrations in the pre-intervention period and 422 patients with 1059 medication administrations in the post-intervention period. The overall error rate fell from 146 to 123 per 100 medication administrations ($p < 0.0001$), and the medication error rate also decreased from 39 to 29 per 100 medication administrations ($p = 0.001$). However, there was no significant change in the potentially harmful error rate (from 0.5 to 0.8 per 100 medication administrations, $p = 0.37$). An intervention component aiming to reduce labeling-not-completed errors was effective in reducing targeted error rates, but other components of the intervention bundle did not show significant improvement in the targeted errors.

Conclusion Development and implementation of the intervention bundle was successful at reducing overall and medication error rates, but some errors remained and the

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potentially harmful error rate did not change. The error-rate reductions were not always correlated with the specific individual interventions. Further investigation is needed to identify the best strategies to reduce the remaining errors. *Clinical Trials Registration* Registered at ClinicalTrials.gov, identifier: NCT02359734.

Key Points

An infusion safety intervention bundle was developed and implemented in multiple hospitals.

The infusion safety intervention bundle was effective in reducing overall and medication errors; however, the potentially harmful error rate did not change, and the effects of some interventions remain unknown.

The experience of implementing the infusion safety bundle provided additional evidence of the importance of multiple strategies to improve medication administration practices and some challenges of implementing effective quality improvement activities in multiple hospitals.

1 Introduction

The medication administration process is complex and includes multiple steps to deliver the right medication at the right time to the right patient [1, 2]. The intravenous (IV) medication administration process is especially complicated, and many medications associated with a high risk for errors are delivered via IV infusions [3–5]. Multiple reports in the literature have identified continued high frequency and degree of patient harm associated with IV medication administration relative to other administration routes [6–8]. Smart infusion pumps (smart pumps) have been implemented to support the safe administration process of these IV medications [9–11]. Smart pumps incorporate software programs known as dose-error reduction systems and drug libraries that allow administrative users to define limits to keep infusions within precise values for specific patient populations and per institutional policies [12].

Although smart pumps are used widely, these devices do not typically achieve their full safety potential; IV medication administration errors persist [13–15]. Husch et al. [16] conducted a prevalence study to investigate IV medication errors in a hospital and evaluated the preventability of identified errors with the use of smart pumps. They identified major safety issues in patients receiving IV medications administered with infusion pumps, including infusions without orders, wrong infusion rates, and other types of IV medication errors. We subsequently conducted a large multi-hospital observational study using similar methodology to identify the key issues related to IV medication administration with smart pumps across ten hospitals in the United States [17]. We found a high rate of error in the administration of IV medications despite the use of smart pumps, though only a small proportion of errors had a high potential for harm. Infusion rate errors were the leading type of errors with high potential for harm, followed by unauthorized medications (defined as IV fluids or medications that are administered to the patient without an active order present in the medical record) and omission or delay of administering IV medications.

After completing the first phase of the study [17], an infusion safety intervention bundle was developed with national patient safety leaders—working in conjunction with the Association for the Advancement of Medical Instrumentation (AAMI), the National Patient Safety Foundation (NPSF), and the Joint Commission, that administers voluntary accreditation programs for hospitals and other healthcare organizations in the United States—to eliminate medication administration errors using smart pumps. The infusion safety intervention bundle was focused on eliminating common and potentially harmful medication errors, which were detected in a previous observational study to identify the effects of smart pumps on medication safety [17]. The bundle was implemented in the participating hospitals from the observational study during a 1-year intervention phase. These interventions were implemented as a quality improvement activity in the participating hospitals and were intended to improve the clinical practice as a collaborative effort in multiple hospitals.

To measure the preliminary effects of the intervention bundle and identify additional issues with IV medication administration using smart pumps, a second data collection was conducted after the 1-year intervention period. In this paper, we report the development of the infusion safety intervention bundle and the comparison of IV medication error rates between pre- and post-implementation of the bundle. In addition, we share our experience and lessons learned from implementing interventions and propose some potential strategies for addressing the remaining issues with IV medication administration errors.

2 Methods

2.1 Measurement of IV Medication Errors

The multi-hospital infusion therapy safety study was conducted over 3 years. In phase 1, we collected data in the

pre-intervention period (February to August 2013). This was followed by intervention development (August to September, 2013) and then an implementation period (October 2013 to September 2014). We then performed phase 2, which included the post-intervention data collection period (October to December 2014). Results of the pre-intervention observation phase were previously published [17].

Participating hospitals were originally recruited at the AAMI Foundation's Healthcare Technology Safety Council meeting in 2012 [17], where interdisciplinary patient safety experts gathered. Our study originally began with ten hospitals; however, one institution could not complete phase 2. Hence it was excluded from the analysis. Nine hospitals in total participated in the United States (see Electronic Supplementary Material 1). At each site, four different inpatient areas—adult medical/surgical units and medical/surgical intensive care units (ICUs)—were selected as study units. Observers (registered nurses and pharmacists) were trained on the data collection protocol by the study investigators. A test data collection pilot was conducted at each institution. Inter-rater reliability testing was performed to ensure the reliability of the observed data (kappa >0.80). Two trained observers collected data using an electronic data collection tool [18] during day shifts for 2–4 days in both data collection periods. The observers and the study units were the same for both pre- and post-intervention observations.

We conducted a before–after study with a prospective point-prevalence approach to investigate errors associated with IV medications administered via smart pumps. Operational definitions of errors for data collection are shown in Electronic Supplementary Material 2. Evaluation of potential for harm was assessed using the National Coordinating Council for Medication Error Reporting Prevention (NCC MERP) index [19] (Electronic Supplementary Material 3).

We approached a nursing director to get permission to conduct observations, and none of the staff nurses were notified until the observer asked the nurse if it was okay to go into a patient's room to view the smart pumps as part of a research study. We had a 12-month intervention period, and education around the practices that were implemented in the first few months of the intervention period continued every month until the post-intervention data collection was conducted. Awareness of the bundle associated with a practice change was part of the intervention, and we believe the Hawthorne effect was at a minimum at the time of the second data collection. Patients were included in the study if they received any IV fluid or medication at the time of observation. Smart pumps for administering general, large and small volume infusions, syringes, and patient-controlled analgesia were included in the investigation. As per our study protocol, we observed IV medications that had been administered (or IV fluids or medications that were running at the time of the observation) and did not observe the administration processes. If a nurse was about to administer IV medications, the observers went into the next room and re-visited the room after the nurse had left the room to minimize the observers' effects. Observers compared the infusing medication, dose, and infusion rate on the pump with the prescribed medication, dose, and rate as ordered in the medical record. Use of a smart pump and the drug library were also assessed. Compliance with placement of IV tubing change tags on IV tubing and hospital labels on IV medications was also assessed. IV labeling and tubing tag non-compliance errors were categorized as violation of hospital policy errors. If an error that had the potential to cause harm was identified during observation, the nurse caring for that patient was discreetly informed so that it could be immediately corrected.

2.2 Outcome Measures

We evaluated two main outcomes and one secondary outcome. The primary outcomes were overall errors, and medication errors. Overall errors were any observed errors in the study. The overall errors were divided into two categories: violation of hospital policy errors and other errors. Among other errors, any errors reaching the patient—those with an NCC MERP severity rating [19] of C or greater—were defined as medication errors. Under our study's operational definition, a violation of hospital policy includes label not completed according to policy and IV tubing not tagged according to policy. A pump setting error is a medication error because the infusion was running with an incorrect setting, which is highly risky. The error of bypassing the use of the smart pump or drug library was, in part, violation of policy; however, these errors were categorized as medication errors because of the high potential risk of harm of these types of errors.

A secondary outcome was potentially harmful errors, which are medication errors with potential for harm categorized as having an NCC MERP severity rating of D or greater. This third category was a secondary outcome because we expected to have limited power to assess whether its frequency changed.

2.3 Intervention

2.3.1 Infusion Safety Intervention Bundle Development

After completion of the initial phase 1 study [17], the identified errors were analyzed to develop an infusion safety intervention bundle to be implemented during a

1-year intervention period. The bundle was developed incorporating the expertise of multidisciplinary research team members representing each participating institution. A conference meeting with all participating site coordinators and other stakeholders from AAMI, NPSF, and the Joint Commission was held to report out and review the phase 1 data collection results. Three sub-groups were formed to evaluate possible causes for each error and to discuss safety improvement strategies for eliminating them. Through a series of discussions, an infusion safety intervention bundle was developed and vetted to obtain consensus from the entire study team. The final infusion safety intervention bundle was deemed by the Joint Commission to be compliant with its IV labeling recommendation as outlined in their national patient safety goals [20].

Each institution attempted to implement all feasible components of the intervention bundle unless they were already in place in phase 1. Post-intervention data collection (phase 2) was conducted at the completion of the year to evaluate the effects of the intervention bundle.

2.3.2 *Infusion Safety Intervention Bundle for Improving IV Medication Administration Practice*

The infusion safety intervention bundle is comprised of three different infusion safety categories, with subsets in each (Table 1). These categories were selected based on the pre-intervention data collection results. The first category of the bundle was intended to improve the compliance of applying IV labels and IV tubing change tags. A standardized labeling toolkit compliant with Joint Commission standards was developed (Electronic Supplementary Material 4). According to the 2014 Joint Commission National Patient Safety Goals (NPSG.03.04.01 and MM.05.01.09) [20], medication name, concentration, amount, diluents, date prepared, and expiration date and time (if expiring within 24 h) are required for medications prepared in the patient ward. Only the expiration date and time are required for IV solutions removed from a medication cabinet.

The second category of the bundle was intended to eliminate the administration of unauthorized medications, and the third category of the bundle was intended to prevent wrong-rate errors and smart pump use errors. Site coordinators at each institution shared the phase 1 results and the proposed intervention plans with their institutional stakeholders and evaluated which intervention would be feasible to implement in the 1-year intervention period.

2.4 Data Analysis

We measured the frequency of errors, broken down by types of errors and their NCC MERP severity rating. Error rate per 100 IV medication administrations was calculated as the number of identified errors per the number of observed IV medication administrations. We compared the error rates in phase 1 and phase 2 using a Poisson regression, with a dichotomous covariate for time (phase 1 vs phase 2) and used a fixed effect for sites and an over-dispersion parameter for possible clustering by unit within site [21]. Based on the previous study of medication errors [16], we expected the medication error rate in the pre-intervention period to be 28 errors per 100 medication administrations, and we powered the study to detect a 20% decrease in the post-intervention period to 22.4 errors per 100 medication administrations. Using a Poisson regression with a fixed site effect and an over-dispersion parameter to account for clustering by unit within each site, we estimated that a total sample size of 1800 medication administrations (900 in pre-intervention and 900 in post-intervention) would provide 80% power to detect this decrease, at a two-sided significance level of 5%. The effects of each intervention were analyzed with the site data only from where the intervention was implemented.

3 Results

3.1 Feasibility of Implementing an Infusion Safety Intervention Bundle

Over the 1-year intervention phase, the infusion safety intervention bundle was implemented at each institution (Table 2). Although all hospitals attempted to implement all components of the intervention bundle, only some of the components were successfully implemented during the intervention period because of limited resources at the hospitals or time constraints associated with the 1-year intervention phase. A compliance of label-related interventions (A-1, A-2) was measured to see if label changes were physically occurring or not in the intervention units. Some hospitals changed medical supply vendors to purchase a new label that was already in compliance with the standardized label, while others customized the existing labels to comply with the standardized label. Education for these label changes was provided by the nursing directors and educators. Compliance with interventions involving hospital policy changes (B-1, B-3) was measured as actual changes that happened in the written hospital policy or nursing practice manuals in the institutions. These changes were disseminated through nursing practice committee meetings or by nursing directors and educators in the intervention units.

Implementation of the "keep the vein open" (KVO) practice-related intervention (B-2) was measured whether the system changes occurred in the electronic health

Table 1 Infusion safety intervention bundle

A. Labeling/IV tubing intervention
A-1: Implement standardized labeling toolkit
Implement Joint Commission compliant standardized labeling toolkit[a]
A-2: Implement standardized IV tubing change labels
Implement standardized IV tubing change labels[b]
B. Unauthorized medication intervention
B-1: Implement standardized discontinuation policy
Implement standardized discontinuation policy statement related to discontinuation of medications within *x* minutes (individual site defined) of time the discontinuation order was written
Implement alert related to discontinued medications (time critical medications)
Caregiver sign off required when medications are discontinued (documentation)
B-2: Implement standardized KVO rates and KVO order sets
Implement standardized policy statement related to KVO rate
Implement standardized KVO order sets
Example for standardized KVO rates: Specified in order as follows: standard rate (central or peripheral line): 10 mL/h; patients with concern about fluid overload: 5 mL/h; PICC or mediport: 20 mL/h
B-3: Implement standardized verbal orders practice recommendation
Investigate frequency of verbal order at each site
Identify verbal order policy at each site
Implement standardized verbal order practice recommendation
B-4: Implement medication barcode scanning compliance rate report
Implement monthly scanning compliance rate improvement report with individualized (or unit-level) feedback
C. Drug library use intervention
C-1: Implement drug library use compliance report with individual feedback
Implement drug library use compliance monitoring (use of basic infusion mode, override data, per medication/solution data)—unit level, individual level
C-2: Implement standardized drug library list
Update drug library, minimize drug library list (e.g., collapse fluids list, use "IV fluids" for KVO solutions) or improve search functions

IV intravenous, *KVO* keep the vein open, *PICC* peripherally inserted central catheter

[a]Refer to Electronic Supplementary Material 4

[b]Refer to Electronic Supplementary Material 5

records or not. These changes usually occurred hospital-wide, and user training was provided at each institution.

For interventions pertaining to generating compliance reports (B-4, C-1), the relevant hospital department provided reports to nursing leaderships per unit level. By means of these monthly reports, monthly educational feedback to individual staff members was provided.

Implementing a standardized drug library list (C-2) involved changes to an existing drug library list. Some intervention sites did not have a comprehensive organizational drug library, but used other institutions' recommended drug library. Additionally, the site coordinator proposed the revision of the drug library to an infusion pump committee at each site. After the evaluation and obtaining a consensus from the committee, a new drug library list was implemented during the intervention period.

3.2 Overall Frequency and Types of Errors

We assessed a total of 418 patients in nine institutions with 972 medication administrations in phase 1 and 422 patients with 1059 medication administrations in phase 2 (Table 3). The overall error rate fell from 146 to 123 per 100 medication administrations in phase 2 ($p < 0.0001$), and the medication error rate decreased from 39 to 29 per 100 medication administrations during phase 2 ($p = 0.001$). The number of potentially harmful errors slightly increased from 0.5 to 0.8 per 100 medication administrations, but the difference in rate was not significant ($p = 0.37$). Overall, violations of IV medication labeling and IV tubing change policies were consistently the most frequent types of errors in both phases (Table 3). Other frequent error categories were also similar to phase 1's results. A breakdown of each

Table 2 Implemented intervention (bundle components) per site

	Site								
	A	B	C	D	E	F	G	H	I
A: Labeling/IV tubing intervention									
A-1: Implement standardized labeling toolkit	√	▼	▼	√	▼	√	√	▼	√
A-2: Implement standardized IV tubing change labels	▼		√	√	▼	√	▼	√	√
B: Unauthorized medication intervention									
B-1: Implement standardized discontinuation policy		√				√	√		
B-2: Implement standardized KVO rates and KVO order sets		▼	▼	√	√	√		√	
B-3: Implement standardized verbal orders practice recommendation	▼	▼	▼	▼	▼	▼	▼	√	▼
B-4: Implement medication barcode scanning compliance rate report	▼	▼		▼	▼	▼	√	▼	▼
C: Drug library use intervention									
C-1: Implement drug library use compliance report with individual feedback	▼	√		▼		√	√	√	√
C-2: Implement standardized drug library list	√	▼	▼	▼	▼		▼	▼	▼

IV intravenous, *KVO* keep the vein open, √ implemented during the intervention phase, ▼ already exist/implemented before phase 1, *blank cell* attempted to implement but could not be implemented during the intervention phase

Table 3 Error frequency and potential harm severity rating in phase 1 and phase 2

	Phase1		Phase 2			Potential harm (phase 1|phase 2) using NCC MERP index[c]									
	N	Rate[a]	*N*	Rate[a]	*p* value	E		D		C		B		A	
Number of patients	418		422												
Observed IV fluids/medications	972		1059												
Label not completed according to policy[b]	596	61.3	594	56.1						506	466	8	29	82	99
IV tubing not tagged according to policy[b]	362	37.2	322	30.4						330	284	1	9	31	29
Unauthorized medication	180	18.5	167	15.8					2	129	111	1	3	50	51
Smart pump/drug library not used	114	11.7	121	11.4						109	109	4	2	4	10
Wrong rate	50	5.1	23	2.2				2	3	45	19			3	1
Omission of IV fluids/medications	50	5.1	25	2.4				1	1	29	22		2	20	
Expired drug	23	2.4	19	1.8				1		19	11	1	5	2	3
Wrong dose	22	2.3	9	0.8			1			19	8	1		2	
Delay	14	1.4	9	0.8		1			1	13	8				
Pump setting error	5	0.5	6	0.6						5	5				1
Wrong IV fluids/medications	3	0.3	5	0.5						3	5				
Wrong concentration	3	0.3	1	0.1			1			3					
All errors	1422	146.3	1301	122.9	<0.0001	1	2	4	7	1190	1048	16	50	194	194
Medication errors	376	38.7	307	29.0	0.001	1	2	4	7	354	298				
Potentially harmful errors	5	0.5	9	0.8	0.370	1	2	4	7						

IV intravenous, *NCC MERP* National Coordinating Council for Medication Error Reporting Prevention

[a]Rate = number of errors/total number of medication administrations observed. Rates are greater than 100 because some infusions had more than one error

[b]Policy violation

[c]Refer to Electronic Supplementary Material 3

institution's error rates is shown in Electronic Supplementary Material 6.

3.3 Error Rates per Intervention

Table 4 shows the outcome rates for institutions that implemented individual components of the intervention bundle. In institutions that implemented the standardized labeling intervention ($n = 5$), the labeling-not-completed error rate decreased from 72 to 63 per 100 medication administrations, and this decrease was statistically significant ($p = 0.01$). Except for one site, all intervention sites' error rates decreased. Among four non-intervention sites, one site's labeling-not-completed error rate decreased without the intervention, but the other sites' rates increased (Electronic Supplementary Material 6).

The IV-tubing-not-tagged error rate went down from 44 to 40 per 100 medication administrations after

Table 4 Number of errors and error rates per intervention component at the site where each component implemented

	Phase 1		Phase 2		
	N	Rate	*N*	Rate	*p* value
A-1: Implement standardized labeling toolkit					
Label not completed according to policy (all intervention sites)	382	72.3	354	62.6	↓ **0.01**
Site A	34	56.7	46	69.7	↑
Site D	11	22.9	12	20.3	↓
Site F	113	94.2	107	87.0	↓
Site G	198	91.7	182	85.0	↓
Site I	26	26.3	7	8.0	↓
A-2: Implement standardized IV tubing change labels					
IV tubing not tagged according to policy (all intervention sites)	214	43.7	209	39.7	↓ 0.23
Site C	49	35.5	33	26.2	↓
Site D	17	35.4	8	13.6	↓
Site F	110	91.7	121	98.4	↑
Site H	15	15.8	13	10.7	↓
Site I	23	23.2	34	39.1	↑
B: Unauthorized medication intervention					
Unauthorized medication errors (all intervention sites)	148	19.5	107	15.8	↓ 0.07
Site B	5	5.7	11	10.4	↑
Site D	11	22.9	1	1.7	↓
Site E	5	4.6	9	5.7	↑
Site F	17	14.2	14	11.4	↓
Site G	96	44.4	62	29.0	↓
Site H	14	14.7	10	8.3	↓
C: Drug library use intervention					
Wrong rate (all intervention sites)	34	3.7	17	2.4	↓ 0.10
Site A	5	8.3	3	4.5	↓
Site B	10	11.4	3	2.8	↓
Site F	6	5	5	4.1	↓
Site G	1	0.5	1	0.5	
Site H	4	4.2	3	2.5	↓
Site I	8	8.1	2	2.3	↓
Smart pump/drug library not used (all intervention sites)	104	11.3	107	13.4	↓ 0.07
Site A	2	3.3	16	24.2	↑
Site B	33	37.5	25	23.6	↓
Site F	31	25.8	33	26.8	↑
Site G	21	9.7	15	7.0	↓
Site H	4	4.2	8	6.6	↑
Site I	13	13.1	10	11.5	↓

Statistically significant *p* values are in bold ($p < 0.05$)

IV intravenous, ↑ rate increased in phase 2, ↓ rate decreased in phase 2

implementing standardized IV tubing change labels; however, this change was not statistically significant ($p = 0.23$). Out of five intervention sites, three sites observed a decrease in tubing-not-tagged errors, but the other two sites observed an increase.

Among all institutions that implemented unauthorized medication interventions ($n = 6$), there was a reduction in unauthorized medication error rates from 20 to 16 per 100 medication administrations, but this was not statistically significant ($p = 0.07$, Table 4). Out of six intervention sites, four sites observed improvement in unauthorized medication error rates, but the other two sites showed an increase in errors regardless of implementing the intervention.

In all sites that implemented the drug library use intervention ($n = 6$), the wrong-rate error rate decreased from 4 to 2 per 100 medication administrations ($p = 0.10$). Except for one intervention site that did not change the error rate, the wrong-rate error rate decreased in all intervention sites. There was no improvement in smart pumps and drug library use errors at intervention sites that implemented the drug library intervention, and the error rates slightly increased.

By investigating individual site-level data, three intervention sites showed reduction in smart pump use errors, but the other three sites did not show any reductions. Smart pump use and drug library compliance rates are shown in Table 5. Although most of the study sites had an almost 100% compliance rate of using a smart pump itself, drug library use compliance rates varied at each institution from 62.5 to 100%. Among six intervention sites, drug library use compliance rates improved in three intervention sites, but one site had a significant decrease in the compliance rate, from 97 to 76%.

4 Discussion

Although we found significant reductions in the rates of errors overall and of medication errors, high rates of these errors persisted in phase 2 and the rate of potentially harmful errors did not change. In addition, the error rate reductions were not always correlated with the specific individual interventions.

Phase 1 of this study found a higher rate of errors, but even in phase 2, many errors persisted and the rates of some types of errors with the potential to cause harm increased, but not significantly. Further investigation will be needed to identify the reasons for these results, but the number of errors with severe harm was small. As per site-level results, six sites demonstrated some improvement in overall and medication error rates. Only four sites showed reductions in medication error rates, and other sites did not show any significant reductions. Site-level evaluation will be required to identify the effects of individual intervention components in order to reduce certain types of errors at each site.

Hospital policy violation errors and the administration of KVO solutions without any orders dominated and were the two most frequently observed types of errors. Following these types of errors, the failure to use smart pump or drug libraries to administer IV fluids and medications happened frequently. In some hospitals, caregivers can access IV solution bags without medication orders and administer them to the patients as KVO solutions. This practice is used in many hospitals as a standard nursing practice, although some hospitals have stricter guidance for use of KVO fluids.

4.1 Effects of the Infusion Safety Bundle

The infusion safety intervention bundle was effective in reducing both overall and medication error rates. However individual bundle components did not show a significant reduction in the targeted errors, except one intervention bundle component.

The labeling intervention significantly affected the rate of the targeted labeling-not-completed errors; however, one intervention site observed an increase of the labeling-not-completed error rate in phase 2. The site coordinator noted that this increase could have been due to transitioning from the old labels to the new labels, which were new to the staff nurses. It may require more time and continuous staff training to be fully compliant with a new labeling policy. In contrast, another site observed a decrease in the labeling-not-completed error rate without any intervention. There were no proactive interventions specific to labeling

Table 5 Compliance rate of smart pump use and drug library use at each site

	Site A	Site B	Site C	Site D	Site E	Site F	Site G	Site H	Site I
Smart pump use compliance rate (%)									
Phase 1	100	100	100	100	98.1	99.2	94.9	100	100
Phase 2	100	100	100	100	98.7	99.2	95.3	100	100
Drug library use compliance rate (%)									
Phase 1	96.7	62.5	100	100	92.5	74.8	95.1	95.8	86.9
Phase 2	75.8	76.4	98.0	100	93.5	73.8	97.5	93.4	88.5

compliance at this site. However, presenting phase 1 results during the intervention period made the nursing staff aware of the required information on the IV labels and resulted in full compliance with the existing labeling policy. The IV tubing intervention did not significantly affect the rate of the targeted IV-tubing-not-tagged errors, but there were some reductions at most of the intervention sites.

The unauthorized medication intervention reduced targeted errors, but the reduction was not statistically significant. With this intervention, we could not achieve improvement at all of the sites. Because the unauthorized medication intervention includes four different interventions to address different causes of unauthorized medication errors, it may depend on correlations between individual bundle components and the cause of unauthorized errors. Further site-level analysis may be required to identify the best strategies to reduce identified errors with one intervention component.

The drug library use intervention was aimed at improving wrong-rate error rates and drug library use compliance. Most of the sites showed a reduction, but it was not statistically significant. Wrong-rate error rates were not high in phase 1; therefore, it may be difficult to show a significant reduction. Further data collection may be required to show the effect of the drug library use intervention. In terms of compliance rates of using the smart pump and drug library, results were not significant and smart pumps and drug library use error rates at the intervention sites slightly increased. The reduction of the drug library use compliance rate in one intervention site may be explained by the implementation of the new drug library. The clinical staff may have missed selecting a certain entry in the new drug library, which led to a lower compliance rate.

Considering other influencing factors on our results, we did not identify any infusion safety activities during the intervention period. One of the study sites implemented a new computerized provider order entry (CPOE) system during the intervention period; however, the medication error reduction was not significant (from 54 to 51 per 100 medication administrations). This site implemented a new KVO order set as a study intervention, which was a part of the new CPOE system, but the CPOE system itself did not seem to affect the results.

Another factor to consider for the observational study is the Hawthorne effect. Our study protocol was designed to minimize the Hawthorne effect, not to observe nurses directly. We approached a nursing director to get permission to do the observations, and none of the staff nurses were notified until the observer asked the nurse if it was ok to go into a patient's room to view the smart pumps as part of a research study. We had a 12-month intervention period, and education around the practices that were implemented in the first few months of the intervention period continued every month until the post-intervention data collection was conducted. Awareness of the bundle associated with a practice change was part of the intervention, and we believe the Hawthorne effect was at a minimum at the time of the second data collection.

To demonstrate the substantial impact of the intervention on the targeted error reduction, we will need to conduct a long-term, large-scale, randomized control trial to clarify the individual interventions' effects. Additionally, it may be ideal to focus on implementing fewer interventions at all sites to eliminate targeted errors.

Overall, reasonable success was achieved in some sites because of leadership buy-into changing hospital practices. This emphasized that involvement and support from stakeholders and hospital leadership is key to any practice change in the hospital setting. Staff education was also an important element to improve practice in institutions, but is not effective when used alone to change behavior and achieve a goal. External guidelines helped institutions change practice as the infusion safety bundle was recognized by patient safety-related organizations.

4.2 Three Major Categories for Infusion Safety Intervention Bundle

The most frequent types of errors were violations of hospital policy and may not have been directly related to IV administration errors with smart pumps. Analysis of the observed errors from the phase 1 data collection showed that the large number of policy violations was caused mainly by either unnecessary or inefficient steps in the processes of IV medication administration. To streamline the processes of IV medication administration and to be compliant with national patient safety goals [20], the study team agreed to include labeling and IV tubing tag compliance as one of the infusion safety intervention bundle components. Another frequent type of error in phase 1 was the administration of unauthorized medication. This type of error could result in serious untoward patient outcomes; hence, this category was included as a component of the intervention bundle. A third category of high frequency errors was drug library compliance errors and wrong-rate errors. These errors are noteworthy because they could be directly related to use of the smart pumps. According to a previous study [16], wrong-rate errors can be intercepted by smart pumps without interoperability with either electronic health record or electronic medication administration record (eMAR). In other words, if the drug library compliance rate is improved, then wrong-rate errors would be expected to decrease. In phase 2, there was no significant improvement in compliance with the use of the drug library across intervention sites, but the use of the drug library did improve in most of the intervention sites.

When the study team developed the intervention bundle, use of a smart pump log as an analytic tool was considered. The effects of using smart pump data logs for improving infusion safety are supported by previous studies [21]; however, some smart pumps did not have wireless network connections to gather the pump log data wirelessly at the time of the study. This tool could be a possible strategy of an effective intervention if all of the smart pumps can send smart pump data logs via a wireless network.

4.3 Evaluation of Implementing the Infusion Safety Bundle

After completing the phase 2 data collection, the experience from implementing the intervention bundle was shared among all study members during an in-person conference.

For example, in order to successfully implement the labeling toolkit, consensus from all stakeholders was required. Some sites required their IV label suppliers to make changes, and one hospital switched to another label supplier to conform to the recommended IV medication and IV tubing change labels. Another barrier related to IV labels was the compatibility with existing medicine cabinet systems. One hospital worked directly with a medical cabinet vendor to see if they could auto print the recommended labels. Implementing standardized IV tubing change labels was also a challenge. Some hospitals could not use colored labels because they had other color-coded labels in place for certain medications or IV lines. Other study members brought up the issue that a problem could occur if caregivers are color-blind. Considering these color issues, the intervention plan was modified to remove color-coded IV tubing labels and the recommendation was to use white labels.

When the study was conducted, there were no standardized practice recommendations or literature available regarding appropriate time intervals for discontinuation of IV fluids/medications after an order to do so was given. Each hospital discussed and made recommendations to their key stakeholders on the need to establish a discontinuation time in an effort to improve patient safety. One study site used a time interval of 30 min for the caregiver to have discontinued a fluid/medication; other study sites used 4 h to stop the infusion and to remove IV bags from the smart pumps. Another important issue was the need to identify a standardized KVO rate because there were no clear standardized KVO rates available either in the literature or in practice guidelines. Our solution was to compare recommended KVO order rates throughout all study hospitals and to make general recommendations. Some hospitals had already implemented KVO order sets in their CPOE systems and were used as a model to develop a recommendation for the study. Implementation of a proposed KVO order set in CPOE systems was hard to achieve since this involved changes to the CPEO system, which tend to take longer to implement than the 1-year study period.

Implementing standardized recommendations for verbal orders was another challenge in the study hospitals. Although most study hospitals did have their own verbal order practice policies to limit administering medications without written physician orders, these policies varied greatly among institutions. The study team reviewed verbal order policies from each institution and established a general recommendation to limit verbal orders except in certain areas of practice or in emergency situations. However, this recommendation was not widely used by study sites since most had a verbal order policy in place.

Standardizing drug libraries was also challenging across study sites because of differences in care settings, hospital practice, or available medications in each hospital. Some hospitals preferred to minimize the drug library list to make them simple, whereas others preferred to use a comprehensive list. The achievement of a balance between efficiency and safety in use of the drug library was an unresolved discussion point; standardization of the drug library across different institutions was a challenge and not achieved.

4.4 Smart Pumps and Other Medication Safety Technologies

While this 3-year study was limited in scope to medications administered via smart pumps, the errors identified highlight areas for improvement in the comprehensive IV medication administration process, rather than smart pump technology per se. Indeed, all sites included in this study utilized smart pumps as well as other technologies such as CPOE, eMAR and barcode medication administration (BCMA), all of which are intended to improve IV medication safety. This study underscores that these technologies, including smart pumps, are only some of the important tools needed to improve the process of administering IV medications. In a previous study, the implementation of the smart pump did not show a reduction in medication errors [22]. A multifaceted approach is evident in our infusion safety intervention bundle. While interventions were designed to improve IV medication error rates for those medications administered via smart pumps, the interventions also focused on the use of adjacent technologies, such as improving the barcode scanning compliance rate on BCMA, implementing order sets changes in CPOE systems, and documenting discontinuation time on the eMAR. Because the phase 1 study revealed a majority of label-related errors, a significant portion of

the bundle focused on the adjacent process of labeling practices. In addition, the intervention bundle did include some recommendations for how the panel felt smart pump use could be improved, via drug library or reporting modifications, to further support the IV medication administration process. The study results highlight the importance of understanding and optimizing all components of the IV medication administration process, to maximize the benefit of using smart pumps and ultimately improve IV medication safety.

4.5 Limitations

The study was conducted as a multi-hospital study and the hospitals sampled were not completely representative of all hospitals in the USA, although the study did include hospitals from different regions, of different sizes, and using different smart pump vendors. We acknowledge that our study used a before–after design with a point-prevalence observational approach and that it is a weak study design. Because we had limited resources and timelines, we added ten hospitals to investigate error trends so that we could develop interventions to eliminate medication errors rapidly. We did not have a control group, but pre-intervention data acted as our control. A larger scale, randomized control trial with multiple sites is needed to show more robust results, as noted in the UK [23]. Our study was conducted as a point-prevalence study and, thus, included a limited number of observations, and a greater number of observations may be needed to demonstrate a substantial impact of the intervention at each site level. Additionally, data collection was conducted in different seasons; therefore, there might be a seasonal effect on our results that was not controlled for in the analysis. Moreover, we could not control site-specific factors either, such as other ongoing safety and quality improvement activities, or clinical system or hospital practice changes, though a new clinical system itself did not affect the study results.

The study was focused on getting a snapshot of current practice and accomplishing rapid development of a quality improvement strategy to improve the practice within a short period of time. We believe that this project is an example of real-world rapid implementation science. Another major factor influencing the study results was that not all institutions could implement all of the components of the implementation bundle because some already had pieces of the bundle active in the pre-intervention time period or could not finish implementing the bundle during the relatively brief intervention period. The intervention period was 1 year; indeed, certain interventions were not feasible within this time frame because of limited resources or constraints of the organization's systems, even though all hospitals attempted to implement the components in their entirety. Lastly, we did not measure the compliance of using each bundle after their implementation; however, we evaluated the implementation of each bundle.

We hope that one next direction for improving safety in this area will be evaluating further the impact of the developed intervention bundle and its refinements to be a more effective intervention bundle at multiple sites.

5 Conclusions

In this multi-hospital, point-prevalence study, we developed an infusion safety intervention bundle, parts of which were implemented in all study institutions. We found a significant improvement in the overall error rate and medication error rate, but many errors persisted. Additionally, individual bundle components did not show significant improvement in targeted errors except the standardized labeling intervention. The experience of implementing the infusion safety bundle provided additional evidence of the importance of multiple strategies to improve medication administration practices and some challenges of implementing effective quality improvement activities in multiple hospitals. Further investigation is needed to identify the best strategies for reducing errors with multiple interventions to reduce remaining errors.

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Compliance with Ethical Standards

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Ethical approval This study was approved by all study sites' institutional review boards. All of the data collected were de-identified in the electronic data collection tool, which did not include any protected health information.

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Brigham and Women's Hospital on the use of decision support software for medical management, licensed to the Medicalis Corporation. He holds a minority equity position in the privately held company Medicalis, which develops web-based decision support for radiology test ordering. He serves on the board for SEA Medical Systems, which makes intravenous pump technology. He consults for EarlySense, which makes patient safety monitoring systems. He receives equity and cash compensation from QPID, Inc., a company focused on intelligence systems for electronic health records. He receives cash compensation from CDI (Negev), Ltd, which is a not-for-profit incubator for health IT startups. He receives equity from Enelgy, which makes software to support evidence-based clinical decisions. He receives equity from ValeraHealth, which makes software to help patients with chronic diseases. He receives equity from Intensix, which makes software to support clinical decision-making in intensive care. He receives equity from MDClone, which takes clinical data and produces de-identified versions of it. His financial interests have been reviewed by Brigham and Women's Hospital and Partners HealthCare in accordance with their institutional policies.

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