Direct Observational Study of Interfaced Smart-Pumps in Pediatric Intensive Care

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Abstract

Background Processes for delivery of high-risk infusions in pediatric intensive care units (PICUs) are complex. Standard concentration infusions (SCIs), smart-pumps, and electronic prescribing are recommended medication error reduction strategies. Implementation rates in Europe lag behind those in the United States. Since 2012, the PICU of an Irish tertiary pediatric hospital has been using a smart-pump SCI library, interfaced with electronic infusion orders (Philips ICCA). The incidence of infusion errors is unknown.

Objectives To determine the frequency, severity, and distribution of smart-pump infusion errors in PICUs.

Methods Programmed infusions were directly observed at the bedside. Parameters were compared against medication orders and autodocumented infusion data. Identified deviations were categorized as medication errors or discrepancies. Error rates (%) were calculated as infusions with errors and errors per opportunities for error (OEs). Predefined definitions, multidisciplinary consensus and grading processes were employed.

Results A total of 1,023 infusions for 175 patients were directly observed over 27 days between February and September 2017. The drug library accommodated 96.5% of infusions. Compliance with the drug library was 98.9%. A total of 133 infusions had $\geq$1 error (13.0%); a further 58 (5.7%) had $\geq$1 discrepancy. From a total of 4,997 OEs, 153 errors (3.1%) and 107 discrepancies (2.1%) were observed. Undocumented bolus doses were most commonly identified ($n = 81$); this was the only deviation in 36.1% ($n = 69$) of infusions. Programming errors were rare (0.32% OE). Errors were minor, with just one requiring minimal intervention to prevent harm.

Conclusion The error rates identified are low compared with similar studies, highlighting the benefits of smart-pumps and autodocumented infusion data in PICUs. A range of quality improvement opportunities has been identified.

Keywords
- critical care
- pediatrics
- error reduction
- smart-pumps
- information system
- documentation

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Background and Significance

Medication errors (MEs) at the point of administration are common, difficult to detect, and pose particular risks.[1,2] Risks are heightened in the pediatric intensive care unit (PICU) where patients, with weights ranging from 0.5 to 100 kg, commonly require multiple concurrent infusions of high-risk medications.[3–5] Error reduction strategies include the use of infusion pumps with dose-error reduction software or "smart-pumps," ideally in conjunction with other health information technology (HIT) systems such as electronic health records (EHRs).[6,7] The use of standard concentration infusions (SCIs), particularly in the pediatric setting, is widely advocated.[8,9] In the United States, 99% of hospitals have at least partially implemented an EHR, with over 80% using smart-pumps.[6,10] Implementation rates remain lower in European hospitals. Many Irish and United Kingdom hospitals are still reliant on paper systems, and approximately 80% of United Kingdom pediatric and neonatal intensive care units (ICUs) have yet to implement both SCIs and smart-pumps.[11–15] Interoperability between smart-pumps and EHRs remains uncommon even in the United States where only 15% of hospitals report having bidirectional interoperability.[6,16]

Research into the incidence of administration errors remains difficult.[2,17] Despite the increased visibility and access to data from HIT systems, comparison between studies is problematic. Impediments include differences in: settings, levels of HIT implementation, methodologies, and error definitions.[18] Two recent multisite studies conducted in the United Kingdom and the United States, employing similar methodologies and gold-standard direct observational methods, identified a wide variability in error rates and infusion practices.[13,19] Pediatric patients were, however, poorly represented (two of 16 United Kingdom sites, no United States site). No site reported pump–EHR interoperability, although a pump interface in one of the United Kingdom adult ICUs is subsequently described by Furniss et al.[16] In Lyons et al's study, only 11 of the 16 United Kingdom hospitals (69%) used smart-pumps, with low numbers (17.7%) of observed infusions ($n = 356$) administered via a drug library.[13] Neither study was specific to the critical care setting, with some differences in ME and discrepancy definitions hampering error rate comparisons. Previous research has highlighted the inappropriateness of extrapolating adult data to pediatrics.[20]

Despite clear benefits, HIT implementation has been associated with unintended consequences and the introduction of technology-generated errors (TGEs).[21,22] Many TGEs are system-specific, and with increasing use of locally customized commercial systems, site-, setting-, and system-specific studies are critical.[16,23]

Objectives

The primary objective was to determine the incidence, distribution, and severity of infusion-related MEs associated with interfaced smart-pumps in PICUs. A secondary objective was to identify contributory factors.

Methods

Setting

This study was conducted in a 23-bed PICU of an Irish tertiary pediatric hospital caring for patients of 0 to 16 years, with over 1,000 admissions annually. Nurse-to-patient ratios are determined on a daily basis by the acuity and needs of the patients. Ratios range from 2:1 for patients requiring advanced life support to 0.5:1 for the less critically ill.

In 2012, a smart-pump drug library of SCIs and electronic ordering using a commercially available clinical information management system (IntelliSpace Critical Care and Anesthesia —ICCA, Philips, United Kingdom) were implemented.[24] All medications are prescribed by doctors using a locally configured electronic drug file. Both "soft" limits, which trigger a color change, and "hard" limits, which prevent order completion, are set for all parameters, e.g., "dose per weight per time" concentration. Prepopulated "standard" orders—assigned to five patient categories—are available for most continuous, and a selection of intermittent, infusions. Only those standard orders applicable to the assigned patient category are available for selection. There are no links or prompts to users regarding documented allergies, drug interactions, duplicate orders, or drug levels. Data are, however, automatically populated into the patient's record from the laboratory information system.

Nurses are prompted to acknowledge all new orders on the electronic medication administration record. Using ward stock, medications are prepared and manually labeled for individual patients by nursing staff. Other than total parenteral nutrition (TPN), chemotherapy, and other hazardous medications, commercially or pharmacy preprepared solutions are not available. Exact intermittent doses are prepared, and postdose flushes administered at the corresponding rate; continuous infusions are generally prepared to a final volume of 50 mL. Where possible, infusion preparation is conducted at the beginning of the morning shift. Two nurses are involved in all stages of the process, from preparation to programming and documentation. Barcoded medication administration is not in use.

Infusions are administered via B. Braun Space pumps uploaded with a locally built pediatric drug library utilizing four weight bands (≤ 5, >5 to ≤ 10, >10 to ≤ 20, and >20 kg). At the time of this study, the drug library contained 61 drug lines, accommodated all commonly used continuous infusions and two high-risk intermittent medications. Within each weight band, a standard and a high-strength concentration, necessary to balance excessive infusion volumes with titratability at a lower dose range, is offered for most medications. Soft and hard limits, and where appropriate bolus dose parameters and clinical advisories, are set for all drug lines.

The nursing flowsheet is autodocumented with near "real-time" infusion pump data from networked docking stations. Autodocumentation requires nursing staff to "manually assign" each pump to the corresponding infusion (►Fig. 1). Documented hourly infusion volumes include the volumes of bolus doses administered from background infusions; however, individual bolus doses require manual documentation. Data transfer is unidirectional only (pump to ICCA) and pump autoprogramming is not available. Continuous quality

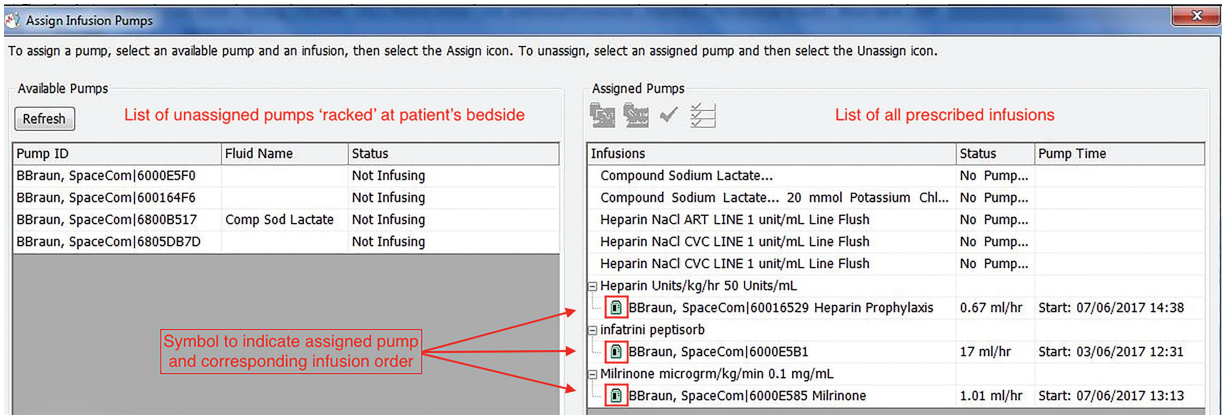

Fig. 1 Screenshot of manual assignment of infusion pump to corresponding electronic infusion order.

improvement (CQI) data software is not in place but data from individual pumps can be exported manually when required.

Study Design

Ethical approval was granted by the hospital's Research Ethics Committee. A pilot study informed data collection methods, including customized daily reports from ICCA and database development. A research pharmacist compared and recorded deviations from three data sources: daily reports of total active infusion ICCA orders (►**Fig. 2**); directly observed infusions at the bedspace; and manually extracted ICCA data. Daily report data were uploaded onto a hand-held device; no patient-identifiable data were recorded. Manually entered data included pump assignment details and nurse-recorded supplementary bolus doses. Manually and autodocumented data were examined for the period 00:00 hours to 2 hours after direct observation (daily range: 11–18 hours).

Data collection occurred in an unobtrusive, disguised manner previously shown to be valid.[25,26] Nurses were informed that data collection was primarily to identify issues with the smart-pump drug library and autodocumentation. Significant incidents or "near-misses" were immediately notified to clinical staff and also reported via the hospital's incident reporting system as per hospital policy. To determine system-level contributory factors, the numbers of patient admissions and prescribed infusions for each observation day were collected as measures of PICU activity.

Inclusion and Exclusion Criteria

Included infusions: continuous and intermittent infusions, either active or in "stand-by" mode (off but still connected to the patient), and administered via a B. Braun Space pump. This included medications, intravenous (IV) fluids, blood products, and TPN.

Excluded infusions: where observation was not appropriate due to clinical activity, or where administration occurred directly into a cannula or via a non-B. Braun Space pump, e.g., nurse-controlled analgesia, epidural and regional blocks.

Definitions

All deviations were categorized as either discrepancies or MEs. This categorization system mirrors that of the United Kingdom multisite study.[13] A ME was defined as "any deviation from the medication order as ordered on the patient's EHR," a commonly used definition slightly amended to make it applicable to electronic rather than paper orders.[1,27] Discrepancies included hospital policy violations and minor deviations with little potential to cause patient harm.

A defined list of ME scenarios based on previously published studies was prepared (see ►**Table 1**).[13,19,26,28–30] Where ambiguity existed, consensus was reached by round-table discussion with a five-person multidisciplinary panel.

With multiple opportunities for error (OEs), and more than one deviation per infusion possible, five OEs were assigned: programming, administration, documentation, pump assignment, and data transfer. Assigned infusions—enabling autodocumentation—and nonassigned infusions were deemed to have five and three OEs, respectively.

Wrong-time and dose-omission errors were excluded as most PICU infusions are prescribed in a range and titrated by nursing staff. Preparation errors (unless apparent from the

EID	Bedspace	Date	Time	Drug	Amount Added	Base Volume	Base Solution	Dose/Weight/Time	Pump Rate	Volume in Last Hour
5518	FL2 Bed 3	21/2/17	09:00	Morphine	5mg	50mL	Glucose 5% w/v	18 microgram/kg/hr	0.68mL/hr	0.7mL
5518	FL2 Bed 3	21/2/17	10:00	Morphine	5mg	50mL	Glucose 5% w/v	18 microgram/kg/hr	0.68mL/hr	0.7mL
5518	FL2 Bed 3	21/2/17	11:00	Morphine	5mg	50mL	Glucose 5% w/v	18 microgram/kg/hr	0.68mL/hr	3.7mL

Fig. 2 Volume differences between infusion rate and volume infused on ICCA infusion report.

Table 1 Scenarios included as medication errors (categorized by opportunity for error)

Programming	Administration	Documentation	Assignment	Data transfer
Incorrect drug line	Expired medication (>28 h since preparation)	Incompletely recorded	Not assigned though possible[a]	Incorrect data (human error)
Incorrect concentration programmed	Incorrect concentration administered	Manual volume entry incorrect	Incorrectly assigned (human error)	Incorrect data (technology error)
Incorrect IV fluid	Incorrect route	Manual entry (other) incorrect	Incorrectly assigned (technology error)	Incorrect data (combined)
Incorrect TPN phase	Incorrect diluent	≥1 undocumented bolus dose[b]	Incorrectly assigned (combined)	Incomplete/missing data (human error)
Incorrect weight	Without corresponding order	Other		Incomplete/missing data (technology error)
Incorrect rate	Y-site incompatibility			Incomplete/missing data (combined)
Incorrect bolus dose	Other			
Off library[c]				
Other				

Abbreviations: IV, intravenous; TPN, total parenteral nutrition.
[a]Determined to be discrepancies by the multidisciplinary panel.
[b]Multidisciplinary panel equivocal about inclusion as a medication error.
[c]Excluding IV fluids, TPN, or blood product which were considered discrepancies by the multidisciplinary panel as weight-based limits not accommodated by the drug library.

infusion label and pump settings) were also excluded. Labeling deviations were recorded but excluded from error rate calculations as: IV fluids and TPN bags are not routinely overlabeled; infusion labels in stand-by mode were not directly observed; and considerable heterogeneity on inclusion of labeling errors exists in the literature.[1,17,30]

Grading of Deviation Severity

Deviations were graded for severity using the "National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index for categorizing medication errors."[31] This consists of nine categories which can be summarized as: A—capacity to cause error; B—did not reach patient; C—reached patient/no harm; D—requiring monitoring/intervention to prevent harm; E—temporary harm/intervention; F—temporary harm/hospitalization; G—permanent harm; H—requiring intervention to sustain life; I—death. Discrepancies were categorized as NCC MERP A, with MEs categorized between B and I. As NCC MERP categorizes actual rather than potential harm, those MEs that failed to reach the patient (NCC MERP B) were further assessed for potential to cause harm by each member of the multidisciplinary panel using a validated 10-point severity grading.[1,32]

Sample Size

A pilot study conducted over 6 nonconsecutive days (August/September 2015) suggested that observation of 1,000 infusions would identify a suitable sample of infusions with at least moderately significant deviations. This sample size is in line with similar studies.[13,19,33]

Statistical Analysis

Standard descriptive statistics were used to describe included infusions, patients, and deviations. Univariate linear regression analyses were conducted using STATA (Stata 13.1) to measure associations between deviations and PICU activity. Significance for all comparisons was defined as $p < 0.05$.

Results

A total of 1,023 infusions were directly observed over 27 days between February and September 2017. A further 133 could not be observed due to time constraints ($n = 94$) or lack of access to pumps due to clinical activity ($n = 39$). The mean number of infusions observed per day was 37.9 (range: 19–59). Infusions for 175 individual patients were observed, 7.2% ($n = 13$) were observed during more than one admission. Most patients were under 1 year (74%); 32% under 1 month; and half (53%) were cardiac/cardiothoracic patients. The majority of infusions (84%) were actively infusing at the time of observation; 16% ($n = 160$) were in stand-by mode. It was determined that 4,997 OEs existed, with 94 and 6% of infusions having five or three OEs, respectively. The drug library accommodated 96.5% ($n = 987$) of infusions, 72.0% ($n = 737$) were SCIs, 12.2% ($n = 125$) IV fluids, and 9.8% ($n = 100$) TPN. Intermittent infusions were infrequently observed (3.5%, $n = 36$; see ►Table 2).

Frequency of Deviations

Discrepancies and MEs were identified in 5.7% ($n = 58$) and 13.0% ($n = 133$) of observed infusions, corresponding to a total deviation rate of 18.7% ($n = 191$). The failure to document one or more bolus doses administered from a background infusion

Table 2 Summary of infusions observed and drug library compliance

Infusion type	Observed (*n*, %)	Accommodated by library (*n*, %)	Drug library by-passed (*n*)	Compliance (*n*, %)
Continuous infusions	987 (96.5%)	965 (97.8%)	10	955 (99.0%)
Standard concentration infusion	737 (72.0%)	737 (100.0%)	0	737 (100.0%)
Intravenous fluid	125 (12.2%)	125 (100.0%)	6	119 (95.2%)
Total parenteral nutrition	100 (9.8%)	100 (100.0%)	4	96 (96.0%)
Flushes	14 (1.4%)	0 (0.0%)	n/a	n/a
ECLS	3 (0.3%)	3 (100.0%)	0	3 (100.0%)
CVVH	3 (0.3%)	0 (0.0%)	n/a	n/a
Other medication	5 (0.5%)	0 (0.0%)	n/a	n/a
Intermittent infusions	36 (3.5%)	18 (50.0%)	1	17 (97.2%)
Blood product	13 (1.3%)	10 (76.9%)	1	9 (92.3%)
Antibiotics	9 (0.9%)	0 (0.0%)	n/a	n/a
Intravenous fluid	6 (0.6%)	6 (100.0%)	0	6 (100.0%)
Potassium chloride[a]	2 (0.2%)	1 (50.0%)	0	1 (100.0%)
Paracetamol[a]	1 (0.1%)	1 (100.0%)	0	1 (100.0%)
Other medication	5 (0.5%)	0 (0.0%)	n/a	n/a
Total	1,023 (100.0%)	983 (96.1%)	11	972 (98.9%)

Abbreviations: CVVH, continuous venovenous hemofiltration; ECLS, Extracorporeal life support.
[a]One of two intermittent medications included in drug library at the time of study.

was the only deviation in 36.1% ($n = 69$) of these. This deviation was discovered during exploration of differences in infusion rates and hourly "volume-infused" data on infusion reports (►Fig. 2).

All but one of these involved either morphine or midazolam, with 36% ($n = 59$) and 33% ($n = 30$) of morphine and midazolam infusions respectively having at least one undocumented bolus error. The decision to retrospectively include this deviation as a ME by the multidisciplinary panel was equivocal. Exclusion of these as MEs decreases the total deviation rate to 11.9% and the ME rate to 5.4% (see ►Table 3).

A total of 260 deviations were observed. Deviation and ME rates per OE ($n = 4997$) were 5.2 and 3.1% respectively, reducing to 3.6 and 1.4%, where undocumented boluses ($n = 81$) are excluded.

Deviation Types

Documentation MEs were most common, occurring in 1.8% ($n = 91$) of total OEs and 8.9% of infusions observed, followed by administration (0.56% [$n = 28$] of OEs, 2.8% of infusions), programming (0.32% [$n = 16$] of OEs, 1.6% of infusions), data transfer (0.22% [$n = 11$] of total OEs, 1.1% of infusions), and assignment (0.14% [$n = 7$] of total OEs, 0.7% of infusions). Further breakdown of these MEs (and the identified discrepancies) is provided in ►Table 4, with all programming MEs detailed in ►Table 5.

Failure to document one or more administered bolus doses accounted for 60.4% ($n = 81$) of all documentation deviations. The most common administration error ($n = 15$) involved expired medications (>4 hours beyond 24-hour expiry), contributing to 53.4% ($n = 15$) of the 28 administration errors identified. Eight further administration errors, and two discrepancies, related to administration without a corresponding order: four involved bolus doses; three infusions prepared in advance for a patient arriving with the transport team. One error occurred where a verbal order for a dose increase necessitated a concentration change; a delay in creation of the new SCI order resulted in inadvertent assignment of the

Table 3 Frequency of deviations, discrepancies, and medication errors for observed infusions

Number of deviations (%)	Discrepancies	Medication errors	Total deviations
Infusions with deviations per infusions observed ($n = 1,023$)			
Including undocumented bolus doses	58 (5.7%)	133 (13.0%)	191 (18.7%)
Excluding undocumented bolus doses	67[a] (6.5%)	55 (5.4%)	122 (11.9%)
Infusion deviations per opportunities for error ($n = 4,997$)			
Including undocumented bolus doses	107 (2.1%)	153 (3.1%)	260 (5.2%)
Excluding undocumented bolus doses	107 (2.1%)	72 (1.4%)	179 (3.6%)

[a]Increased due to recategorization of infusions ($n = 9$) with undocumented bolus doses and an additional discrepancy.

Table 4 Frequency and Severity of Discrepancies, Errors and Total Deviations in Observed Infusions per Opportunities for Error

	Discrepancies		Medication errors				Deviations
	NCC MERP category (Note: no errors categorized as E–I were observed)						
Deviation Categories by OE	**A**	**% of OEs**	**B**	**C**	**D**	***N* (% of OEs)**	***N* (% of OEs)**
Programming	12	0.24%	0	15	1	16 (0.32%)	28 (0.56%)
Off library unnecessarily	11	0.22%	–	–	–	–	11 (0.22%)
Incorrect drug line	–	–	–	7	–	7 (0.14%)	7 (0.14%)
Incorrect intravenous fluid	–	–	–	3	–	3 (0.06%)	3 (0.06%)
Other	1	0.02%	–	–	–	–	1 (0.02%)
Incorrect TPN phase	–	–	–	1	–	1 (0.02%)	1 (0.02%)
Incorrect weight	–	–	–	1	–	1 (0.02%)	1 (0.02%)
Multiple	–	–	–	–	1	1 (0.02%)	1 (0.02%)
Incorrect rate	–	–	–	1	–	1 (0.02%)	1 (0.02%)
Incorrect bolus dose	–	–	–	1	–	1 (0.02%)	1 (0.02%)
Incorrect concentration	–	–	–	1	–	1 (0.02%)	1 (0.02%)
Administration	8	0.16%	0	28	0	28 (0.56%)	36 (0.72%)
Expired medication	–	–	–	15	–	15 (0.30%)	15 (0.30%)
Without corresponding order	2	0.04%	–	8	–	8 (0.16%)	10 (0.20%)
Other	6	0.12%	–	–	–	–	6 (0.12%)
Incorrect diluent	–	–	–	2	–	2 (0.04%)	2 (0.04%)
Incorrect concentration	–	–	–	1	–	1 (0.02%)	1 (0.02%)
Incorrect medication	–	–	–	1	–	1 (0.02%)	1 (0.02%)
Incorrect dose	–	–	–	1	–	1 (0.02%)	1 (0.02%)
Documentation	43	0.86%	0	91	0	91 (1.82%)	134 (2.68%)
≥ 1 undocumented bolus dose	–	–	–	81	–	81 (1.62%)	81 (1.62%)
Admin information incomplete	30	0.60%	–	8	–	8 (0.16%)	38 (0.76%)
Manual volume entry incorrect	12	0.24%	–	2	–	2 (0.04%)	14 (0.28%)
Manual entry (other) incorrect	1	0.02%	–	–	–	–	1 (0.02%)
Assignment	10	0.20%	1	6	0	7 (0.14%)	17 (0.34%)
Incorrectly assigned (combined)	5	0.10%	1	2	–	3 (0.06%)	8 (0.16%)
Incorrectly assigned (human error)	–	–	–	4	–	4 (0.08%)	4 (0.08%)
Not assigned though possible	5	0.10%	–	–	–	–	5 (0.10%)
Data transfer	34	0.68%	8	3	0	11 (0.22%)	45 (0.90%)
Incomplete/missing data (combined)	23	0.46%	–	3	–	3 (0.06%)	26 (0.52%)
Incomplete/missing data (human error)	2	0.04%	–	–	–	–	2 (0.04%)
Incomplete/missing data (tech error)	7	0.14%	–	–	–	–	7 (0.14%)
Incorrect data (combined)	2	0.04%	–	–	–	–	2 (0.04%)
Incorrect data (tech error)	–	–	8	–	–	8 (0.16%)	8 (0.16%)
Total deviations *(incl. undocumented boluses)*	107	2.14%	9	143	1	153 (3.06%)	260 (5.20%)
Total deviations *(excl. undocumented boluses)*	107	2.14%	9	62	1	72 (1.44%)	179 (3.58%)

Abbreviations: NCC MERP, National Coordinating Council for Medication Error Reporting and Prevention; OE, opportunity for error; TPN, total parenteral nutrition.

new infusion to the original order and erroneous display of the dose infusing on the nursing flowsheet.

Of the 28 programming deviations identified, 39.3% ($n = 11$) involved unnecessary off-library programming; none of these involved a medication. Sixteen programming deviations were categorized as MEs (see ►**Table 5**). Four errors involved inappropriate use of the drug library to administer a medication to which a second medication had been added; three albumin 20% with added furosemide, and one potassium chloride with added magnesium. One SCI selection error was identified, resulting in half the intended dose of heparin being administered for almost 1 hour.

Table 5 Summary of all directly observed programming errors

Programming error type and medication	NCC MERP category	Errors (*n*)	Description
Incorrect bolus dose		1	
Morphine	C	1	Two boluses of 40 mg/kg instead of intended dose of 10 mg/kg (total bolus dose 40 mg)
Incorrect drug line/TPN phase		9	
Albumin 20%	C	3	Albumin 20% with added furosemide via "albumin 20%" drug line
Heparin	C	1	Heparin therapeutic line for under 1 year selected for patient over 1 year. The same concentration applies to both and the correct rate was programmed.
Paracetamol	D	1	Paracetamol programmed as "compound sodium lactate" bolus. Rate set at 75 mL/h instead of 75 mL over 15 min. Patient received dose over 1 h 10 min instead of 15 min
Potassium chloride	C	1	Potassium chloride + magnesium sulfate mixed in syringe being run through potassium chloride drug line
TPN aqueous phase	C	1	TPN standard bag drug line used for TPN aqueous phase
TPN standard bag	C	2	TPN aqueous drug line used for TPN standard bag
Incorrect IV fluid		3	
Compound sodium lactate + glucose 5%	C	2	• 20 mL/kg bolus given using IV fluid with added glucose, in place of plain IV fluid. • Programmed and assigned as "compound sodium lactate." Appeared on ICCA that patient not receiving added glucose.
Compound sodium lactate + glucose 5% + potassium	C	1	Potassium added to bag, but assigned to order for bag with added glucose only. Appeared on ICCA that patient not receiving fluids with added potassium
Incorrect rate		1	
Vancomycin	C	1	Not available on drug library. Infusion set to run over 60 h, instead of 60 min. Identified at the beginning of infusion and corrected
Incorrect concentration		1	
Heparin	C	1	Prophylactic heparin infusion re-prescribed as therapeutic heparin but prescribed concentration not changed. Pump programmed as 10,000 units/50 mL (therapeutic standard concentration) but 5000 units/50 mL in syringe. 50% dose delivered for a short period
Incorrect weight		1	
Midazolam	C	1	Patient weight increased on ICCA flowsheet to 3.41 kg, but pump remained programmed at 3.0 kg. ICCA displaying dose calculated on 3.41 kg (0.9 mg/kg/min), pump displaying 1 mg/kg/min
Total		16	

Abbreviations: NCC MERP, National Coordinating Council for Medication Error Reporting and Prevention; TPN, total parenteral nutrition.

Missing or duplicate volumes for 1 or more hours on the observation day were involved in 76% ($n = 34$) of data transfer deviations, all were categorized as discrepancies. The most common data transfer deviation involved "blank" infusion volumes (see ►Fig. 3). This was identified in 37.7% ($n = 17$) of 45 data transfer deviations and 1.7% of all observed infusions.

Eleven data-transfer MEs (1% of observed infusions) were identified. Eight involved erroneous autodocumented infusion volumes, six of these involving concurrently infusing medications for a single patient. In all eight cases, the doses infused were accurately recorded. Two of the other three MEs involved incorrect manual volume adjustment subsequent to a data-transfer issue; the third, unexplained missing data for 5 hours. Four of the seven assignment MEs involved incorrect IV fluid assignment, two temporary assignments to an incorrect SCI order, and one to an incorrect SCI diluent.

Labeling errors were identified in 21.5% ($n = 153$) of the included infusions ($n = 710$), with 60.8% ($n = 93$) of these being incomplete, 13.7% ($n = 21$) incorrect, and 11.8% ($n = 18$) partially visible in the syringe driver due to poor label positioning.

Severity

Almost all MEs were minor and caused no patient harm (see ►Table 4). Although most reached the patient, only one programming error was categorized as NCC MERP D (requiring monitoring/intervention to prevent harm); paracetamol

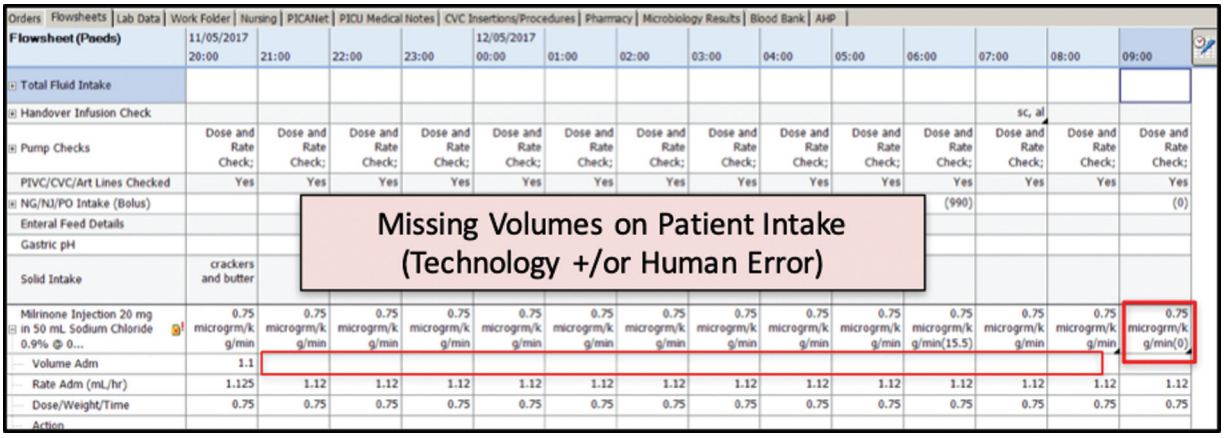

Fig. 3 Blank infusion volumes on nursing flowsheet.

was programmed as an IV fluid bolus and administered over 60 instead of 15 minutes until intercepted by the research pharmacist. The patient, who had a severe head injury and required cooling, suffered no harm although was still pyrexic when the error was identified. The potential to cause harm was considered low (mean: 2.4; range: 1.6–2.6) for the nine NCC MERP B errors not reaching the patient. Where undocumented boluses are excluded, no deviations were identified for 63.4% ($n = 111$) of included patients ($n = 175$), one for 14.9% ($n = 26$), and two or more for 21.7% ($n = 38$).

Drug Library Compliance

The drug library accommodated 96.1% ($n = 983$) of all observed infusions, with a compliance rate of 98.9% (see ►Table 2). Infusions not accommodated by the drug library most commonly involved flushes for maintaining line patency or draining of the alimentary canal and antibiotics. Five continuous medication infusions could not be administered via the drug library. Five discrepancies and one ME (vancomycin programmed as mg/minute rather than mg/hour) were identified in these non-drug library infusions. All infusions programmed off-library unnecessarily ($n = 11$) involved either IV fluids, TPN, or a blood product; all were categorized as discrepancies by the panel.

Contributory Factors

The mean deviation rate — number of deviations (including undocumented bolus doses) per OE — for each of the 27 observation days was 3.8% (standard deviation: 2.3%). The corresponding mean ME rate was 2.6% (standard deviation: 1.5%). A moderate correlation was found between the mean deviation rate and both number of patients admitted in the 24 hours of the observation day (Pearson's coefficient = 0.41) and total number of prescribed infusions (Pearson's coefficient = 0.43). Although simple linear regression found both these correlations to be statistically significant ($p = 0.03$), the reported coefficients are so small as not to be clinically significant. A weak correlation (Pearson's coefficient = 0.34) was found between mean MEs per OE and number of patients admitted in that 24-hour period; this was not found to be significant ($p = 0.08$). No relationship between the total number of prescribed infusions and the mean ME rate was found.

Discussion

Our observed ME rate of 13.0% and overall deviation rate of 18.7% (5.4 and 11.9% excluding undocumented bolus doses) are low compared with many administration error studies. The recent multisite study of 10 United States hospitals reported a corresponding deviation rate of 60% (range: 6–78%). The United Kingdom multisite rates were lower (MEs: 11.5% [95% confidence interval, CI: 10.2–13.0%] and discrepancies: 53.0% [95% CI: 50.8–55.2%]).[13,19] Despite using parallel methods, differences in categorization largely account for these disparities.[17] To facilitate meaningful comparison with the United States data, excluding errors involved labeling and "keep veins open" infusions, suggesting that 20% of United States infusions had a deviation. This is comparable to our 18.7% deviation rate, with undocumented bolus doses. Their reported rates for more serious errors such as wrong fluid/medication (0.3%), wrong rate (4.6%), and wrong dose (2%), though low, suggest they occurred more frequently.

Error rate comparison with the United Kingdom study is simpler, as they also differentiated deviations as MEs or discrepancies. Their inclusion of minor deviations such as labeling and patient identification violations accounts somewhat for the higher error rates and proportion of infusions with errors and discrepancies (0.2 vs. 0.07 errors per infusion; 0.74 vs. 0.1 discrepancies). However, further comparison is hampered by the fewer patients receiving IV medications (23.8%) and poor pediatric representation (two of 16 hospitals). The impact of smart-pumps (17.1% of observed infusion) is difficult to ascertain as they report similar error rates for infusions administered via smart and non-smart infusion pumps. This difficulty in isolating the impact of smart-pumps is also noted by Blandford et al in their recent comparison of the two multisite studies. This highlights the limitations of comparing simple outcome measures without factoring in particular configurations, processes, and settings.[16,17]

Comparison with studies using different outcome measures and methodologies is difficult. A single study in Ohashi et al's 2014 systematic review of smart-pumps was conducted in a PICU; based on a review of CQI data, direct comparison is not possible. Extrapolating adult findings to the PICU setting is unwise. Hennings et al reported increased

limit overrides and 1.68 times more reprogramming events for pediatric compared with adult patients in intensive care.[20] Benefits may be increased due to the particular advantages smart-pumps offer in this complex setting, such as supporting the programming of weight-band and care-unit specific SCIs.[34,35]

The extensive and highly customized nature of the library and the strong safety culture in our PICU are likely contributors to the low error and high compliance rates identified. As has been previously shown, smart-pump error reduction is dependent on both good compliance and the specific configuration and parameters of the drug library.[6,29] Audit and feedback from PICU nursing staff have demonstrated drug library use as deeply embedded and well-received. The enhanced visibility provided by the pump interface, in addition to the alerts from limits built into ICCA and the pumps, are other likely contributory factors.

The low programming error rate (1.6%), in particular the single SCI selection error, is an important finding. These errors are of particular concern in the PICU setting where multiple weight bands and more than one SCI are required to facilitate dose titration and complex dosing regimens, while maintaining accurate delivery and avoiding fluid overload. Although barcoded ready-to-administer infusions and bidirectional pump interfaces have potential to mitigate some but not all such errors, these are unlikely to be widely available in Europe for some time.[11,36] For example, the inadvertent administration of a morphine bolus of 40 microgram/kg rather than 40 micrograms to a 4-kg infant is difficult to prevent in an environment where use of the bolus function is commonplace. Even with appropriate bolus limits, pediatric and neonatal patients remain at risk where differences between patient weights in kilograms are of the same magnitude as normal dose ranges. Also, the heparin error, which occurred during reprogramming from prophylactic to therapeutic treatment, is unlikely to have been prevented without forcing functions to ensure rescanning of the previously loaded syringe. This level of interoperability, particularly outside the United States, has rarely been achieved.[15,37,38] The errors at transitions of care require further system integration. Delays in creating electronic patient records for newly admitted patients has been identified as a risk, specifically in the pediatric setting.[21]

Pump–EHR interoperability—although still uncommon even in the more digitally advanced United States—remains the goal for health care systems to optimize patient safety.[6,39] There are few published studies looking at these processes, with existing literature either qualitative or based on individual case reports or extracted pump data.[16,40,41] The exploration of autodocumented data are, therefore, particularly valuable. Although rare and potentially serious errors may not have been observed, the low data transfer error rate (1% of observed infusions) and minor clinical significance of assignment and data-transfer deviations is encouraging. In the absence of an interface, Russell et al reported a 24% discrepancy rate between electronic medication infusion orders and programmed smart-pump settings in a PICU.[33]

Despite the benefits of autodocumentation, e.g., improved documentation, increased visibility and alerting errors where documented and pump data are not aligned, new OEs, e.g., assignment errors, can arise. Novel error types are also introduced: automatic discontinuation of orders when altered results in missing autodocumented data; and increased duplicate orders can lead to incorrect assignment, resulting in inaccurate data. Investigation of "blank" infusion volumes revealed that manual prospective entry of data other than administered volumes, e.g., a syringe level check, creates a blank "volume administered" field for that time slot (which has yet to occur). This prevents internal volume differential calculations for that hour, which continues until rectified (see ►Fig. 3). Although infrequent and minor, the presence and novel nature of data-transfer errors warrants consideration in the context of bidirectional data transfer where substantially higher potential for adverse outcomes exists should autoprogramming errors occur.

The poor compliance with bolus dose documentation places the relative accuracy of autopopulated and manually populated data in stark contrast. In the absence of either local preimplementation data or any published studies in the administration and documentation of boluses from background analgesic and sedative infusions, it is difficult to determine how these rates compare. It is, however, widely recognized that despite best efforts by PICU nursing staff, retrospective documentation of bolus doses can be suboptimal where patients are clinically unstable, requiring multiple boluses over a short time period. Enhanced autodocumentation functionality, to include individual bolus doses, would bring clear benefits.

The findings from this study have informed several changes to the drug library, including addition of most intermittent infusions and combined medication drug lines. Its use has also been extended to non-critical areas within the hospital, with the data on SCI selection errors informing increased use of care units within the library and a single concentration for each medication outside of the PICU. The findings have also been instrumental in driving a project to standardize pediatric and neonatal infusions at a national level, including recent adoption of our institution's SCI drug library as a national standard of care.

Lower leverage risk reduction strategies, including vigilant double-checking procedures and education, remain central to patient safety as we progress toward greater levels of digital maturity. Development of a preprinted infusion prescription sheet to mitigate errors at transitions of care and local two-dimensional barcode labeling solutions are being explored. Educational programs have been updated.

Limitations

The absence of a control group limits interpretation of the impact of the interventions on error rates. The range of errors identified was limited by the methodology, sample size, and use of a single observer on each observation day. The low number of overall observations limited identification of serious and relatively rarer errors. CQI software would provide useful data on near-misses and limit overrides and

further programming errors, but not on other OEs. Some of the errors identified may not be generalizable to settings with less comprehensive smart-pump drug libraries and no interface.

Despite some evidence to the contrary, nurses' perceptions of being observed may have increased vigilance.[25,26,30] Behavior modification has been shown to be minimal once the researcher is an accepted group member and part of the social context; the research pharmacist had a regular presence in the PICU outside of her role in this study.[26]

About one-third of infusions had an error recorded at more than one OE; due to a knock-on effect, each identified error may not represent a distinct error of omission or commission. For infusions included more than once, the number of programming OEs may be inflated by inability to identify where the "use last therapy" option had been used during syringe changes. Due to resource constraints, exploration of system-level contributory factors was limited to the available measures of PICU activity.

Conclusion

This study has identified low ME rates on implementation of SCIs, a smart-pump drug library, and autodocumented infusion pump data. Although broader implementation of interoperable HIT systems is required to protect against the full range of errors, this study has positively demonstrated the use of a locally customized pediatric drug library and lower levels of HIT integration in the high-risk PICU setting. The findings have driven a range of quality improvements and been a key driver in the expanded use of the drug library.

Difficulty in comparing these results to other studies reinforces the complexity and nuances of ME research and emphasizes the need to evaluate complex HIT interventions across multiple settings. The insight into new errors has provided a more complete understanding of potential unintended consequences, the processes underlying them, and enabled feedback to system vendors. These will inform stakeholders in the implementation, use, and further development of infusion management and associated HIT systems in the wider health care setting.

Clinical Relevance Statement

The findings from this study have added value to the evidence base, supporting ongoing efforts to increase adoption of smart-pumps and implement standardized pediatric and neonatal infusions both locally and internationally. Since study completion, several drug library upgrades, directly informed by the findings, have occurred, ensuring the safety of intravenous medication practices in pediatric patients continues to be optimized.

Multiple Choice Questions

1. Implementation of smart-pumps with a pediatric drug library of SCIs into a PICU can:
   a. Eliminate all intravenous medication errors as a single intervention.
   b. Eliminate a wide range of potentially severe programming errors.
   c. Replace all paper-based documentation processes.
   d. Eliminate all programming errors.

   Correct Answer: The correct answer is option b. Safety agencies, including the Institute for Safe Medication Practices (ISMP), have been advocating the use of standard concentration infusions for over 10 years, and smart-pumps for over 20 years. Even when used optimally, smart-pumps do not eliminate all intravenous medication errors but should ideally be implemented as one component of a closed loop intelligent infusion management system.

2. Which of the following is a true statement regarding interoperability of smart-pumps with clinical information management systems (CIMS) and electronic health records (EHR)?
   a. Smart-pump–EHR interoperability is commonplace in the United States and European hospitals.
   b. To enhance medication safety, both autoprogramming and autodocumentation, i.e., bidirectional data transfer is necessary.
   c. Unidirectional data transfer ensures seamless autodocumentation of all data from the pumps into the EHR.
   d. Unidirectional data transfer can provide clinicians with near-real time infusion data, alert programming discrepancies, and reduce documentation burden.

   Correct Answer: The correct answer is option d. Successful implementation of interoperability between smart-pumps and other technologies can effectively reduce a variety of error types not eliminated by smart-pumps as a single intervention. These include errors in programming, wrong drug concentration, wrong rate, wrong drug, and patient weight. Implementation is, however, complicated and costly requiring long-term organizational commitment and has yet to occur in the majority of hospitals.

Protection of Human and Animal Subjects

There was no direct patient involvement in this study. Observations were limited to infusion pumps and electronic data within the PICU clinical information management system.

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Conflict of Interest

None declared.

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