Barriers to Medication Reconciliation:
Recording of Patient's Home Medication Doses by Inpatient Providers on Admission to a Pediatrics Hospital

Emily Rothbaum, M.D.
Department of Pediatrics, Children's Hospital of New York Presbyterian

Study Rationale and Purpose:

Dosing errors are the most common type of medication error in pediatrics. Calculation or communication errors, caused by weight-based dosing and the variety of available formulations for a given medication, contribute heavily to these dosing errors.[1][2][3]

Physicians generally calculate and prescribe medication doses in mass units (mcg, mg, g). But when teaching parents how much medicine to give, instructions are generally given in volume units (teaspoons, milliliters, tablets) based on the specific medication formulation prescribed. Thus, on admission to the hospital, parents often report their home medications in volume units. This can introduce ambiguity—and the potential for dosing errors—in the home medication doses recorded by admitting physicians and nurses. However, little has been documented about the prevalence of this problem and whether it increases the risk of dosing errors in home medications during hospital admissions.

The purpose of this study is to examine the prevalence and consequences of reporting home medications only in volume units on the medication reconciliation lists compiled by providers during admission. We hypothesize that inpatient providers commonly record home medications doses only in volume units (e.g. 1 tablet of oxycodone or 5ml of amoxicillin)—and more frequently that the admitting outpatient provider. We further hypothesize that home medications listed only in volume units are more likely to be associated with medication errors during the inpatient stay.

This study is undertaken as an adjunct to hospital-wide efforts to reduce errors in home medication dosing during inpatient admissions, following national recommendations.[4] The study hospital had computerized order entry, notes, and medication reconciliation systems in place throughout the study period. But a recent study, in a hospital using the same computer system as the study hospital, revealed that

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[1] Wong IC, Ghaleb MA, Franklin BD, et al. Incidence and nature of dosing errors in paediatric medications: a systematic review. *Drug Safety* 2004; 27 (9): 661-70.
[2] American Academy of Pediatrics, Committee on Drugs and Committee on Hospital Care. "Prevention of Medication Errors in the Pediatrics Inpatient Setting." Pediatrics 2003; 112: 431-436.
[3] The Joint Commission. Preventing pediatric medication errors. *Sentinel Event Alert #39, Apr 11, 2008.* http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_39.htm. (5/11/08)
[4] Fortesque, EB, Kaushal, R, Landrigan, CP et al. Prioritizing Strategies for Preventing Medication Errors and Adverse Drug Events in Pediatric Inpatients. *Pediatrics*. 2003; 111, 722-729.

computerized order entry alone did not reduce dosing errors.[5] This and other studies emphasize the need for improved communication between families, physicians, and nurses about home medication doses.[6][7] The results of this study may help identify targets for improved communication that will help reduce dosing errors in pediatric inpatients.

Study Design:

This study will be an observational study of existing data. All data will be collected by retrospective chart review. Data from inpatient charts will be collected from physician and nursing admission notes and medication orders in Eclipsys records. Data from outpatient charts will be collected from Eclipsys or from the admitting subspecialty's clinic charts.

Data collected includes date and time of admission, patient age, admitting service, use of medication reconciliation outpatient medication profile, and numbers and names of medications listed in the documents described above. Medications will be classified as listed with appropriate, specific units (e.g. Tacrolimus 2mg or Tacrolimus 1mg/ml, 2ml PO BID); as volume-only units (e.g. Tacrolimus 2ml PO BID), or as no units (Tacrolimus PO BID). Medications that are generally dosed in volume units (e.g. Trivisol 1ml or Bactrim DS 1tab), will be counted as appropriately dosed medications. All data will be recorded using a unique identifier for all patients that is distinct from their MRN.

Also documented will be the number of changes to home medication doses in the computerized orders during the first 24 hours of admission. The frequency of changes to volume-unit only medications will be compared to that to appropriately recorded medications. This variable serves as a proxy for medication errors and a significant difference between the two groups is the primary outcome of this study.

Study Subjects:

Data will be collected on consecutive admissions to the pediatrics medicine service during the study period. Patients for whom no admission notes or no outpatient notes within 6 months of admission are available will be excluded from data analysis. The study period will start in November 2008.

Data will be collected on 500 admissions for whom the necessary documents are available, as the calculated sample required to show the expected difference between medication changes in a chi-square test analysis from volume-only and other medications is 442 total patients. This power was calculated based on the expected difference between

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[5] Walsh, KE, Landrigan, CP, Adams, EG et al. Effect of Computer Order Entry on Prevention of Serious Medication Errors in Hospitalized Children. *Pediatrics* 2008; 121: e421-e427.

[6] Zandieh SO et al. Risk Factors in Preventable Adverse Drug Events in Pediatric Outpatients. *Journal of Pediatrics* 2008;152(2):225-231.

[7] The Joint Commission. Using medication reconciliation to prevent errors. *Sentinel Event Alert #35, Jan 25, 2006.* http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_35.htm. 5/11/08)

outpatient and inpatient physician notes, as the proportion in nursing notes is expected to be higher than for physicians.

The vast majority of study subjects will be minors, as we will include patients 1 day old to 25 years old. This is necessary because weight-based dosing and its consequences are a problematic particularly in the pediatric population.

Study Procedures, Drugs, and Devices: The subjects of this study will not be exposed to any procedures, drugs, or devices outside of their regular medical care. This study will not affect their future medical care directly in any way.

Data Analysis:

Data will be aggregated and analyzed using chi-square tests. The studied is primarily powered to evaluate whether having one or more medications listed in volume-only units lead to an increase in changes to home medication doses during the first 24hrs of admission. This is a proxy for medication errors, as presumably those changed orders reflected incorrect doses.

Chi-square analysis will also be used to evaluate for significant group differences between proportion of medications listed in volume-only units and other medications by outpatient vs. inpatient providers. Prevalence data will be reported about the categories of medications most likely to be listed as volume-only units on outpatient and inpatient providers notes.

Confidentiality of Study Data:

All study data will be coded with a unique identifier; all personal identifiers will be removed. Permission will be obtained from all outpatient clinics to review their records. Data will be secured in a password-protected computer, accessible only to investigators. No outpatient clinic notes will be duplicated or removed from the clinic.

Potential Risks and Benefits:

There is very minimal risk of harm to patients in this retrospective chart review. The major risk is breach of confidentiality of data, which will be guarded against by deidentifying the data and keeping it password-protected.

There will be no direct benefit to the subjects of this study; we will not be contacting them or their families directly if we identify ambiguities in dosing of their home medications. This study will benefit children—including possibly the study subjects—who are admitted to our hospital in the future, as we plan to use our findings to identify targets from improvement in the medication reconciliation system.

Compensation or Costs to Subjects:

The subjects will not incur any costs, nor will they receive compensation.