Automated Dose-Rounding Recommendations for Pediatric Medications

WHAT'S KNOWN ON THIS SUBJECT: Pediatric electronic-prescribing systems improve care by providing weight-based dose calculations. However, they often generate liquid medication doses that are difficult for families or caregivers to measure and administer accurately and do not consider dosing guidelines of the prescribed drug.

WHAT THIS STUDY ADDS: This study provides evidence-based and expert-validated rounding recommendations. These data are usable by commercial vendors to improve the rounding capabilities of electronic-prescribing systems. This process should continue with infrequently prescribed medications to improve pediatric prescribing safety.

abstract

BACKGROUND: Although pediatric electronic prescribing systems are increasingly being used in pediatric care, many of these systems lack the clinical decision-support infrastructure needed to calculate a safe and effective rounded medication dose. This infrastructure is required to facilitate tailoring of established dosing guidance while maintaining the medication's therapeutic intent.

OBJECTIVE: The goal of this project was to establish best practices for generating an appropriate medication dose and to create an interoperable rounding knowledge base combining best practices and dose-rounding information.

METHODS: We interviewed 19 pediatric health care and pediatric pharmacy experts and conducted a literature review. After using these data to construct initial rounding tolerances, we used a Delphi process to achieve consensus about the rounding tolerance for each commonly prescribed medication.

RESULTS: Three categories for medication-rounding philosophy emerged from our literature review: (1) medications for which rounding is used judiciously to retain the intended effect; (2) medications that are rounded with attention to potential unintended effects; and (3) medications that are rarely rounded because of the potential for toxicity. We assigned a small subset of medications to a fourth category—inadequate data—for which there was insufficient information to provide rounding recommendations. For all 102 medications, we were able to arrive at a consensus recommendation for rounding a given calculated dose.

CONCLUSIONS: Results of this study provide the pediatric information technology community with a primary set of recommended rounding tolerances for commonly prescribed drugs. The interoperable knowledge base developed here can be integrated with existing and developing electronic prescribing systems, potentially improving prescribing safety and reducing cognitive workload. *Pediatrics* 2011;128:e422–e428

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KEY WORDS

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ABBREVIATION

e-prescribing—electronic prescribing

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Pediatric prescribing is a complicated process that requires the prescriber to calculate a medication dose that is appropriate for the treatment goals and for the child's weight or body surface area.[1] Although some medications are relatively tolerant of inaccurate dosing, others that have narrow therapeutic indices, such as digoxin or insulin, have a great potential for adverse consequences if dosed improperly.[2–4] This process is sufficiently complicated that most pediatricians rely on prescribing guides in print or electronic form to practice safely.[5,6] Emerging therapies with less well-published dosing guidelines also make safe and effective pediatric prescribing difficult.[5,7]

Electronic prescribing (e-prescribing) has become a national initiative supported by the Centers for Medicare & Medicaid Services, the Institute of Medicine, the American Academy of Pediatrics, and other professional societies and organizations. In part, this support has been facilitated by mounting evidence about prescribing errors that have been well summarized[8–10] and that promise to improve the rate of medication errors in pediatrics.[1,11,12]

There are less data to support the use of e-prescribing in the ambulatory pediatric community,[13] despite the challenges associated with pediatric patient medication management.[14] A study by Kaushal et al[15] noted the potential for e-prescribing to prevent up to 21% of adverse drug events in outpatient settings, including those related to drug frequency and weight/dose checks. Most e-prescribing systems do not generate easily administered (rounded) doses. Therefore, these systems often require clinicians to edit the computed dose, increasing the risk of introducing dosing errors.[16] In addition, there is no validated resource containing knowledge about the appropriate rounding tolerances for different pediatric medications. There also is no established approach for generating a rounded dose that is easily administered by patients; therefore, it is difficult for e-prescribing systems to adopt a rounding algorithm with the currently available knowledge. The goal of this project was to establish best practices for generating an appropriate medication dose and to create an interoperable rounding knowledge base combining best practices and dose-rounding information.

METHODS

To address the project goals, we relied on information from interviews and a literature review. We also used a consensus-based process to validate proposed rounding tolerances.

Interviews

We conducted semi-structured interviews to assess the overall considerations used in rounding prescribed medications. We used a purposive sampling plan to recruit subjects who included local and national experts in general pediatrics, subspecialty pediatrics, pediatric pharmacy, biomedical informatics, and pharmacology. The sampling plan focused primarily on ambulatory locations, where medication dosing takes into account the needs of home caregivers who must measure and administer the medication.

A member of the project team provided a brief project overview to each domain expert before the interview. Each interview started with a recapitulation of the project goals, and then focused the interview around 3 framing questions: "Please describe how you create a prescription where the effects, both intentional and unintentional, are related to the dose"; "Please describe the process for prescribing a compound medication"; and "What is your process for rounding?" All interviews were transcribed and posted to a project Wiki site (www.dokuwiki.org) with restricted access for review and discussion among project team members. An iterative process based on discussion and revision of rounding techniques was used to focus and refine subsequent interviews. Results from the interviews were used to help define practical approaches to rounding and to develop a framework for categorizing medications according to the usual rounding philosophy as described by our experts.

Literature Review

We reviewed pharmacologic information for 120 medications that comprised >95% of the most commonly prescribed pediatric medications in 2 academic medical centers.[17] We collected weight-based dosing guidelines, minimum and maximum dosing amounts, and drug toxicity or adverse effect information from a series of commonly cited articles and texts.[18–20] We also consulted the gray literature, including Web resources and the US Food and Drug Administration Web site, for information about some medications. Using the framework developed in the interview phase, we evaluated dosing knowledge for each medication and assigned it to a category within this framework. We used the properties of the assigned rounding category, along with dosing information from domain experts and information about the drug's therapeutic intent and potential adverse reactions obtained from the literature review, to propose an initial rounding percentage.

Rounding Percentage Validation

We used a Delphi approach aimed at generating consensus about each rounding recommendation. This technique works well "to correlate informed judgments on a topic spanning a wide range of disciplines."[21] In our project, this model for consensus

TABLE 1 Rounding Survey Sample Question

Pretend you have a patient who is being prescribed a dose of each medication below. You have calculated this dose using standard milligram per kilogram per day formulae and arrive at 5.82 mL/dose, and there is only 1 formulation to choose from. The e-prescribing system you use returns a rounded dose, based on ease of home administration.
If the medication allows 0% rounding, the dose will be 5.8 mL.
If the medication allows 1% rounding, the dose will be between 5.7 and 5.9 mL. You would likely pick 5.9 mL.
If the medication allows 5% rounding, the dose will be between 5.5 and 5.9 mL. You would likely pick 5.9 mL.
If the medication allows 10% rounding, the dose will be between 5.2 and 6.4 mL. You would likely pick 6 mL.
If the medication allows 15% rounding, the dose will be between 4.9 and 6.7 mL. You would likely pick 6 mL.
Give these choices, for each drug below, do you agree or disagree with the maximum amount we would suggest to allow rounding?
Digoxin. Do not round further; okay?
Must provide value
Calcitriol. Do not round further; okay?
Must provide value
Ondansetron (Zofran). Do not round further; okay?
Must provide value
Morphine. Do not round further; okay?
Must provide value
Tylenol with codeine, round by 5%; okay?
Must provide value
Clarithromycin (Biaxin), round by 5%; okay?
Must provide value
Diphenhydramine, round by 5%; okay?
Must provide value
Griseofulvin, round by 10%; okay?
Must provide value
Penicillin, round by 15%; okay?
Must provide value
Guaifenesin/dextromethorphan, round by 15%; okay?
Must provide value

building was ideal for a primarily online group of pharmacists, primary care providers, and hospitalists to discuss the degree to which medications should be rounded automatically.

We began by entering proposed rounding percentages into an electronic survey instrument familiar to the expert reviewers called REDCap.[22] Each question presented the recommended rounding percentage and allowed each group member to agree or disagree with the recommendation. A sample question is shown in Table 1. Each expert completed the survey anonymously. After experts completed the first round of surveys, a facilitator (Dr Johnson or Dr Helmke) tabulated all responses and provided feedback to the expert group as a whole. All medications for which there was <80% consensus about the proposed rounding percentage were discussed among the participants. On the basis of this discussion, we modified the rounding percentages for these medications, and completed a second round of the survey. We included 2 pediatric neurologists later in this process to review and agree on rounding tolerances for sets of medications typically prescribed by members of that specialty. Finally, there were 16 medications that the group unanimously agreed were out of scope for this effort, either because the group was unfamiliar with their use (eg, ziprasidone) or because it was determined that dosing in pediatric offices typically did not use existing weight-based guidelines (eg, ursodiol). Group consensus for all other medications was achieved after 4 rounds of discussion.

RESULTS

Rounding Framework Development

Table 2 describes the experience and the roles played by each member of the advisory group. Some members participated in interviews or rounding knowledge validation, or both, as designated below.

On the basis of these interviews, we discovered that domain experts approach medication dosing and rounding by balancing the goals of therapy with the potential for adverse effects related to dosing. Three philosophical approaches emerged. We also created an additional category for medications with insufficient data available to assess the risk of automated rounding.

Dose-Dependent Intended Effects

The first approach was relevant when the intended effect was itself dose dependent. The iconic active ingredient for this approach was furosemide, which produces diuresis in rough proportion to the amount of the medication given per dose. In this case, domain experts typically start low and titrate the drug upward, typically in

TABLE 2 Expert Working Group Specialties and Activities

Pediatric Specialty	Total Participants, *n*	Median Time in Specialty, y	Interviewed, *n*	Validated Knowledge (Delphi Process), *n*
Generalist	7	25	4	6
Hospitalist	2	13	2	1
Cardiologist	1	24	1	1
Nephrologist	1	22	1	0
Pharmacist (PharmD)	5	22	3	3
Hematology	1	8	1	0
Neurologist[a]	2	15	0	2

[a] Involved in second and third rounds of consensus.

small (10%) increments. Medications in this group may be automatically rounded up or down in increments smaller than 10% to reach a more easily administered dose with the same intended effect.

Dose-Dependent Unintended Effects

The second approach had as a goal avoiding unintentional adverse effects. This approach is typically used for medications such as antibiotics or systemic steroids, in which dose-dependent adverse effects may be avoided by lowering the dose. For most medications in this group, dosing tends to begin at the highest well-tolerated dosage for the indication, and then rounded down to an easily administered dose, bearing in mind the maximum dosing recommendation guidelines.

Narrow Therapeutic Range

The third approach recognized the potential for drugs to have a narrow therapeutic index and a high risk for toxicity. Drugs such as digoxin and insulin are in this category and typically are not rounded, or are rounded to the nearest one-tenth of a milliliter from the originally calculated dose.

Insufficient Data Available

We included a fourth category for medications, such as mesalamine, in which insufficient data exist about the proper dosing model for children, and toxicity is likely with even a slight overdose based on adult data. In these cases, no rounding is typically performed. For many of these medications, there is no manufactured liquid formulation, further complicating the automated process by requiring the pharmacist to construct a compounded form of the medication. Because the final formulation may not be known, it is not possible to create an easy-to-administer dose during the e-prescribing process.

Recommendations for Rounding

On the basis of conversations with domain experts, we assigned tolerable rounding ranges to each category above. These data are listed in Table 3.

Table 4 lists the medications, rounding categories, and rounding percentages for each of the 120 medications in our database along with degree of agreement among all members of the advisory group. Medications such as amitryptyline and digoxin were sufficiently toxic that our team recommended rounding down to the nearest one-tenth of a milliliter.

In most cases, expert review resulted in a widening, rather than a narrowing, of the rounding tolerance. For example, despite the risk of dose-dependent tardive dyskinesia associated with using metoclopramide, in practice this drug is often rounded more aggressively. Therefore, the rounding percentage was increased from 5% as initially proposed to 10%. We achieved unanimous consensus for 39% of the proposed medication-rounding tolerances in the first round of voting. There were medications that the group agreed were rarely used in practice and were therefore out of scope for this initial project. These drugs included antiretroviral medications (ritonavir, oseltamivir, and lamivudine) and some rarely used neurologic medications. After discussion at a face-to-face meeting, 2 subsequent rounds resulted in all but 7 medication-rounding percentages being acceptable to the group. This final group of medications, typically started by pediatric neurologists, required extensive discussion between the expert group and 2 guest neurologists before consensus was reached.

DISCUSSION

Using information obtained from pediatricians, pharmacists, and an extensive literature review, we proposed and validated a set of rounding ranges and then assigned each medication to a rounding category. These data form an important body of knowledge that can be used by e-prescribing systems to automatically calculate administrable and

TABLE 3 Summary of Rounding Tolerance Categories

Category	Unintended Adverse Effects Dependent on Dose	Impact of Effect Dependent on Dose	Narrow Therapeutic Index	Rounding Tolerance, %
Avoiding unintentional adverse effects	Yes	No	No	10–15
Controlling intended effects	No	Yes	No	5–10
Avoiding toxicity	No	No	Yes	1–5
Insufficient data	NA	NA	Usually	0–1

NA indicates not available.

safe doses for young children. Moreover, by using an iterative consensus process, we obtained a high level of agreement across 99.3% of all medications.

Our validation process was limited in power by the relatively small number of pediatricians and pharmacies in our advisory group; however, the high level of agreement among pediatricians with an average of 20 years of experience suggests that our set of recommendations can serve as the critical first step to establishing a comprehensive knowledge base. Additional studies should evaluate the extent to which these recommendations are accepted or overridden by pediatric prescribers, as well as the incidence of adverse events that may arise related to rounding. We also were only able to create rounding tolerances for a subset of medications that are commonly prescribed. This process should be continued to address other medications prescribed using weight or body surface area to derive a dose. In addition, it will be important to reconvene an expert group to evaluate new medications that reach the consumer market. We estimate that this process would need to be done at least every 3 years, to address the ~12 new medications that are added to the *Harriet Lane Handbook* every edition (C. K. K. L., unpublished data, 2011).

As noted here, this project is the first attempt at creating a knowledge base of pediatric rounding tolerances that can be incorporated into any e-prescribing system whose vendor has an interest in using this knowledge. However, this work is only the beginning of developing tools required to create a safe pediatric e-prescribing environment. In part, the challenge to this task is the lack of evidence supporting common dosing standards, such as those published in typical pediatric textbooks. However, even these "eminence-based" recommendations do

TABLE 4 Summary of Medication-Rounding Tolerances

Medication (Rounding Tolerance)	Category	Consensus Round
Amitriptyline (0%)	Unintended effects	2
Acetaminophen (10%)	Toxicity	1
Amlodipine (10%)	Unintended effects	1
Amoxicillin/clavulanic acid (15%)	Unintended effects	1
Amoxicillin (15%)	Unintended effects	1
APAP/codeine (5%)	Unintended effects	3
Aspirin (10%)	Unintended effects	1
Atenolol (5%)	Excess intended effect	2
Methotrexate (0%)	Toxicity	1
Azathioprine (5%)	Unintended effects	2
Azithromycin (15%)	Unintended effects	2
Budesonide (10%)	Unintended effects	1
Carbamazepine (2%)	Unintended effects	4
Cefdinir (10%)	Unintended effects	1
Cefixime (10%)	Unintended effects	1
Cefuroxime (10%)	Unintended effects	1
Cephalexin (15%)	Unintended effects	1
Chlorothiazide (10%)	Excess intended effect	1
Cimetidine (10%)	Unintended effects	1
Ciprofloxacin (1%)	Unintended effects	2
Clarithromycin (10%)	Unintended effects	2
Clindamycin (10%)	Unintended effects	2
Clonazepam (0%)	Toxicity	4
Clonidine (0%)	Toxicity	2
Cyproheptadine (5%)	Unintended effects	3
Dexamethasone (5%)	Unintended effects	2
Dextroamphetamine (10%)	Unintended effects	1
Diazepam (2%)	Toxicity	4
Digoxin (0%)	Toxicity	2
Diphenhydramine (10%)	Excess intended effect	3
Docusate sodium (10%)	Unintended effects	2
Doxycycline (10%)	Unintended effects	2
Enalapril maleate (10%)	Unintended effects	1
Erythromycin (10%)	Unintended effects	2
Ethosuximide (2%)	Toxicity	3
Famotidine (15%)	Unintended effects	1
Felbamate (0%)	Unintended effects	3
Fluconazole (10%)	Unintended effects	1
Fluoxetine (5%)	Unintended effects	3
Folic acid (10%)	Unintended effects	1
Furosemide (5%)	Excess intended effect	2
Gabapentin (10%)	Unintended effects	1
Glycopyrrolate (5%)	Unintended effects	3
Griseofulvin (10%)	Unintended effects	2
Guaifenesin (15%)	Unintended effects	1
Hydrocodone/APAP (5%)	Unintended effects	3
Hydroxychloroquine (0%)	Toxicity	2
Hydroxyzine (10%)	Unintended effects	1
Ibuprofen (15%)	Unintended effects	1
Iron supplements (10%)	Unintended effects	3
Ketoconazole (10%)	Unintended effects	1
Lamotrigine (10%)	Unintended effects	1
Levetiracetam (2%)	Toxicity	2
Levofloxacin (1%)	Unintended effects	2
Levothyroxine (0%)	Toxicity	2
Lithium (0%)	Toxicity	3
Lorazepam (2%)	Toxicity	3
Mercaptopurine (0%)	Toxicity	2
Mesalamine (0%)	Insufficient evidence	4
Methadone (0%)	Toxicity	2
Methimazole (5%)	Unintended effects	1
Methylprednisolone (10%)	Unintended effects	1

TABLE 4 Continued

Medication (Rounding Tolerance)	Category	Consensus Round
Metoclopramide (10%)	Unintended effects	1
Metronidazole (5%)	Unintended effects	2
Minocycline (10%)	Unintended effects	1
Morphine (0%)	Toxicity	2
Moxifloxacin (1%)	Unintended effects	2
Mycophenolate (5%)	Unintended effects	1
Naproxen (10%)	Unintended effects	1
Nortriptyline (0%)	Insufficient evidence	2
Omeprazole (10%)	Unintended effects	2
Ondansetron (10%)	Unintended effects	2
Oxcarbazapine (5%)	Unintended effects	4
Oxycodone (5%)	Unintended effects	2
Oxycodone/APAP (5%)	Unintended effects	2
Pancreatin (15%)	Unintended effects	3
Pancrelipase (15%)	Unintended effects	3
PEG (15%)	Unintended effects	3
Penicillin V (15%)	Unintended effects	2
Permethrin (15%)	Unintended effects	3
Phenobarbital (2%)	Toxicity	4
Pimozide (15%)	Unintended effects	4
Prednisolone (10%)	Unintended effects	1
Prednisone (10%)	Unintended effects	1
Pregabalin (2%)	Unintended effects	3
Propranolol (5%)	Excess intended effect	2
Pyridoxine (15%)	Unintended effects	1
Ranitidine (15%)	Unintended effects	1
Risperidone (5%)	Toxicity	3
Rizatriptan (5%)	Toxicity	3
Sertraline (15%)	Unintended effects	3
Spironolactone (10%)	Excess intended effect	1
Sucralfate (15%)	Unintended effects	1
Sumatriptan (5%)	Toxicity	1
Tizanidine (5%)	Toxicity	3
Topiramate (2%)	Excess intended effect	4
Trazodone (15%)	Excess intended effect	4
Trimethoprim/SMX (10%)	Unintended effects	2
Valproic acid (2%)	Toxicity	4
Warfarin (0%)	Toxicity	1
Zolmitriptan (15%)	Excess intended effect	1
Zonisamide (2%)	Unintended effects	4

Category refers to the general dosing philosophy used by practitioners for this medication; consensus round refers to the number of times this medication was discussed before consensus was achieved. APAP indicates acetaminophen; PEG, polyethylene glycol; SMX, sulfamethoxazole.

not exist in a computable form. In an era in which there are mandates and incentives for adopting e-prescribing systems, this deficit is likely to negatively impact the otherwise highly usable systems recommended by regional extension centers or certifying bodies. Our study provides an initial expert-developed set of recommendations that can be readily incorporated into an evolving pediatric e-prescribing milieu. It is our hope that these recommendations will provide a starting point for all vendors to improve their automated processes.

It is also important to recognize the challenges of home medication administration, as noted by Kaushal et al,[15] when creating a medication dose. These recommendations will need to be combined with models that facilitate the cognitive processes associated with selecting an appropriate formulation, taking into account variables such as the patient's age, the presence of a feeding tube, patient preferences for volume of medication, and other considerations.

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