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Parenteral Beta-Lactam/Beta-Lactamase Inhibitor Ordering in Hospitals That Provide Care for Pediatric Patients

Kristen R. Nichols, PharmD; Emily N. Israel, PharmD; Nicolette A. Gordon, PharmD Candidate; Darcie D. Streetman, PharmD; Nathan S. Walleser, PharmD; and Chad A. Knoderer, PharmD

OBJECTIVES The purpose of this study was to define current practices related to beta-lactam/beta-lactamase inhibitor (BL/BLI) dose descriptions in hospitals that provide care for pediatric patients and to identify perceived implications of standardizing BL/BLI dose communication and ordering to a total drug-based strategy.

METHODS A 27-item electronic survey was distributed via 4 pediatric pharmacy and infectious diseases listservs. Survey questions pertained to hospital demographics, dosing communication practices, BL/BLI ordering and labeling practices, obstacles to safe BL/BLI use, and the effects of potential standardization to a total drug communication strategy. SPSS was used for quantitative analysis and MAXQDA was used for qualitative analysis.

RESULTS A total of 140 unique survey responses were analyzed after exclusion of incomplete responses and reconciliation of multiple responses from the same institution. Overall, 56.2% of institutions order BL/BLIs by BL component for pediatric patients, and 22% of institutions order by BL component for adult patients. Approximately half (51.8%) of respondents felt that standardizing to total drug would have a negative effect at their institution; perception of potential effect varied based on the institution's ordering strategy.

CONCLUSION Communication and ordering of BL/BLIs is inconsistent across institutions and between pediatric and adult patients. In the short term, the perception is that standardization would compound institutional challenges.

ABBREVIATIONS BL, beta-lactam; BLI, beta-lactamase inhibitor; CPOE, computerized prescriber order entry; EHR, electronic health record; FDA, US Food and Drug Administration

KEYWORDS beta-lactam; combination drug; informatics; medication safety

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Introduction

Communication of drug dosages for pediatric patients is less straightforward than for adults. Doses may be described based on weight (e.g., mg per kg per dose, mg per kg per day), flat doses (e.g., mg), or even in liquid volumes. Combination drugs (i.e., products containing 2 or more drugs within 1 dosage form) may present additional complexity because doses may be calculated off either drug component or a sum of components.

Beta-lactam/beta-lactamase inhibitors (BL/BLIs) are combination drugs commonly used in both adult and pediatric patients; the BLI is included to overcome inactivation of the BL by bacterial beta-lactamase enzymes. The method of reporting doses for parenteral BL/BLIs varies. In adults, doses of parenteral BL/BLIs (e.g., ampicillin/sulbactam) are typically described in terms of total drug (i.e., the sum of the strength of the BL and BLI). In pediatric patients, they are typically described in terms of the BL component only, which works because only 1 product ratio is available for each combination in the United States. However, even among pediatric patients or BL/BLI options, communication of the dose can vary. This situation can be contrasted with that of amoxicillin/clavulanate, of which multiple products with varying amoxicillin to clavulanate ratios are available, and for which doses are communicated in amoxicillin component for both adult and pediatric patients.

Descriptions of pediatric BL/BLI dosing vary among manufacturer's labeling for different products and across tertiary dosing references. The manufacturer's labeling for the first parenteral BL/BLI approved in the United States, ticarcillin/clavulanate (Timentin), described adult doses in terms of total drug (mg ticarcillin + mg clavulanate = total mg recommended per dose),

with milligrams of the individual components provided in parentheses. When pediatric dosing was added, it was described in terms of BL component (mg per kg of ticarcillin); the US Food and Drug Administration (FDA)–approved dose of ticarcillin/clavulanate (now discontinued) was "200 mg/kg/day based on ticarcillin content in divided doses every 6 hours."[1] This pattern was also observed with piperacillin/tazobactam until 2020, when product labeling was updated.[2–4] Product labeling for ampicillin/sulbactam, ceftazidime/avibactam, and ceftolozane/tazobactam provides dosing using a total drug scheme, with component doses following in parentheses.[2,5,6] In literature and practice, parenteral BL/BLIs doses are often communicated as BL component for pediatrics and total drug for adults. Some tertiary dosing references follow this pattern consistently, whereas some vary, likely due to matching the source document (Table 1).

Communicating BL/BLI dosing differently for pediatrics and adults, by BL component or total drug, can lead to confusion and potential medication errors. It is unknown if pediatric ordering strategies differ by type of institution and whether that institution also provides care for adult patients. The purpose of this study was to describe current practices related to BL/BLI dose recommendations and ordering in hospitals providing care for pediatric patients and to identify perceived implications of standardizing dose communication and ordering for BL/BLI antibiotics to a total drug strategy.

Materials and Methods

A cross-sectional survey was conducted in 2022 to determine practices related to BL/BLI dose recommendations and ordering in hospitals that provide care for pediatric patients. This survey focused on parenteral BL/BLI available in the United States at the time of the survey.

The electronic survey was created in the Qualtrics platform (Qualtrics Inc, Provo, UT) and included 27 total items. Conditional logic was employed to improve the applicability of items to participants and to decrease completion time. Survey items included open-ended and multiple-choice questions and response matrices. Facility name and location were collected to reconcile or eliminate duplicate responses, and additional facility-specific questions identified institution type, number of beds, and use of technology (i.e., electronic health record [EHR] and infusion pump software). Reference-centered questions focused on internal and external references used for parenteral antibiotic dosing. Questions related to the format in which parenteral BL/BLI antibiotics are ordered and labeled at the respondent's institution (ie, in total drug or BL component) formed the bulk of the survey. Free text responses allowed respondents to describe challenges associated with safe parenteral BL/BLI use at their institution and to comment on the potential effect of changes in the way doses are described in references or ordered.

The survey was distributed electronically and it targeted primarily pharmacists who work in institutions caring for hospitalized pediatric patients. The survey was distributed to Pediatric Pharmacy Association members, the American College of Clinical Pharmacy Pediatric Practice and Research Network listserv, the American College of Clinical Pharmacy Infectious Diseases Practice and Research Network listserv, and the Washington University Pediatric Infectious Diseases Listserv. The survey was distributed in March 2022, with a reminder email sent 2 weeks after initial communication, and remained open for 6 weeks.

Data were exported from Qualtrics into SPSS Statistical Software (IBM Corp, Armonk, NY) for quantitative analysis. Responses from duplicate institutions were reconciled using facility name and location. If multiple responses from the same institution were concordant, only 1 was included in the analysis. If multiple respondents from the same institution provided discordant responses (e.g., different EHR systems, different ways of ordering), all responses from that institution were excluded from further analysis. Responses with survey completion <50% were excluded. Data were analyzed descriptively and inferentially, comparing responses based on type of institution or method of BL/BLI ordering using χ^2 analysis.

For qualitative analysis of free-text responses, data were exported into MAXQDA (VERBI Software, Berlin, Germany). Responses were read and thematically tagged by 1 investigator, with a second investigator performing independent verification. Data were analyzed to evaluate the frequency of various themes and association with institution factors; the number of individual institutions providing responses was used as the denominator, but each response could result in multiple coded segments (e.g., 1 response for BL/BLI ordering obstacles could have resulted in 3 different obstacles: newer BL/BLIs, maximum doses, and rotating prescribers).

Results

A total of 261 total responses were received. A total of 64 incomplete responses were excluded from further analysis, leaving 197 responses for evaluation. For quantitative analysis of survey questions for which there were discrete choices, 23 responses were from duplicate institutions and could not be reconciled because of conflicts, and 54 individual responses from 20 institutions were reconciled into 20 responses. This left 140 unique responses for analysis. Responses were from individuals practicing at free-standing children's hospitals (n = 53; 37.9%), children's hospitals within adult hospitals (n = 58; 41.4%), and adult hospitals with pediatric beds (n = 29; 20.7%). Of free-standing children's hospitals, 54.7% (n = 29) indicated that they were

Table 1. Dose Recommendations for Beta-Lactam/Beta-Lactamase Inhibitor (BL/BLI) in Common Dosing References

Reference	Group	Ampicillin/ Sulbactam	Ceftazidime/ Avibactam	Ceftolozane/ Tazobactam	Piperacillin/ Tazobactam
Manufacturer's labeling[2,5–7]	Pediatric	Total drug, followed by explanation of amounts of each component per total	Total drug followed by each component in highlights and dosing paragraph	Total drug only	Total drug, followed by each component in parentheses
	Adult	Total drug followed by each component in parentheses	Mix: total drug followed by each component in highlights, dosing paragraph, and renal dosing table; total drug only in dosing table	Mix: total drug only in highlights and dosing table; total drug followed by each component in parentheses in dosing paragraph and renal dosing table	Total drug followed by each component in parentheses in some places, only total drug in others (renal impairment section)
Lexicomp[8–11]	Pediatric	BL component (neonatal and pediatric)	BL component (pediatric; no neonatal dosing)	BL component (neonatal and pediatric)	BL component (neonatal and pediatric)
	Adult	Total drug	Total drug	Total drug	Total drug
Micromedex[12–15]	Pediatric	Total drug (pediatric)	Total drug followed by each component in parentheses (pediatric)	Total drug only for weight-based dosing; two-thirds maximum doses use total drug followed by each component in parentheses (pediatric); total drug only (neonatal)	Mix: weight-based doses contain both components, flat doses for larger patients total drug only (pediatric) BL component only (neonatal)
	Adult	Mix: total drug only for some indications, total drug followed by each component in parentheses for some indications; sulbactam only for some maximum doses	Total drug followed by each component in parentheses	Total drug followed by each component in parentheses	Mix: mostly total drug, but some indications and maximum doses provide both components
AAP Red Book[16–18]	Pediatric	BL component (pediatric)	Both components (pediatric; no neonatal dosing)	—	BL component (pediatric and neonatal)
Sanford Guide[19–21]	Pediatric	Unclear (appears to be in BL component) (pediatric)	Mix: total drug followed by each component in parentheses; total drug only in renal dosing table (pediatric)	—	Unclear (appears to be in BL component) (pediatric)
	Adult	Total drug followed by each component in parentheses	Total drug only	Total drug only	Total drug

AAP, American Academy of Pediatrics

affiliated with a health system that also provides care for adults. The median (IQR) number of pediatric/neonatal beds reported by free-standing children's hospitals was 310 (159.5–443) with 335 (180.54–55.75) total beds; free-standing children's hospitals as part of a health system reported 250 (143.5–311.75) pediatric beds and 315 (233–830.5) total beds; children's hospitals within adult hospitals reported 107 (82.25–149) pediatric beds and 642 (450–804.5) total beds; and adult hospitals reported 50 (33.75–70.75) pediatric beds and 382.5 (243.25–562.5) total beds. Responses were from 44 US states and the District of Columbia (99.3%; n = 139), and Canada (n = 1).

All respondents reported using an EHR with medication orders entered via computerized prescriber order entry (CPOE). Epic was the EHR used by most individuals (67.1%; n = 94), followed by Cerner (25.7%; n = 36); the remainder used Sunrise, Allscripts, or Meditech. Most respondents use BD Alaris smart infusion pump software (64.3%; n = 90/137), with the remainder reporting a variety of vendors, including Medfusion, Spectrum IQ, B. Braun, and a combination. Order sets, guidelines, and intranet pages were the most common sources of internal antibiotic dosing recommendations (Table 2). Lexicomp was the most reported external dosing reference (Table 3); all children's hospitals reported use of Lexicomp, compared with 83.3% (n = 25/30) of adult hospitals with pediatric beds. Micromedex (and/or Neofax) use was reported in 61.3% of children's hospitals (n = 68) and 72.4% (n = 21) of adult hospitals.

Table 2. Reported Sources for Internal Antibiotic Dosing Recommendations

Recommendation Format	Responses, n (%)*
Order sets	126 (90)
Institutional guidelines	99 (70.7)
Order sentences	63 (45)
Formularies	56 (40)
Intranet page	45 (32.1)
System guidelines	39 (27.9)
Other†	13 (9.3)

* Respondents could select more than one response

† Other mechanisms for internal recommendations included physical dosing cards, links within the electronic health record, apps (e.g., Firstline), pharmacist antibiotic dosing protocol, and interaction with pharmacists.

Table 3. External Antibiotic Dosing References Reported

Reference	Respondents Selecting, n (%)*
Lexicomp	136 (97.1)
Micromedex	89 (63.6)
AAP Red Book	63 (45)
Sanford Guide	31 (22.1)
Harriet Lane Handbook	21 (15)
Nelson's Pediatric Antimicrobial Therapy Handbook	13 (9.3)
Clinical Pharmacology	9 (6.4)
Other†	2 (1.4)

* Respondents could select more than 1 response.

† Other external references included guidelines, Johns Hopkins Antimicrobial Guide, and the Firstline app.

Overall, 56.2% (n = 77/137) reported ordering BL/BLIs in pediatrics based on BL component and 14.6% (n = 20) based on total drug (Table 4). For 24.1% (n = 33) of respondents, BL/BLIs are ordered in BL component for patients under a certain weight and total drug for patients over that weight. Ordering varies based on the specific BL/BLI for 5.1% of respondents (n = 7).

When BL/BLIs are ordered in total drug for pediatric patients, 75% of respondents (n = 15/20) indicated that some assistance with conversion from BL component is provided, either in CPOE at the time of order entry (n = 11), through internal recommendations (n = 1), or as a comment within the drug order (n = 3). In pediatrics, 50.8% (n = 65/128) of respondents label products (physical intravenous bag or syringe) in the BL component, 37.5% (n = 48) label in total drug, and 11.7% (n = 15) say it is drug dependent. In adults, doses included on the physical product labeling are in total drug for 79.2% (n = 99), BL component for 17.6% (n = 22), and drug dependent for 3.2% (n = 4).

A total of 62 respondents provided free-text responses regarding encountered obstacles at their institutions when dosing, ordering, or administering parenteral BL/BLIs. These resulted in 81 total coded obstacle responses. Confusion about ordering by BL or total drug was most common (29.6%), followed by education of prescribers (16.1%), new/rotating prescribers (12.4%), maximum doses or exceeding maximum doses (11.1%), medication errors (9.9%), and accommodating newly approved BL/BLIs (3.7%). Other coded obstacles included extended infusions, infusion pump interoperability challenges, CPOE auto-adjustments, dose rounding, drug shortages, premade adult products, non-formulary drugs, sharing CPOE with the adult system, and different ordering processes for pediatric and adult patients.

If dosing references (eg, AAP Red Book, Lexicomp, Micromedex) made a wholesale change to provide all BL/BLI doses in terms of total drug, only 27.7% of respondents (n = 31/112) felt that this would result in a positive effect at their institution; 51.8% (n = 58) felt that it would result in a negative effect, and 20.5% (n = 23)

Table 4. Beta-Lactam/Beta-Lactamase Inhibitor (BL/BLI) Ordering

Institution Type	BL/BLI Ordering for Pediatric Patients, % (n)					BL/BLI Ordering for Adult Patients, % (n)				
	n*	BL Component	Total Drug	Depends on Patient Weight	Depends on Specific Antibiotic	n*	BL Component	Total Drug	Depends on Specific Antibiotic
Free-standing children's hospital	24	79.2 (19)	12.5 (3)	8.3 (2)	—	22	68.2 (15)	31.8 (7)	—
Free-standing children's hospital within health system	29	65.5 (19)	13.8 (4)	17.2 (5)	3.4 (1)	26	30.8 (8)	57.7 (15)	11.5 (3)
Children's hospital within adult hospital	57	47.4 (27)	12.3 (7)	35.1 (20)	5.3 (3)	54	7.4 (4)	88.9 (48)	3.7 (2)
Pediatric beds within adult hospital	27	44.4 (12)	22.2 (6)	22.2 (6)	11.1 (3)	25	4 (1)	96 (24)	0
Overall	137*	56.2 (77)	14.6 (20)	24.1 (33)	5.1 (7)	127*	22 (28)	74 (94)	3.9 (5)

* Not all survey respondents provided responses for these items.

felt that the effect would be neutral. More respondents (31.8%; n = 29/91) from adult hospitals, children's hospitals within adult hospitals, or free-standing children's hospitals affiliated with health systems that include adult hospitals felt that changing references to provide BL/BLI doses in total drug would result in a positive effect compared with respondents from free-standing children's hospitals (9.5%; n = 2/21; p = 0.039).

The perceived effect of dosing references providing all doses in terms of total drug varied based on how BL/BLIs are ordered at the institution; 12.5% (n = 8/64) of institutions that order by BL component for pediatric patients felt that this would result in positive effect as compared with 87.5% (n = 14/16; p < 0.001) of institutions that order by total drug. Similarly, none of the 27 institutions that order by BL component for adults felt that reference standardization would result in a positive effect, compared with 38.8% (n = 31/80) of institutions that order by total drug.

A total of 74 respondents provided free-text descriptions of the anticipated effect if all dosing references presented doses in total drug as the standard. These responses resulted in 109 coded effects. The most common anticipated effects included confusion (20.2%), need to rebuild existing systems (18.4%), need for a practice shift (15.6%), and need to provide education (9.2%). Respondents were mixed in terms of whether standardization would increase medication errors (7.3%) and confusion (20.2%) or improve appropriateness/consistency of ordering (9.2%), decrease confusion (5.5%), reduce medication errors (4.6%), and prevent underdosing (2.8%). Other potential effects mentioned were exceeding maximum doses and conflict with guideline recommendations if they continue to recommend doses in terms of BL component.

Discussion

Survey responses, reflecting a variety of hospital sizes and types, indicate there is no standard for ordering BL/BLI antibiotics as BL component or total drug. For pediatric patients, more than half of institutions report ordering by BL component, with an additional quarter ordering in BL component for smaller patients and total drug in larger patients. In contrast, BL/BLI antibiotics are more often ordered in terms of total drug in adults, with nearly three fourths of institutions reporting this method. Unsurprisingly, adult doses tend to be ordered in total drug because drug product labeling is also reflective of total drug. These fixed doses are easier to remember and communicate than weight-based doses of BL components. Free-standing children's hospitals, conversely, order doses for both pediatric and adult patients in BL component (79.2% and 68.2%, respectively). This likely reflects the tendency for pediatric dosing recommendations in the literature and dosing references to be based on BL component, whereas in adult literature and references, they are communicated in total drug.

Communication of BL/BLI antibiotic doses is a complex issue, affecting many aspects of patient care, from ordering to product labeling. There is no established standard, and as observed in our survey, practices vary widely. Survey respondents reported a lack of clarity around best practices and concern for potential for drug errors related to BL/BLI practices. Prescribers who practice at multiple institutions (e.g., medical trainees) may be unaware that ordering processes differ across the health system and may incorrectly apply one method uniformly, increasing risk for error. Because a range of weight-based doses may be appropriate for a specific pediatric patient, depending on indication and clinical factors, misdosing may go unnoticed by other health care providers (i.e., pharmacists) and patients may receive more or less than the intended dose. Differences in strategy between tertiary references and hospital-specific systems or product labeling may create more ambiguity related to BL dosing, especially if it is unclear whether automatic conversion from one method to another is provided within the her. Confusion may also occur in larger pediatric patients, including those near or above the weight at which adult doses become appropriate. Many respondents commented on the challenges associated with larger pediatric patients and capping doses at usual adult values.

Manufacturers' labeling and dosing references describe BL/BLI doses in a variety of ways, and multiple presentations exist even within the same reference (Table 1). To our knowledge, specific recommendations on dose communication for BL/BLIs from professional organizations or regulatory bodies are not available. In 2015, errors were reported because of vial and carton labels of ceftazidime/avibactam displaying the amount of each component in the vial without including the total drug amount. The labels were then revised to include the total drug content (2.5 g) in addition to the amount of each component separately (ceftazidime 2 g and avibactam 0.5 g).[22,23] No additional published reports on this issue were available at time of manuscript preparation. The FDA does not offer any guidance or resources on the communication of BLI/BLI doses (FDA Center for Drug Evaluation and Research, Division of Drug Information, personal communication, July 27, 2023).

Communicating doses of parenteral BL/BLI using total drug plus amount of each component may improve clarity. However, this approach would lengthen provided information, potentially making it more difficult to efficiently identify the most appropriate dose and increasing the risk that the wrong number is read and then prescribed. For example, piperacillin/tazobactam 75 mg piperacillin/kg/dose every 6 hours becomes piperacillin/tazobactam 84.4 mg/kg/dose (piperacillin 75 mg/kg and tazobactam 9.4 mg/kg) every 6 hours. Providing pediatric doses in terms of the BL component allows for brevity when including doses in references, guidelines, or articles, although many authors and organizations could be clearer in specifying whether the dose provided represents total drug, BL component, or something else. If parenteral BL/BLIs were available in more than 1 ratio, it would be necessary to specify dose of each component.

Respondents expressed many obstacles related to current state for dosing, ordering, or administering parenteral BL/BLIs safely. Prescriber confusion, including adequate understanding and education about the issues as well as practitioners rotating through different hospitals, was noted by nearly two thirds of respondents. This highlights the need for internal and external references and systems to be clear and consistent with respect to which dose (BL or total drug) is being communicated. Although education of prescribers is one way to decrease confusion, higher level strategies, such as standardization, are required. Standardization affects pharmacists, nurses, and prescribers and must span the entire medication use process, including product labeling, prescribing, order verification, dispensing, and administration. Our survey results highlight difficulties related to standardization. In one institution, dosing was expressed differently based on product dispensed; doses dispensed in syringes were expressed as the BL component, whereas intravenous piggybacks were expressed as total drug. Some respondents reported discrepancies with newer BL/BLIs compared with older products, or that newer options are yet not built in the system at all. Several respondents emphasized how the free-text input of non-formulary drugs that may not yet have pediatric dosing recommendations (e.g., meropenem/vaborbactam) can be problematic. Other systems issues identified by respondents included sharing CPOE systems with adults (where the adult approach is then applied also to pediatric patients), lack of clarity/transparency regarding automatic dosing conversions occurring within CPOE systems, consistency with embedded dosing checks, infusion pump software limitations, and inability of systems to automatically cap doses. Internal resources for customization may be limited.

Unsurprisingly, respondents prefer dosing references to match their institution's method of ordering. Because practices are so mixed, standardization, whether in references or in institutional ordering and labeling processes, would require some hospitals to change. If standardization to communication via total drug occurred, free-standing children's hospitals would be disproportionately affected because these institutions most commonly order by BL component. The burden would mostly fall on each institution to address these operational issues with internal procedures and education.

Many respondents feared increased confusion and the significant need for labor and education should standardization occur. Updates would be required for internal documents (e.g., order sets, order entries, clinical guidelines), systems (CPOE/EHR builds and calculations, embedded dosing alerts, medication labels), and infusion pump software. Strong educational efforts to highlight the change for pharmacy, nursing, and medical staff would be needed; this would take significant resources and would be prioritized against competing workload needs. Even with these efforts, respondents fear increased risk of medication errors, at least in the short term, including at order entry and medication preparation steps, possibly contributing to underdosing or overdosing. One respondent pointed out that the transition time may be treacherous, because health care providers may have access to older internal guidance or hard-copy reference books. The expected effects have a range, with many respondents reporting that standardization would *decrease* confusion and medication errors, and others reporting that it would *increase* confusion and medication errors, causing "lots of problems." Multiple respondents indicated that the initial increase in confusion would abate—that new dosing would be learned, and that providers would soon be more comfortable with dosing in total drug. In the words of one respondent, it would be "likely short-term pain but long-term gain."

Conclusion

Standardizing how doses of parenteral BL/BLIs are communicated (i.e., in BL component, total drug, or a combination) is one strategy to decrease confusion around BL/BLI dosing. Our survey indicates that standardization would present many challenges for organizations. It would be a large undertaking and would require guidance and leadership from professional organizations and/or regulatory agencies following an in-depth assessment of the issue. It seems unlikely that this would occur given the long-standing history of the problem and the unclear benefits of standardization. Because there is a mix of practices, standardization would require many institutions to change their practice, potentially causing confusion and increasing the risk of errors in the short term.

Article Information

Affiliations. Wolters Kluwer Health (KRN, DDS), Hudson, Ohio; College of Pharmacy (ENI), Purdue University, Lafayette IN; College of Pharmacy and Health Sciences (NAG, CAK), Butler University, Indianapolis, IN; Medication Safety (NSW), Indiana University Health.

Correspondence. Chad Knoderer, PharmD, FPPA; cknodere@butler.edu

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