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Clinical Investigation

Improving Pediatric Outcomes through Intravenous and Oral Medication Standardization

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BACKGROUND Standardization is an invaluable tool to promote safety, improve care, and decrease costs, which ultimately improves outcomes. However, a pediatric setting presents unique challenges with its wide variety of weights, medications, and needs that are distinctly different. Our goal was to develop and implement standards in complex high risk areas that show improved outcomes and safety.

PROGRAM DESCRIPTION A computerized prescriber order entry program with decision support for pediatrics was developed for parenteral nutrition prescribing. The program included dosing, calculations, calcium phosphate compatibility checks, automated IV compounder interface, osmolarity route calculation, end product testing verification, aluminum exposure and many other quality improvements. This same electronic order program, interface to sterile compounders, and end product testing was used to standardize and make common non-manufactured intravenous solutions. The drip compounding process was reengineered to include standard concentrations, label changes, and beta-testing of a smart syringe pump with dosing ranges for pediatrics. Common standard oral doses were developed along with standard oral formulations.

CONCLUSIONS Total parenteral nutrition (TPN) error rates decreased from 7% to less than 1% and compatibility issues decreased from 36 to 1 per year. Neonatal osteopenia rates decreased from 15% to 2%. Results from end product testing of TPN solutions were within USP standards showing statistical correlation ($p<0.001$). Intravenous standardization decreased error rates by 15% and compounding time decreased by 12 minutes (64%). Drip standardization allowed for drug concentration and smart pump standardization and decreased drip errors by 73% from 3.1 to 0.8 per 1000 doses. Compounding errors decreased from 0.66 to 0.16 per 1000 doses and ten-fold errors decreased from 0.41 to 0.08 per 1000 doses. Eleven oral liquids, including 329 different doses, were standardized, decreasing the number of doses to 59 (83% change). This decreased workload 15%, wastage 90%, improved turnaround time 32%, and saved $15,000/year. One hundred evidence-based standard oral formulations were developed and used in 22 different hospitals.

KEYWORDS continuous infusions, intravenous, oral liquids, standardization

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INTRODUCTION

The practice of pediatrics has always been complicated; small doses and multiple dose variations are commonplace. Manipulating doses increases the risk for error which can adversely affect patient outcomes. The Institute of Medicine recommends that hospitals "implement standard processes for medication doses, dose timing, and dose scales in a given patient care unit."[1-2] At our 232-bed pediatric tertiary trauma one care center, our major areas of concern leading to multiple variations and errors are the following: parenteral nutrition formulations, intravenous solutions, drip compounding, and oral liquid doses and formulations (Figure 1). When parenteral nutrition formulations were calculated without standardized computerized systems, for

ABBREVIATIONS CPOE, computerized prescriber order entry; PN, parenteral nutrition; TPN, total parenteral nutrition

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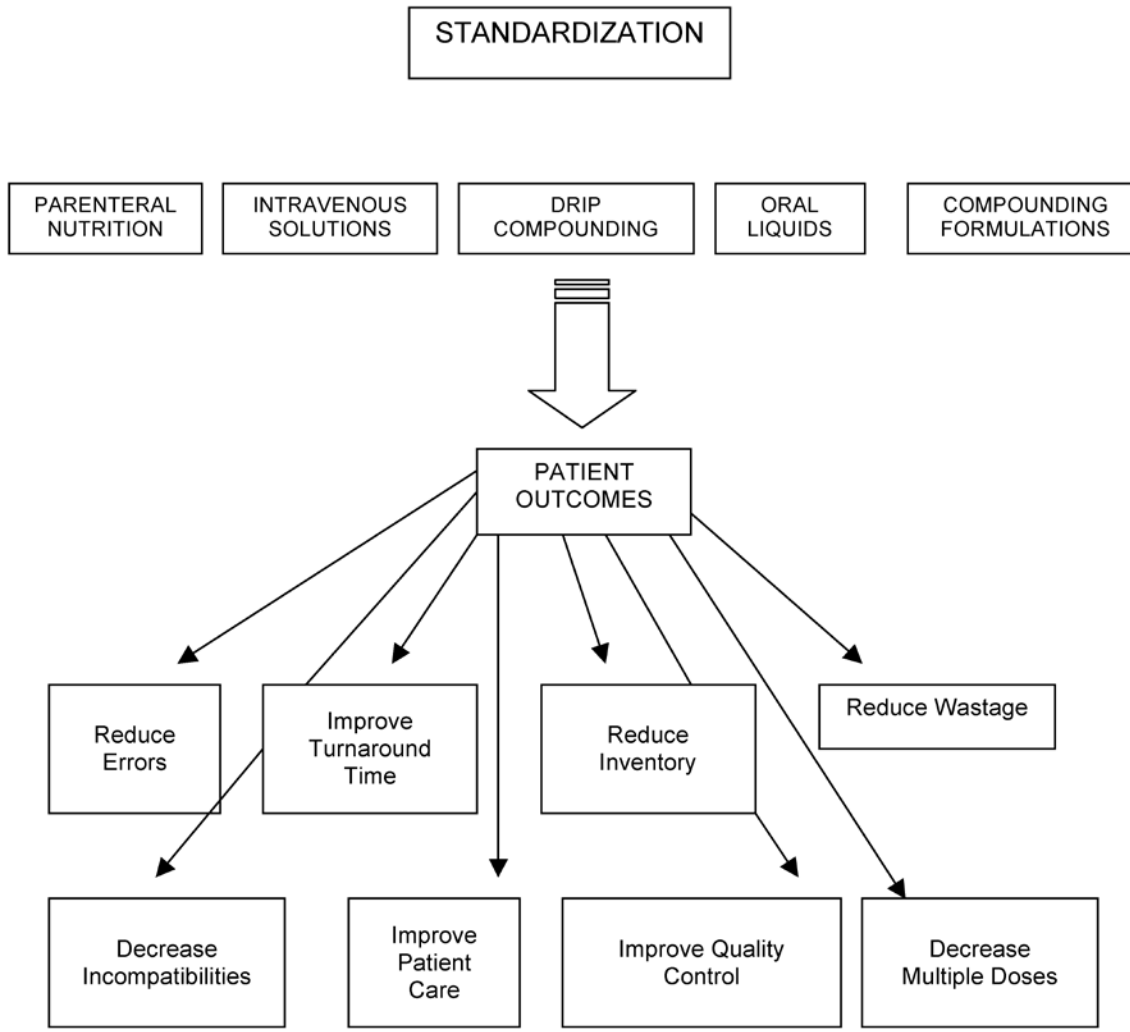

Figure 1. Improving patient outcomes by controlling distribution and administration.

example, we had errors occurring on up to 7% of these formulations and 1 to 3 bags per week precipitating due to calcium/phosphorous incompatibility. We postulated that implementing standard processes in these areas could reduce errors, decrease dispensing turnaround times, reduce wastage, improve quality control, and decrease manual dispensing workload, especially in light of personnel shortages, while at the same time improving pharmacy practice and patient outcomes.

METHODS

Parenteral Nutrition

Ordering, compounding, and verification of parenteral nutrition (PN) is a complex process.3 Pre-printed order forms help prevent omission and some communication errors but do little for calculation, transcription, and compatibility errors. Using computerization we were able to eliminate the pre-printed order forms and provide solutions for calculations, transcription, and compatibility errors. Our nutrition support team met with the hospital's computer programmer and developed the first known computerized prescriber order entry (CPOE) for pediatric PN. The CPOE was developed electronically in such a way that the order is checked for accuracy, dosage correctness, physical and chemical compatibilities, and provides necessary information to solve any unacceptable problems. The CPOE order was interfaced into an automated compounding device with barcode ingredient checks, decreasing the risk of human error in ordering, transcribing, and compounding. Safety and computer interface

procedures were researched and developed to allow pharmacist approval prior to the order's electronic transmission. The computer program was developed with a decision tree for all PN ingredients, such as default standard ingredients, doses, and safe ranges for specific patient weights. Ingredient compatibility checks, especially calcium/phosphate compatibility ranges, were developed to prevent precipitation. Other additions to the PN program were total aluminum contamination concentration, barcoding the TPN label in order to ensure the correct patient order during automated compounding, and osmolarity calculations to avoid extravasation injury. End product testing of PN solutions through laboratory analysis was developed to assure the most accurate and safe compounding of glucose, sodium, potassium, calcium, magnesium, and phosphate. End product testing and refractive index were tested against the laboratory tested values for each PN and a paired sample t test was used to determine the compounding accuracy.

Intravenous Solutions (IVs)

After having success in improving and standardizing the complex PN process, it was concluded that the same principles could be applied to intravenous solutions. A program very similar to the previously described PN process was developed but simplified to accommodate commonly compounded IVs. This would allow the same electronic order transmission, automated calculations, automated compounding, and barcoding safety standardizations. This process would be used to determine the time reduction to intervene with IV ordering and clarification prior to compounding. We will determine the reduction in time for compounding and the improvement in turnaround time.

Drip Compounding

In 2002, prior to the Joint Commission National Patient Safety Goal, our institution changed from weight-based individually compounded drips to standard concentrations used on "smart" syringe pumps. This took a large interdisciplinary group that included intensivists, nurses, neonatologists, pharmacists, anesthesiologists, and many others over one year in planning and evaluation. It was a paradigm shift in how drips were ordered, manufactured, and administered. The hope was that the change would decrease the number of steps in the process, resulting in a decrease in errors. Concerns about giving too much fluid volume, especially in neonates, were addressed and monitored closely. We surveyed other pediatric centers and did "mock" conversions in order to determine the appropriate concentrations. We also used manufacturer-provided concentrations whenever possible to decrease the risk of compounding errors.

Standardizing Oral Liquids

Providing standardized liquid medications within predetermined dosage ranges has not been the standard of practice in pediatrics. Instead, the practice is to multiply the patient's weight by the dose requirement and then round the dose to an appropriate number. These results in a large number of individual doses compounded for specific patients with an increased risk for error each time a separate dose is prepared. The large variation in pediatric weights was thought to be the reason that standardizing pediatric oral doses could not be done. It was hypothesized that pediatric weight-based dosing could be standardized into therapeutic dosing ranges by developing a mathematical formula that allowed for weight-based dosing within therapeutic ranges, resulting in a reduction of the total number of different doses, waste and the potential for error. In order to increase acceptance of this type of process, medications with a large therapeutic window and a low side effect profile were chosen, such as calcium carbonate and docusate. As practitioners felt increasingly more comfortable with the process, more medications such as furosemide and iron were added. Standardizing the oral liquid medications allows for standardization of compounding formulas. The end point of oral standardization was to standardize 80% of the oral liquids chosen. The recipes for making oral suspensions were also reviewed for potential standardization.

RESULTS

Parenteral Nutrition (12,000 solutions per year)

In conjunction with a multidisciplinary team, a computerized worksheet was developed in such a way that a PN order could be electronically processed and checked for dosing, incompatibilities, precipitates, caloric intake and volumes,

Table 1. Example TPN Ordering Worksheet

TPN ORDERING SCREEN

Name: Test Patient	Medical Record #: 345987	Unit: Infant
Weight (kg): 2	Date: 12.8.2006	Time: 1300
	Author: Jones, MD	

	Dosage	
Dextrose %	15	Dextrose = 11.5 mg/kg/min
AA (gm/kg)	2	Amino Acids: TrophAmine 10%

Volume	mL/kg	mL/day
TPN	110	220.1
LIPID	10	19.9
TOTAL	120	240

Cysteine (mg/gm)	50
Na (mEq/kg)	4
K (mEq/kg)	3
Cl (mEq/kg)	2.99
Acet (mEq/kg)	2.25
Mg (mEq/kg)	0.3
Ca (mEq/kg)	2.8
P (mM/kg)	1.2
Zn (mcg)	300
Cu (mcg/kg)	20
Mn (mcg/kg)	5
Cr (mcg/kg)	0.14
Sel (mcg/kg)	5
Io (mcg/kg)	5
Fe (mg/kg)	0
Vitamins (mL/day)	4
Vit K (mcg/day)	160
Vit C (mg/day)	64
Heparin (units/mL)	0
Albumin (gm/day)	0
Lipid (gm/kg)	2
Volume (mL/kg)	120
Insulin (units/kg/hr)	0
Zantac (mg/kg/day)	0
Reglan (mg/kg/day)	0
Carnitine (mg/kg)	0

	AMOUNTS				
	gm/kg	gm/day	cal/kg	cal/day	%Cal
Dextrose	16.5	33	56.1	112.2	66.8
Protein	2	4	8	16	9.5
Lipid	2	4	19.9	39.8	23.7
Total			84	168.1	100

Na (mEq/L)	36	Ca (mg/kg/day)	56
K (mEq/kg/hr)	0.13	P (mg/kg/day)	37.2
K (mEq/L)	27	Ca mg: P mg	1.51
NPCal: gm Nit	238	(Ca* P) / %AA	154.3
TPN mOm/L	1088 w lipid	Precipitation Limit	280.1
		Al (mcg/kg/day)	53.03

* Nursing orders
Run 20% lipid @ 0.83 mL/hr for 24 hours/day
Run TPN Centrally @ 9.17 mL/hr for 24 hours/day

COMMENTS

Function Key	
F1	Instructions
F2	Save Preliminary
F3	Print and Save
F4	Pharmacy Review
F6	Restart
F7	Exit TPN

Educational Window

Dose Check Window

osmolarity, and highlight dosing that may be inappropriate.[4-6] (Table 1) Precipitates due to calcium and phosphate are identified for each solution and dosage changes suggested to eliminate the precipitate.[7-10] (Figure 2) An educational window is provided to give appropriate suggestions when needed to maintain dosages within patient needs, such as bone accretion rates. The computerized worksheet acts as a computerized prescriber order entry (CPOE), and provides

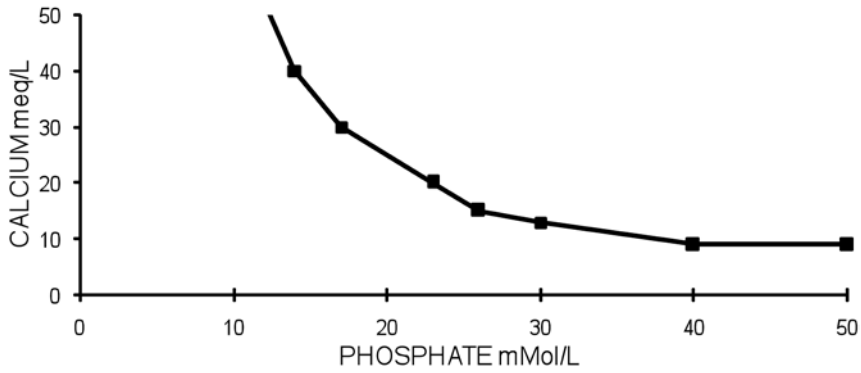

Figure 2. Precipitation of calcium and phosphate in a nutrient solution containing 2% amino acids and 10% dextrose with a pH of 5.5. Area above the curve indicates risk of precipitation and area below the curve indicates no risk for precipitation.

checking and teaching screens for each medication ordered. After pharmacy review, the CPOE data is transmitted to the pharmacy department where the order is barcoded into an automated compounder and prepared for patient use. Once complete the PN undergoes end product testing for glucose, sodium, potassium, calcium, magnesium and phosphorous concentrations.

Going from a paper order to a computerized worksheet reduced calculation errors. Each PN required 60 calculations with an error rate of 7%. Most error calculations involved converting milliequivalents to milligrams or millimoles, and calculating the calcium/phosphate compatibility. Using computerized worksheets reduced the calculation error rate to zero. Prior to completing the calcium/phosphate compatibility curves, 1 to 3 PNs would precipitate weekly. Once the calcium and phosphate curves were automated, the incompatibility problem rate decreased to less than one per year. Knowing how to maintain chemical stability with the required elements added to the PN, one could maximize the calcium and phosphate to obtain appropriate bone accretion rates. The computerized worksheets guide the practitioner by maintaining a calcium/phosphorous ratio (mg:mg) between 1.3-2.2:1 with weight-based doses.[11-13] Prior to implementing the worksheet, the ratio was 0.4:1 and 15% of the patients showed osteopenia on x-ray. Knowing how to maintain solubility of calcium and phosphate in PN and using appropriate doses and ratios reduced the osteopenia occurrence to 2%.

Improvements in the ordering process allowed the clinical pharmacists to concentrate on patient-oriented care (appropriate nutrition and disease state management) rather than task-oriented issues (incompatibilities, compounding, and order transcription). Changing to the computerized worksheet lead to a paradigm shift in clinical practice. Originally the pharmacists spent 80% of their time performing calculations and determining compatibility of the PN. After making the change the pharmacists now spend 10% of their time in calculation and compatibility and 70% in patient-oriented care. Once the pharmacists had more time to devote to optimizing patient-oriented care, it was noted that patients receiving PN and povidone for line change or surgery preparation had elevated urinary iodine levels, resulting in increased monitoring and decreased iodine dosage.[14]

End product testing was completed by comparing the calculated value against the laboratory analyzed value for sodium, potassium, calcium, magnesium, and phosphorous. Glucose concentration was determined by calculating the refractive index of glucose against the measured refractive index. The automated compounder was evaluated by comparing the calculated value against the pumped value. The PN was deemed correct if the calculated versus the laboratory values were within one standard deviation. A paired sample t test for the calculated and laboratory values was p= 0.000.

Intravenous Solutions (50,370 solutions per year)

Compounding sterile products is a critical function of pediatric pharmacy practice, and our institution compounds over 140 intravenous solutions daily. Applying the same concept of computerized worksheet to ordering intravenous solutions provided a sterile product that was accurate, compatible, and could be end product tested. Initially it was found that 15%

of all IV orders required intervention before compounding. Using the electronic worksheet reduced the intervention rate to less than 1%, once again allowing the pharmacists to provide more patient-oriented care. Orders are entered on the worksheet and electronically submitted to the pharmacy where they are barcoded into an automated compounding machine. Using the manual process of compounding intravenous solutions required 35 minutes; converting to the worksheet reduced the time to 12 minutes, or a 64% reduction in turnaround time.

Drip Compounding (24,500 drips per year)

Thirty-two drips were standardized according to concentration, allowing for the elimination of the rule of six calculations and the implementation of "smart" pump technology.[15-16] Once these 32 were incorporated into the "smart" pump library (Table 2), nursing staff only needed to enter each patient's weight and dose into the pump, eliminating the rule of six. Comparing the reported errors pre- and post-implementation of the standardized drips, the reported number of errors decreased by 73%. The reported error risk dropped from 3.1 to 0.8 per 1000 doses. Compounding errors made by pharmacy decreased from 0.66 to 0.16 per 1000 doses and the number of ten-fold errors decreased from 0.41 to 0.08 per 1000 doses. Standardized drug concentrations and "smart" pump technology reduced errors associated with continuous medication infusions.

Standardizing Oral Liquids (233,604 doses per year)

The mainstay for dosing oral liquid medications in pediatrics is based on each patient's weight. Using standardized doses improves patient care by reducing errors and promoting medication safety and control; additionally, it allows for medications to be placed in automated devices.[17] A mathematical process was developed to standardize medications into therapeutic dosing ranges. Eleven medications were chosen, comprising 80% of the oral liquid medications dispensed in our facility (19,467 doses per month). The 11 medications required 329 different weight-based doses. Standardizing the doses reduced the number of different doses to 59, a decrease of 83%. Evaluating the standardization of iron, 1,732 doses were prepared monthly from 42 different milligram amounts. Standardizing iron reduced the different doses to 5 standardized doses, a reduction of 88%. (Table 3) Standardized dosing reduced the workload hours by 15% and reduced wastage by 90%. The overall compliance increased from 15% to 86% and resulted in cost savings of $15,000 per year. The number of errors was not tabulated but it was noted that there was a perceived reduction in error rate, and turnaround time decreased by 32%. Standardizing oral liquids as individual doses also lead the project to document over 100 recipes into standardized compounding formulations. These formulas are used in 22 hospitals, more than 100 clinics, and in conjunction with a CPOE outpatient prescription program.

DISCUSSION

Most medications developed by manufacturers meet the needs of adult patients. In pediatrics, adult doses are manipulated to meet the needs of the patients. It has been shown that the more a medication is manipulated the greater chance for error. Error contributes to patient harm. At our institution we used the Institute of Medicine safety practice of standardizing doses, dosing times, and medication processes to reduce error rates and improve patient outcomes. The areas that we focused on were parenteral nutrition formulations, intravenous solutions, drip compounding, oral liquid dosage standardization, and compounding formulations. Over the years we have taken each area and developed processes to standardize the practice in pediatrics. Each area was developed with recursive evaluations and point-in-time changes to evaluate the effectiveness of the change, allowing for modification where necessary.

Precise calculations are required for parenteral nutrition in pediatric patients. Additionally, within the practice of pediatrics, each patient population requires specific tailoring to achieve maximal nutritional benefit. The utilization of clinical pharmacists to follow each patient receiving PN coupled with a computerized worksheet and automated compounding devices has achieved a dramatic reduction in errors and improved patient outcomes. Using CPOE principles our process improved ordering, checking, compounding, and end product testing. This increased the time available for the pharmacists to concentrate on evidence based medicine

Table 2. Medications Selected for Standard Drug Concentrations

Medication	Concentrations		
	1	2	3, 4
Amiodarone	2 mg/mL	6 mg/mL	-
Aprotinin	1.4 mg/mL	-	-
Dobutamine	1 mg/mL	4 mg/mL	-
Dopamine	0.8 mg/mL	3.2 mg/mL	-
Epinephrine	8 mcg/mL	64 mcg/mL	-
Esmolol	10 mg/mL	-	-
Fentanyl	10 mcg/mL	50 mcg/mL	-
Furosemide	1 mg/mL	10 mg/mL	-
Heparin	50 units/mL	100 units/mL	-
Hydromorphone	1 mg/mL	-	-
Insulin	0.1 unit/mL	1 unit/mL	-
Isoproterenol	8 mcg/mL	64 mcg/mL	-
Ketamine	10 mg/mL	100 mg/mL	-
Lidocaine	4 mg/mL	8 mg/mL	-
Midazolam	1 mg/mL	5 mg/mL	-
Milrinone	200 mcg/mL	-	-
Morphine	1 mg/mL	-	-
Nitroprusside	400 mcg/mL	1 mg/mL	-
Norepinephrine	8 mcg/mL	64 mcg/mL	-
Pancuronium	1 mg/mL	-	-
Phenylephrine	50 mcg/mL	100 mcg/mL	-
Potassium	0.2 mEq/mL	1 mEq/mL	-
Procainamide	4 mg/mL	8 mg/mL	-
Propofol	10 mg/mL	-	-
Prostaglandin E1	5 mcg/mL	-	-
Remifentanil	25 mcg/mL	50 mcg/mL	-
Sodium Bicarbonate	1 mEq/mL	-	-
Sufentanil	0.5 mcg/mL	1 mcg/mL	5 mcg/mL, 10 mcg/mL
Terbutaline	1 mg/mL	-	-
Tranexamic acid	5 mg/mL	10 mg/mL	25 mg/mL, 50 mg/mL
Vasopressin	0.025 unit/mL	1 unit/mL	-
Vecuronium	2 mg/mL	-	-

through patient outcome data, which improved patient therapy. In the future the pharmacists will concentrate more on medication and disease state management and monitoring patient outcomes.

Intravenous solutions, both simple and complex, are a source of errors nationally. Through the utilization of a computerized order entry system interfaced with an automatic compounding device, error rates have been reduced. Additionally, using this process has eliminated the need for pharmacy to obtain clarification for intravenous solutions, and for a pharmacist to compound intravenous solutions. Technicians are used in place of pharmacists to operate the automated compounding of intravenous solutions. Reassigning both the pharmacist and the technician workload decreased the time required for compounding IVs and increased

Table 3. Example of Oral Liquid Dosage Standardization

Weight (kg)	Dose (mg)		Dose (mL)		Standard Dose
	Minimal (2 mg/kg)	Maximum (4 mg/kg)	Minimal (2 mg/kg)	Maximum (4 mg/kg)	
1	2	4	0.08	0.16	**2 mg**
1.2	2.4	4.8	0.1	0.19	
1.4	2.8	5.6	0.11	0.22	
1.6	3.2	6.4	0.13	0.26	
1.8	3.6	7.2	0.14	0.29	
2	**4**	8	0.16	0.32	**3.75 mg**
2.2	4.4	**8.8**	0.18	0.35	
2.4	4.8	9.6	0.19	0.38	
2.6	5.2	10.4	0.21	0.42	
2.8	5.6	11.2	0.22	0.45	
3	6	12	0.24	0.48	
3.2	6.4	12.8	0.26	0.51	
3.4	6.8	13.6	0.27	0.54	
3.6	7.2	14.4	0.29	0.58	
3.8	7.6	15.2	0.3	0.61	**7.5 mg**
4	8	16	0.32	0.64	
4.2	8.4	16.8	0.34	0.67	
4.4	8.8	17.6	0.35	0.7	
4.6	9.2	18.4	0.37	0.74	
4.8	9.6	19.2	0.38	0.77	
5	10	20	0.4	0.8	
5.2	10.4	20.8	0.42	0.83	
5.4	10.8	21.6	0.43	0.86	
5.6	11.2	22.4	0.45	0.9	**11.25 mg**
5.8	11.6	23.2	0.46	0.93	
6	12	24	0.48	0.96	
6.2	12.4	24.8	0.5	0.99	
6.4	12.8	25.6	0.51	1.02	
6.6	13.2	26.4	0.53	1.06	
6.8	13.6	27.2	0.54	1.09	
7	14	28	0.56	1.12	
8	16	32	0.64	1.28	**15 mg**

Arrows represent minimal doses within specific weight ranges allowing for doses to be standardized. The standard dose for patients weighing up to 1.00 kg is 2 mg; patients weighing 1.01-2.00 kg receive 3.75 mg; patients weighing 2.01-4.00 kg receive 7.5 mg; patients weighing 4.01-5.60 kg receive 11.25 mg; patients weighing 5.81-8.00 kg receive 15 mg.

time available for pharmacist to complete clinical responsibilities.

Drip medications usually require manipulation of the solution prior to infusion for pediatric patients. Through the elimination of the rule of six, establishing standardized drip concentrations,

and implementing "smart" pump technology, the error rate relating to the infusion of these medications was dramatically reduced. In combination with these practices the use of manufactured drip solutions further reduces the time to deliver medications to patient care areas and reduces the probability of compounding error.

Preparation of oral liquid medications is a resource consuming process for the pharmacy department. By using a mathematical approach to determine oral standard doses the process was streamlined. Medications that used to be prepared individually for each patient are now placed in automated dispensing devices and in the robotic dispensing machine. This has allowed for rapid turnaround times from the pharmacy department and a cost savings to the institution. The goal to have 80% of the oral liquid medications dispensed in this manner has been realized. Standardizing oral liquids allowed for standardization of liquid formulations compounded for inpatients and outpatient prescriptions. Our next step is to close the final loop in the process to incorporate bedside barcoding for all intravenous products and oral medications.

CONCLUSION

The ability of our institution to adopt these changes has promoted more concise and productive interdisciplinary communication with the pharmacy department. Nursing and pharmacy have both benefited from the implementation of standardization though reduced errors, rapid medication procurement, and improved patient safety. Not only did the vision of standardization positively effect our patient population but the information is contributing to changing the practice of pediatric pharmacy. Standardization of parenteral nutrition formulations, intravenous solutions, drip compounding, and oral liquid dosages can be accomplished in pediatrics. Through the standardization of oral dosing formulations patients received accurate doses faster and with decreased cost to the health care system. Through the standardization and automation of compounded intravenous solutions pharmacists can increase time spent evaluating and improving patient-oriented care while accurate solutions are delivered to the patient in a more timely manner. Adding computerized technology to PN writing has lead to a significant decrease in the adverse outcomes to our patients through the elimination of calcium/phosphate precipitates and the optimization of nutritional outcomes, while also drastically decreasing the amount of time it takes to write the PN. With these PN process changes, more potential problems were identified and subsequently rectified to further optimize patient outcomes. With the standardization of the drips in our facility, patient safety was substantially increased by implementation of the "smart" pump technology leading to minimal potential for medication calculation and delivery errors. All of these standardization programs together reduced errors, decreased dispensing turnaround times and manual dispensing workload, and lead to improved therapeutic patient outcomes.

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