CLINICAL INVESTIGATION

Standard Dose Development for Medications Commonly Used in the Neonatal Intensive Care Unit

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OBJECTIVES: To establish standardized, rounded doses of medications for neonates in the neonatal intensive care unit (NICU) through a multi-institutional peer-reviewed process.

METHODS: Pediatric faculty and pediatric pharmacy residents from the Ernest Mario School of Pharmacy (Piscataway, NJ) conducted a systematic review of rounded, weight-based medication information for neonatal patients from September 2010 to April 2011. After initial review, an expanded workgroup of expert neonatal pharmacy clinicians from academic institutions throughout the United States were invited to conduct a final review. The workgroup identified 74 medications or indications in the NICU. Recommended standardized doses were established for discrete weight categories at workgroup consensus web meetings conducted from June to December 2011. Workgroup recommendations were cross-referenced with published neonatal pharmacology resources. Consensus was obtained when references provided insufficient information on medication information.

RESULTS: Seventeen weight categories of increasing ranges were used, from 40 g for the lowest weights (e.g., 410–450 g) to 840 g for the highest weights (e.g., 3660–4500 g). Medications were divided into 3 categories of administration routes: oral (n = 4), intermittent intravenous (n = 64), and other (e.g., intramuscular; n = 6). A significant majority of standardized doses (84%) were within 15% of their corresponding weight-calculated dose.

CONCLUSIONS: Establishment of a portfolio of standardized, rounded doses of medications commonly used in the NICU was feasibly established by a multi-institutional peer review process, with the great majority of standardized doses being within clinically acceptable ranges of administration. Use of standardized, rounded doses for reduction in dosing errors may be feasible on a systematic level.

INDEX TERMS: dose banding, dose rounding, medications, neonate, preterm, rounding tolerance, standardization

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INTRODUCTION

In 2001, Kaushal et al¹ reported that pediatric inpatients are at a three times higher risk for potential adverse drug events (ADEs) compared with hospitalized adults. Of importance, neonates are a particularly vulnerable population. Kaushal et al¹ reported that the highest rate of ADEs (46 per 100) occurred in the neonatal intensive care unit (NICU). Overall, the most common medication error and potential ADE was improper dose, occurring most frequently in the prescribing process. An analysis of medical

errors in the NICU as part of the Neonatal Intensive Care Quality Collaborative sponsored by the Vermont Oxford Network revealed that 47% of errors were due to wrong medication, dose, frequency, or infusion rate.² A total of 16% of these were prescribing errors. A more recent study, using a NICU-focused trigger tool, detected 2.96 triggers and 0.74 adverse events per patient, indicating that adverse event rates in the NICU may be higher than previously described.³

One of the many reasons for this higher risk in pediatric patients is the universal challenge of calculating individualized doses using weight

or body surface area. Pediatric-specific calculations are necessary but increase the possibility for errors. The American Academy of Pediatrics, Pediatric Pharmacy Advocacy Group (PPAG), Institute for Safe Medication Practices, and The Joint Commission are a few organizations recognizing calculations as a major challenge and cause of pediatric medication errors.⁴⁻⁶ Neonatal drug dosage calculations also frequently require the use of decimals, leading to dosing errors, the most common subtype of medication errors in pediatrics. Advanced technology, such as computer provider order entry, also known as electronic prescribing (e-prescribing), demonstrated reductions in these calculation errors.⁷ In neonates who need smaller dosages, however, e-prescribing can also contribute to calculation-related medication errors because of the required use of multiple decimal places and the uncertainty of rounding numbers with multiple significant figures.

Another strategy to reduce medication errors is drug dosage standardization. Standard doses reduce the interpatient variation of drug dosages and the labor of pediatric-specific calculations. Even when pediatric practitioners agree on a drug's weight-based dosing scheme, such as 0.1 mg per kg, the calculation of the final dose with a practically infinite number of weights results in equally infinite dose variations. "Standard doses," "dose banding," and "rounding tolerance" are terms used to describe predefined doses by using each patient's weight for calculation without altering clinically desired effects. Clinical studies on the use of this standardized dosage system have not been described in the neonatal population. Therefore, the purpose of this innovative initiative was to establish a consensus on standardized, rounded doses of medications for neonates in the NICU through a multi-institutional peer-reviewed process.

MATERIALS AND METHODS

From September 2010 to April 2011, members of the pediatric pharmacy faculty and postgraduate pediatric pharmacotherapy program from a central institution (Ernest Mario School of Pharmacy at Rutgers, The State University of New Jersey, Piscataway, NJ) completed a prephase review of dose-rounding, weight-based neonatal medication information. For subsequent systematic re-

view, an expanded expert workgroup consisting of a neonatologist and invited neonatal pharmacy clinicians from academic institutions throughout the United States was identified through PPAG membership. From June to December 2011, this workgroup met monthly via web conferencing sponsored by PPAG. A total of 15 participants from 13 institutions with Level III NICUs attended the web conferences. Cumulatively, the workgroup had more than 100 years of clinical experience in neonatal pharmacology. Discrete weight categories and minimum and maximum weights were established by group consensus. For potential error reduction, weights were rounded to the nearest 10 g (i.e., 604 g rounded down to 600 g, and 605 g rounded up to 610 g) by consensus to avoid numbers with three places past the decimal point when converted to kg for dose calculations. A list of commonly used NICU medications and medications associated with significant risk for error or harm with incorrect use was developed by group consensus. A standardized template was developed to facilitate consistency in the group review and discussion of each medication and included the following categories: drug, dose, indication, reference, standardized dose for each weight category, frequency, monitoring/dose adjustment, black box warning (if applicable), administration, and preparation. The midrange weight for each category was used to calculate an initial dose, which was then evaluated by the workgroup for feasibility and practicality, and rounded based on consensus. Standard doses for each weight category are reported in this manuscript; additional data are available upon request. Each category was reviewed on the basis of consensus web conferences using the nominal group technique.⁸ Both prephase and workgroup recommendations and changes for each drug were recorded and cross-referenced by selected team members using the following published neonatal pharmacology resources: *Neofax* (Thomson Reuters),⁹ *Pediatric & Neonatal Dosage Handbook* (Lexi-Comp),¹⁰ primary literature, and national guidelines. Categories for each drug were then iteratively reviewed again at subsequent web conferences for final consensus approval.

RESULTS

A total of 7 in-person process review meetings

Table 1. Designated weight categories and range within each

Weight (grams)	Range* (grams)	Weight (grams)	Range* (grams)
350-400	50	1010-1200	190
410-450	40	1210-1450	240
460-500	40	1460-1750	290
510-550	40	1760-2100	340
560-600	40	2110-2500	390
610-700	90	2510-3000	490
710-800	90	3010-3650	640
810-900	90	3660-4500	840
910-1000	90		

*Range = maximum minus minimum

were completed during the prephase with each member of the pediatric faculty and pediatric pharmacy resident at the central institution (Ernest Mario School of Pharmacy). Categories reviewed by the faculty included medication subsections, such as dose, preparation and administration, and remarks. The initial review contained a list of 67 intravenous and 61 oral medications. Several medications either had multiple indications (e.g., sodium bicarbonate for resuscitation and metabolic acidosis) or required a bolus plus maintenance dose (e.g., caffeine). Each indication, bolus, or maintenance dose required an individual review and was tallied based on medication/indication. The prephase process review resulted in an agreement of 184 medications/indications identified for use in this study.

The consensus process review phase consisted of 8 web conferences chaired by one of the authors (J.C.). Of the 184 medications/indications, the working group selected 74 medications/indications of significant and primary importance in the general neonatal population. A total of 17 weight categories with various predefined intervals, from 40 to 50 g for the lowest weights (e.g., 350-400 g) and 840 g for the highest weights (e.g., 3660-4500 g) were established (Table 1). The current roster was selected with particular consideration toward health care settings where trained neonatal/pediatric pharmacists or practitioners are not immediately available and where risk for neonatal medication errors is greatest (e.g., community birth center).⁶

On the basis of the 74 medications/indications, 3 routes of administration categories were identified. The great majority of the medications (86.5%) were classified as intermittent intravenous medications; an additional 5.4% were categorized as oral formulations; and the remaining

8.1% were categorized as “other” agents (e.g., intratracheal or intramuscular). Standardized dosing per weight strata was created for each of the 74 medications/indications. Workgroup and peer-review consensus was obtained when references provided inconclusive or insufficient data on medication information. A total of 84% of medications/indications had standard doses rounded within 15% of the corresponding weight-calculated dose, and 100% of standardized, rounded doses were within 20% of the corresponding weight-calculated dose.

DISCUSSION

A multi-institutional peer review process feasibly established standardized, rounded doses of medications commonly used in the NICU by use of a prephase review by a task force at a central institution followed by a comprehensive systematic review by a national expert workgroup. The consensus group represented more than 100 years of experience in the area of neonatology from 13 pediatric health care institutions throughout the United States. Significantly, the final roster of standardized, rounded doses for 74 essential neonatal medications and indications was clinically acceptable across regional and institutional pharmacologic and medical practices in neonatal-perinatal medicine. All standardized doses mathematically varied less than 20% from their corresponding weight-calculated doses, with the great majority differing less than 15%. The medications/indications listed in the current roster are not intended to be comprehensive for all pharmacologic therapies used in neonatal critical care medicine, but rather provide a resource for facilities, especially those that may not have access to trained neonatal/pediatric pharmacists

Table 2. Standardized Single Doses of Medication

Medication (Intravenous Unless Noted)																	
350-400	410-450	460-500	510-550	560-600	610-700	710-800	810-900	910-1000	1010-1200	1210-1450	1460-1750	1760-2100	2110-2500	2510-3000	3010-3650	3660-4500	
Acyclovir, mg	8	9	10	11	12	14	16	18	20	22	26	32	40	46	56	70	80
Adenosine first dose, mcg	40	45	50	55	60	70	80	90	100	110	130	160	200	230	280	350	400
Adenosine second dose, mcg	80	90	100	110	120	140	160	180	200	220	260	320	400	460	560	700	800
Adenosine third dose, mcg	120	135	150	165	180	210	240	270	300	330	390	480	600	690	840	1050	1200
Amikacin, mg	7.2	8.1	9	10	11	12	14	16	18	17	20	24	30	35	42	53	60
Amphotericin B: conventional, mg	0.4	0.45	0.5	0.55	0.6	0.7	0.8	0.9	1	1.1	1.3	1.6	2	2.3	2.8	3.5	4
Amphotericin B: Abelcet or Ambisome, mg	2	2.3	2.5	2.7	3	3.5	4	4.5	5	5.5	6.5	8	10	12	14	18	20
Ampicillin meningitis/severe GBS, mg	40	45	50	55	60	70	80	90	100	110	130	160	200	230	280	350	400
Ampicillin not meningitis/severe GBS, mg	20	22	25	27	30	35	40	45	50	55	65	80	100	115	140	165	200
Beractant LUNG, mL	1.6	1.8	2	2.2	2.4	2.8	3.2	3.6	4	4.4	5.2	6.4	8	9.2	11	14	16
Caffeine citrate load, mg	8	9	10	11	12	14	16	18	20	22	26	32	40	46	56	70	80
Caffeine citrate maintenance, mg	3.2	3.6	4	4.4	4.8	5.6	6.4	7.2	8	8.8	10	13	16	18	22	28	32
Calcium chloride, mg	8	9	10	11	12	14	16	18	20	22	26	32	40	46	56	70	80
Calcium gluconate, mg	40	45	50	55	60	70	80	90	100	110	130	160	200	230	280	350	400
Calfactant LUNG, mL	1.2	1.3	1.5	1.6	1.8	2.1	2.4	2.7	3	3.3	3.9	4.8	6	6.9	8.4	10	12
Cefazolin, mg	10	11	12	14	15	17	20	22	25	28	33	40	50	58	70	88	100
Cefepime, mg	20	22	25	27	30	35	40	45	50	55	65	80	100	115	140	165	200
Cefotaxime, mg	20	22	25	27	30	35	40	45	50	55	65	80	100	115	140	165	200
Ceftazidime, mg	20	22	25	27	30	35	40	45	50	55	65	80	100	115	140	165	200
Epinephrine, mg	0.01	0.015	0.015	0.015	0.015	0.02	0.02	0.025	0.03	0.03	0.04	0.05	0.06	0.07	0.08	0.1	0.12

Table 2. Standardized Single Doses of Medication (cont.)

Medication (Intravenous Unless Noted)																
350-400	410-450	460-500	510-550	560-600	610-700	710-800	810-900	910-1000	1010-1200	1210-1450	1460-1750	1760-2100	2110-2500	2510-3000	3010-3650	3660-4500
Fentanyl, mcg	0.4	0.4	0.5	0.6	0.7	0.8	0.9	1	1.1	1.3	1.6	2	2.3	2.8	3.5	4
Fluconazole prophylaxis, mg	2.4	2.7	3	3.3	3.6	4.2	4.8	5.4	6	6.6	7.8	9.6	12	14	17	24
Fluconazole treatment, mg	4.8	5.4	6	6.6	7.2	8.4	9.6	11	12	13	16	19	24	28	34	48
Fosphenytoin load PE, mg	7	9	10	11	12	13	15	17	19	22	27	32	37	44	53	80
Fosphenytoin maintenance PE, mg	1.5	1.7	1.9	2.1	2.3	2.6	3	3.4	3.8	4.4	5.3	6.3	7.4	8.8	10.6	16.2
Furosemide, mg	0.4	0.5	0.5	0.6	0.6	0.7	0.8	0.9	1	1	1.5	2	2	3	3	4
Ganciclovir, mg	2.4	2.7	3	3.3	3.6	4.2	4.8	5.4	6	6.6	8	10	12	14	17	24
Gentamicin, mg	2	2.3	2.5	2.8	3	3.5	4	4.5	5	4.4	5.2	6.4	8	9.2	11	16
Ibuprofen lysine first dose, mg	4	4.5	5	5.5	6	7	8	9	10	11	13	16	20	23	28	40
Ibuprofen lysine second and third doses, mg	2	2.3	2.5	2.8	3	3.5	4	4.5	5	5.5	6.5	8	10	12	14	20
Immunoglobulin, mg	300	335	375	400	450	525	600	675	750	825	975	1200	1500	1725	2100	3000
Indomethacin: postnatal age less than 12 hr, mg	0.04	0.045	0.05	0.055	0.06	0.07	0.08	0.09	0.1	0.11	0.13	0.16	0.2	0.23	0.28	0.4
Indomethacin: postnatal age 12-96 hr, mg	0.08	0.09	0.1	0.11	0.12	0.14	0.16	0.18	0.2	0.22	0.26	0.32	0.4	0.46	0.56	0.8
Indomethacin: postnatal age greater than 96 hr, mg	0.12	0.13	0.15	0.16	0.18	0.21	0.24	0.27	0.3	0.33	0.4	0.5	0.6	0.7	0.8	1
Lamivudine PO, mg	0.8	0.9	1	1.1	1.2	1.4	1.6	1.8	2	2.2	2.6	3.2	4	4.6	5.6	8
Lorazepam, mg	0.04	0.04	0.05	0.05	0.06	0.07	0.08	0.09	0.1	0.11	0.13	0.16	0.2	0.23	0.28	0.4
Meropenem, mg	16	18	20	22	24	28	32	36	40	45	50	60	80	100	120	160
Methadone, mg	0.04	0.04	0.05	0.05	0.06	0.07	0.08	0.09	0.1	0.11	0.13	0.16	0.2	0.23	0.28	0.4
Metronidazole load, mg	6	6.5	7.5	8	9	10	12	13	15	17	20	24	30	35	42	60

Table 2. Standardized Single Doses of Medication (cont.)

Medication (Intravenous Unless Noted)		Weight, g																
		350-400	410-450	460-500	510-550	560-600	610-700	710-800	810-900	910-1000	1010-1200	1210-1450	1460-1750	1760-2100	2110-2500	2510-3000	3010-3650	3660-4500
Metronidazole maintenance, mg		3	3.3	3.5	4	4.5	5	6	6.5	7.5	8	10	12	14	18	20	25	30
Midazolam, mg		0.04	0.04	0.05	0.05	0.06	0.07	0.08	0.09	0.1	0.11	0.13	0.16	0.2	0.23	0.28	0.35	0.4
Morphine, mg		0.04	0.04	0.05	0.05	0.06	0.07	0.08	0.09	0.1	0.11	0.13	0.16	0.2	0.23	0.28	0.35	0.4
Nafcillin meningitis, mg		20	22	25	27	30	35	40	45	50	55	65	80	100	115	140	165	200
Nafcillin not meningitis, mg		10	11	12	13	15	17	20	22	25	27	30	40	50	55	70	80	100
Naloxone partial reversal, mg		0.004	0.004	0.005	0.005	0.006	0.007	0.008	0.009	0.01	0.011	0.013	0.016	0.02	0.023	0.028	0.035	0.04
Naloxone total reversal, mg		0.04	0.04	0.05	0.05	0.06	0.07	0.08	0.09	0.1	0.11	0.13	0.16	0.2	0.23	0.28	0.35	0.4
Oxacillin meningitis, mg		20	22	25	27	30	35	40	45	50	55	65	80	100	115	140	165	200
Oxacillin not meningitis, mg		10	11	12	13	15	17	20	22	25	27	30	40	50	55	70	80	100
Palivizumab IM, mg		5	6	7	7.5	8.5	9.5	11	12	14	16	19	23	27	33	39	49	60
Pancuronium, mg		0.04	0.04	0.05	0.05	0.06	0.07	0.08	0.09	0.1	0.11	0.13	0.16	0.2	0.23	0.28	0.35	0.4
Penicillin G benz/proc IM syphilis, units		20,000	22,000	25,000	27,000	30,000	35,000	40,000	45,000	50,000	55,000	65,000	80,000	100,000	115,000	140,000	165,000	200,000
Penicillin G potassium syphilis, units		20,000	22,000	25,000	27,000	30,000	35,000	40,000	45,000	50,000	55,000	65,000	80,000	100,000	115,000	140,000	165,000	200,000
Penicillin G potassium bacteremia, units		20,000	22,000	25,000	27,000	30,000	35,000	40,000	45,000	50,000	55,000	65,000	80,000	100,000	115,000	140,000	165,000	200,000
Penicillin G potassium meningitis, units		40,000	44,000	50,000	54,000	60,000	70,000	80,000	90,000	100,000	110,000	130,000	160,000	200,000	230,000	280,000	330,000	400,000
Penicillin G potassium GBS, units		40,000	44,000	50,000	54,000	60,000	70,000	80,000	90,000	100,000	110,000	130,000	160,000	200,000	230,000	280,000	330,000	400,000
Pentobarbital, mg		0.7	0.8	0.9	1	1.2	1.3	1.5	1.7	1.9	2.2	2.7	3.2	3.7	4.4	5.3	6.6	8
Phenobarbital load, mg		7	9	10	11	12	13	15	17	19	22	27	32	37	44	53	66	80
Phenobarbital maintenance, mg		1.5	1.7	1.9	2.1	2.3	2.6	3	3.4	3.8	4.4	5.3	6.3	7.4	8.8	10.6	13.1	16.2
Phenytoin load,mg		7	9	10	11	12	13	15	17	19	22	27	32	37	44	53	66	80

Table 2. Standardized Single Doses of Medication (cont.)

Medication (Intravenous Unless Noted)		Weight, g																
		350-400	410-450	460-500	510-550	560-600	610-700	710-800	810-900	910-1000	1010-1200	1210-1450	1460-1750	1760-2100	2110-2500	2510-3000	3010-3650	3660-4500
Phenytoin maintenance, mg		1.5	1.7	1.9	2.1	2.3	2.6	3	3.4	3.8	4.4	5.3	6.3	7.4	8.8	10.6	13.1	16.2
Phytonadione IM, mg		0.1	0.15	0.15	0.15	0.18	0.2	0.2	0.25	0.3	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Piperacillin, mg		40	44	50	54	60	70	80	90	100	110	130	160	200	230	280	330	400
Piperacillin-Tazobactam (mg piperacillin)		40	44	50	54	60	70	80	90	100	110	130	160	200	230	280	330	400
Poractant alfa LUNG first dose, mL		1	1.1	1.2	1.4	1.5	1.8	2	2.3	2.5	2.8	3.3	4	5	6	7	9	10
Poractant alfa LUNG second and third doses, mL		0.5	0.6	0.6	0.7	0.8	0.9	1	1.1	1.2	1.4	1.6	2	2.5	3	3.5	4.5	5
Ranitidine, mg		0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.5	0.6	0.7	0.8	0.9	1	1.5	5	6
Rifampin, mg		4	4.4	5	5.4	6	7	8	9	10	11	13	16	20	23	28	33	40
Sildenafil PO, mg		0.2	0.225	0.25	0.275	0.3	0.35	0.4	0.45	0.5	0.55	0.65	0.8	1	1.15	1.4	1.75	2
Sodium bicarbonate, mEq		0.4	0.4	0.5	0.5	0.6	0.7	0.8	0.9	1	1.1	1.3	1.6	2	2.3	2.8	3.5	4
Tobramycin, mg		2	2.3	2.5	2.8	3	3.5	4	4.5	5	4.4	5.2	6.4	8	9.2	11	14	16
Vancomycin, mg		6	6.8	7.5	8.2	9	10	12	14	15	17	20	24	30	35	42	50	60
Zidovudine PO GA less than 35 wk, mg		0.8	0.9	1	1.1	1.2	1.4	1.6	1.8	2	2.2	2.6	3	3.6	4.6	5.6	7	8
Zidovudine PO GA 35 wk and over, mg		1.6	1.8	2	2.2	2.4	2.8	3.2	3.6	4	4.4	5.2	6	7.2	9.2	11	14	16
Zidovudine, mg		0.6	0.7	0.7	0.8	0.9	1	1.2	1.3	1.5	1.7	2	2.4	3	3.5	4.2	5.3	6

GBS, group B streptococcus; LUNG, intratracheal; PE, phenytoin equivalent; PO, oral; IM, intramuscular; benz/proc, benzathine/procaine; mEq, milliequivalents

GA, gestational age; GBS, group B streptococcus; LUNG, intratracheal; PE, phenytoin equivalent; PO, oral; IM, intramuscular; benz/proc, benzathine/procaine; mEq, milliequivalents

and practitioners. Whether this percent difference may be deemed significant for medications and indications not included cannot be assumed and would require additional review.

In 2007, only 74.7% of very low birth weight infants (<1500 g) were delivered at facilities designated at the highest level of care for high-risk neonates (i.e., Level III) in the United States.¹¹ These numbers would be expected to be lower when considering neonates of all birth weights. At institutions without at least a Level III NICU, trained neonatal/pediatric pharmacists and practitioners are generally not immediately or systematically available, significantly increasing the risk for neonatal medication errors and poorer outcomes.^{6,12} Given that first-contact critical care for ill neonates may occur at institutions without at least a Level III NICU, resources to assist and ensure appropriate neonatal medication usage and dosing are essential.

To our knowledge this project is the first aimed at establishing an approach to standardized drug dosing in the neonatal population. MacKay et al¹³ describe the development of pediatric standard doses for 11 oral medications; however, neonatal patients, especially low birthweight ones, are not specifically addressed. Johnson et al¹⁴ created a list of commonly prescribed medications with dose-rounding information for the pediatric population. Johnson and colleagues¹⁴ adapted the Delphi model and recruited a group of national experts to complete the consensus of dose-rounding recommendations. In contrast, this project used the nominal group technique and listed individual standard drug doses with the neonate's respective weight. Although our project did not focus on incorporating the neonatal standardized doses for e-prescribing, the data provided in Table 2 can be integrated into this technology.

The current project focused on the 74 essential medications/indications in neonatal medicine, as determined by its expert workgroup. Expansion of this roster to include additional medications and indications will be considered in the near future. Like pediatric patients, neonates pose a unique challenge regarding the need for weight-based dosing calculations and precise measurements.⁵ Standardized dosing is a strategy to reduce medication errors, and we hope this project proves the feasibility of establishing

standard doses in the NICU setting, particularly in health care settings where an experienced pediatric or neonatal pharmacist or practitioner is not immediately available.

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Abbreviations ADE, adverse drug event; NICU, neonatal intensive care unit; PPAG, Pediatric Pharmacy Advocacy Group

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