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Using Home Visits to Understand Medication Errors in Children

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Comments

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Abstract

Current research methods are not well designed to detect medication errors that occur at home. We developed home visit methods to investigate home medication errors in children with chronic conditions. These methods include observation of parent administration of medication to the child by a trained nurse observer who takes detailed ethnographic notes; review of all prescription and over-the-counter medications for dispensing errors, pill counts, and medication reconciliation; and parent interviews to identify barriers to effective home use of medications, prior home medication errors that parents are aware of, and suggestions for systemic improvements. Details about each possible error detected are recorded using a structured data collection form (allergies, medication list, dispensing errors, administration errors). We conducted several pilot home visits and found that this approach has the potential to help understand home medication errors in order to develop interventions to improve the safety of medication self-management.

Introduction

Despite over 3,000 publications about medication safety over the last 5 years, there continue to be "enormous gaps in the knowledge required to implement a safe medication-use system," according to the July 2006 Institute of Medicine (IOM) report, *Preventing Medication Errors*.[1] This report called for research on the rate of errors in ambulatory care, particularly home care and pediatric care, and support for medication self-management. Among children, the rate of potentially dangerous medication errors is three times that of adults and outpatient wrong dose ordering errors are common, due to the complexity of weight-based dosing.[2, 3, 4, 5, 6] Although the majority of pediatric medications are taken in the home, data on pediatric medication errors in the home setting are limited, and risks for children with chronic conditions, who use many medicines, may be great.[7, 8] Research methods are needed to describe errors in the home use of pediatric medications.

Medical record review is not well suited for detecting medication administration errors.[9] The most efficient and accurate method to detect medication administration errors in the hospital setting is through direct observation of nurses by a trained researcher.[10, 11, 12] It is reasonable to expect that direct observation would also be a good method of detecting medication errors in the home setting, and so we sought to develop comparable methods. To that end, we reviewed the literature, developed home visit methods, and conducted a pilot study. Each of these steps is described in separate sections in this article.

Literature Review

We searched PubMed, Cochrane Collaborative, Up-to-Date, and Clinical Evidence for all articles relevant to home medication errors. We identified a total of 13 articles related to parent administration of medications to children; only one included visits to the home (Table 1). We also identified 10 articles related to adult patient medication errors (Table 2).

Table 1. Literature related to home medication errors in children

Study	Methods	Setting	Findings
Alander, et al 2000[19]	Retrospective chart review	Two hospitals	322 patients with acetaminophen overdose included 10 with dosing errors with therapeutic intent over 10 years.
Arnhold, et al 1970[29]	104 home visits	Parents recruited from group practice	Only 1/3 of teaspoons measured within 4.5 - 5.5 ml; 4/104 parents misunderstood dosing instructions; 15 were noncompliant.
Cohen 2006[18]	Case series	Email solicitation of medical examiners	3 deaths reported from National Association of Medical Examiners from over-the-counter (OTC) cold medicine; all children under 6 months of age.
Frush, et al 2004[28]	Randomized controlled trial	Parents waiting in pediatric emergency department	Color-coded method to measure acetaminophen reduced average deviation from correct dose from 26% deviation to 2% deviation
Gunn, et al 2001[17]	Case series	1 hospital	3 admissions for OTC cold medicine overdoses with therapeutic intent, including one death; all in children under age 3 years.
Heubi, et al 1998[14]	Case series	Cases from 1 hospital, FDA reports, literature	47 cases of hepatotoxicity after multiple overdoses of acetaminophen found, with 20 surviving, including 4 liver transplant patients.
Henretig, et al, 1989[13]	Case series	One hospital	2 children with hepatotoxicity due to repeated acetaminophen overdoses, both survived without transplantation.
Li, et al 2000[20]	Cross-sectional parent survey	Urban academic pediatric emergency department	51% of parents reported an inaccurate dose of antipyretic given prior to ED visit; children under age 1 year were more likely to receive inaccurate doses.

Table 1. Literature related to home medication errors in children (continued)

Study	Methods	Setting	Findings
Litovitz 1992[15]	Case series over 8 days	Calls to poison control centers associated with use of dispensing cups	34 reported cases over 3 days in children and adults.
Marinetti, et al, 2005[16]	Case series	Montgomery County Coroner's office	10 deaths associated with toxic levels of OTC cold medicine in children under age 12 months; 8 due to accidental overdose.
McMahon, et al, 1997[26]	Stratified randomized convenience sample	General pediatric clinic	Parents of children on liquid antibiotics underwent education, went to pharmacy, returned with med, and demonstrated dose. Verbal instructions only: 37% correct; 32 - 147% of dose). Verbal instructions: syringe with line marked: 83% correct (20 - 152% of dose). Verbal instructions: marked syringe, dose demonstrated: 100% correct
Taylor, et al 2006[27]	Prospective observational study	Outpatient pediatric oncology clinic	Parents of 69 children with cancer demonstrated how they would administer home medications (71% brought from home; 29% given sample medications in clinic); 12 medication errors detected; 5 prescribing errors.

Table 2. Literature related to home medication errors in adults

Study	Methods	Setting	Findings
Bedell, et al 2000[36]	Patient report, bottle review	Outpatient private practice	76% of patients had discrepancies between the medication list from the medical record and patient report or bottles from home medicines. 51% medications not recorded; 29% not taking medications on list; 20% wrong dose.
Britten, et al 2000[35]	Qualitative interviews	20 general practices in England	14 types of misunderstandings between physicians and patients involved in prescribing decisions are described.

Table 2. Literature related to home medication errors in adults (continued)

Study	Methods	Setting	Findings
Ernst, et al 2001[46]	Prescription renewals compared to med lists	Family medicine outpatient clinic	26% of requests were different from the medical record medication list; 59% were medications not on the list.
Field, et al 2007[31]	Chart review, computer-generated signals, and incident report review	Medicare enrollees in a group practice	Review of patient-related errors from Gurwitz study.[30] 32% administration errors, 42% changed medication regimen, 22% did not follow clinical advice about medication use (e.g., avoid alcohol on this medicine).
Gandhi, et al 2003[32]	Chart review, telephone interview	4 adult primary care practices	25% of patients had an adverse drug event. 19 of these events could have been ameliorated by physicians but were not because the patient failed to report symptoms
Gurwitz, et al 2003[30]	Chart review, computer-generated signals, and incident report review	Medicare enrollees in a group practice	13.8 preventable adverse drug events per 1,000 person-years found. 20% of these related to patient use of medications in the home.
Kuzel, et al 2004[34]	38 interviews	Random digit telephone dial	221 “problematic incidents” including problems with access, doctor-patient relationship, and racism. 23% resulted in physical harm to patients.
Manley, et al 2003[40]	Monthly drug interviews	Hemodialysis center	30% of patients had discrepancies between interview reports and their medication list. 50% placed patients at risk for adverse events and 30% for dosing errors.
Richelman, et al, 2007[37]	Patient survey	Outpatient oncology clinic	27% of patients had a drug interaction, 8% of patients were taking duplicate medications, most often corticosteroids, proton-pump inhibitors, or benzodiazepines.
Weingart, et al, 2005[38]	Patient interview, chart review	4 adult primary care practices	Only 69% of medication-related symptoms were discussed with patient’s doctor. This resulted in injury in 2 of 90 patients and in excessive pain that could have been ameliorated had they been discussed with doctors in 19 of 90 patients.
Wilson, et al 2006[39]	Cross-sectional survey	Community dwelling Medicare beneficiaries, national sample	27% of those who skipped doses did not discuss with doctor. 39% of those with cost-related nonadherance did not discuss with a doctor.

Pediatric Studies

Many studies have used parent report to detect administration errors. Several of these have described pediatric patients injured by parents who accidentally gave the children an overdose of medications.[13, 14, 15, 16, 17, 18, 19] In a case series of calls to poison control centers, Litovitz described 34 dispensing cup errors due to one of three causes: (1) confusing teaspoon and tablespoon, (2) assumption that the dispensing cup was the unit of measure, or (3) assumption that the full dispensing cup was the actual dose.[15] Heubi, et al., described cases of pediatric hepatotoxicity after multiple overdoses of acetaminophen, speculating that parents may have run out of pediatric acetaminophen and used the adult preparation for convenience, misread the label, or administered more medication because the child's fever was high.[14] Marinetti, et al., described 10 deaths from over-the-counter cold medicine toxicity in infants, of which 8 were accidental overdoses.[16]

Several surveys asked parents to recall their child's dose of medications.[20, 21, 22] In a cross-sectional survey of 200 parents of young children in an emergency department (ED), Li, et al., found that 51 percent of parents reported giving acetaminophen doses that were incorrect.[20] Yin, et al., surveyed caregivers of young children waiting in an ED and found that parents with a lower reading comprehension were more likely to use a nonstandard measuring instrument (e.g., a teaspoon rather than a measuring cup or syringe).[21] However, in another study, where less than 67 percent of parents were able to accurately repeat back medication use instructions, parental literacy level was not associated with use of preventive pediatric services or ability to follow medical instructions.[22]

We found three studies that discussed pediatric medication errors involving parents.[23, 24, 25] Of these, two surveyed parents about hypothetical errors.[23, 24] One interviewed parents about "mistakes, errors, and carelessness"; only two errors were described.[25] None of the studies systematically interviewed parents about medical errors, and none addressed errors in ambulatory care.

Three studies involved observation of parent administration of medication in the clinic or ED.[26, 27, 28] McMahon, et al., performed a study in which parents of young children with ear infections who had been prescribed liquid antibiotics were randomized to three forms of instruction about medications.[26] Parents then went to the pharmacy, filled the prescription, and returned to the clinic to demonstrate the dose using syringes and teaspoons provided by research staff. Only 37 percent of parents who received verbal instructions measured the correct dose. Of those with verbal instructions and a syringe with a line marked, 83 percent measured the correct dose. Of those with verbal instructions, a syringe with a line marked, and the dose demonstrated, 100 percent measured the correct dose.

In a study by Taylor, et al., parents of 69 children diagnosed with cancer demonstrated in clinic how they would dose their child's home medications.[27] Parents were given measurement tools, and those without their own medication were provided medications to use. Administration errors occurred with 7 percent of medications.

Frush, et al., developed a color-coded system to avoid home liquid acetaminophen administration errors.[28] Parents used a syringe with colored lines to measure doses and a chart to select the correct lines. Parents in an ED waiting room who used the color-coded system had an average

dose deviation of 1.7 percent compared to 25.8 percent for parents who used conventional measuring methods.

In each of these studies, measurement instruments were provided by research staff, so problems with measurement instruments could not be assessed. In 1970, Arnhold, et al., visited the homes of 104 pediatric patients recruited from private practices.[29] During the visits, researchers measured the teaspoons used to dispense medications and measured the quantity of the medication remaining to assess missed doses. Several parents stopped the medication before completing the prescribed course of treatment. Fifteen parents skipped medication doses. Of the teaspoons used to dispense the medications, one-third measured between 4.5 ml and 5.5 ml, 40 were less than 4.4 ml, and eight were above 5.5 ml. To our knowledge, this is the only study using home visits to study patient or parent medication administration errors.

Studies of Adults

Two medical record review studies in adult patients detected and described home medication errors.[30, 31, 32] Gurwitz studied outpatient adverse drug events among older individuals using medical record review, computer generated signal review, and incident report review, and found a rate of 13.8 adverse drug events caused by error per 1,000 person-years.[30] Of those adverse drug events caused by error, 20 percent were related to patient use of medications in the home. Field, et al., further described these patient medication errors which fell into six categories:[31]

1. Medication filling and refilling errors.
2. Medication administration errors.
3. Failure to perform some parts of the medication regimen.
4. Failure to follow clinical advice.
5. Failure to report information to providers.
6. Failure to adhere to followup.[31]

Gandhi, et al., used medical record review and patient report to describe adverse drug events and errors in outpatient adults. She described 19 adverse drug events that could have been ameliorated by proper medical care but were not because patients failed to inform their doctors of symptoms.[32]

Some investigators have used telephone interviews combined with chart review in adult patients to improve the detection of adverse drug events and errors.[32, 33] However, telephone interviews will only identify errors of which parents or patients are aware, making this method susceptible to reporting bias and to missing accidental measurement errors parents may not have noticed.

In adult patients, several studies have used in-depth interviews about medication errors and communication problems.[34, 35, 36, 37, 38, 39, 40, 41] Three studies about communication failure indicated that many patients who skip doses, stop medications, or experience side effects from medications do not inform their doctors.[36, 39] Britten described several misunderstandings about medication prescribing, such as a patient changing a dose without informing the doctor and two doctors each telling the patient to use a different dose.[35] Riechelman asked outpatients with cancer to describe what medications they took at home, and found that 8 percent were taking duplicate medications, and 27 percent had at least one potential drug interaction.[37] A fourth study

evaluated discrepancies between home medication regimens in physician medication lists in transplant patients and found patient errors and ordering errors to be common.[42]

In our review of the literature, rates of parental administration errors ranged from 0 to 63 percent of administrations. More than half of pediatric papers were case series. Only one study involved home visits, where all medications, including over-the-counter medications, could be reviewed, measurement instruments could be inspected, and administration could be observed.[29] Taken together, the findings from this literature review reveal that current methods used to detect errors, such as chart review, are not well designed for pediatric home administration errors. While the literature is limited, parent medication administration errors appear to be frequent, and parents may be unaware of the errors they are making. Research from adult patients indicates that communication problems between patients and physicians regarding medication use commonly occur and may affect patient safety.

Methods

Our approach to using home visits (Figure 1) to examine medication errors in children has four components: (1) observation of medication administration, (2) medication review, (3) in-depth parent interviews about errors in home medication use, and (4) event classification. Prior to the home visit, the research assistant obtains the patient's age and diagnoses from the chart. The patient's weight, height, and all medication allergies are also recorded. Dose and frequency of administration for all medications prescribed for home use are obtained from the chart and from copies of prescriptions written during the clinic visit (if available). All prescriptions are checked for physician errors. All medication doses are recalculated to check for dosing errors. Doses that deviate more than 10 percent from the correct dose are considered dosing errors.

Observation of Medication Administration

Home visits are to be performed by a study nurse or pharmacist trained in nonintrusive and nonjudgmental research methods. Methods used for direct observation are modeled after those used in hospitals to identify administration errors[10, 11, 12, 43] and refined based on pilot testing. These established methods employ ethnographic techniques, rooted in social anthropology.[44, 45] This technique emphasizes context in understanding errors and can "allow comparison between what people say and what they actually do."[45] The study nurse is instructed to observe the administration of each dose and not to review the patient's medication list until after performing direct observation of medication administration.[44]

Visits should be scheduled at the time when most medications are being administered to the child and when the person who normally administers medications to the child is available. Children and adolescents who self-administer medications should be asked to participate in the home visit.

The person who normally administers the medications is asked to administer medications exactly as he or she normally would, as if the study nurse were not present.

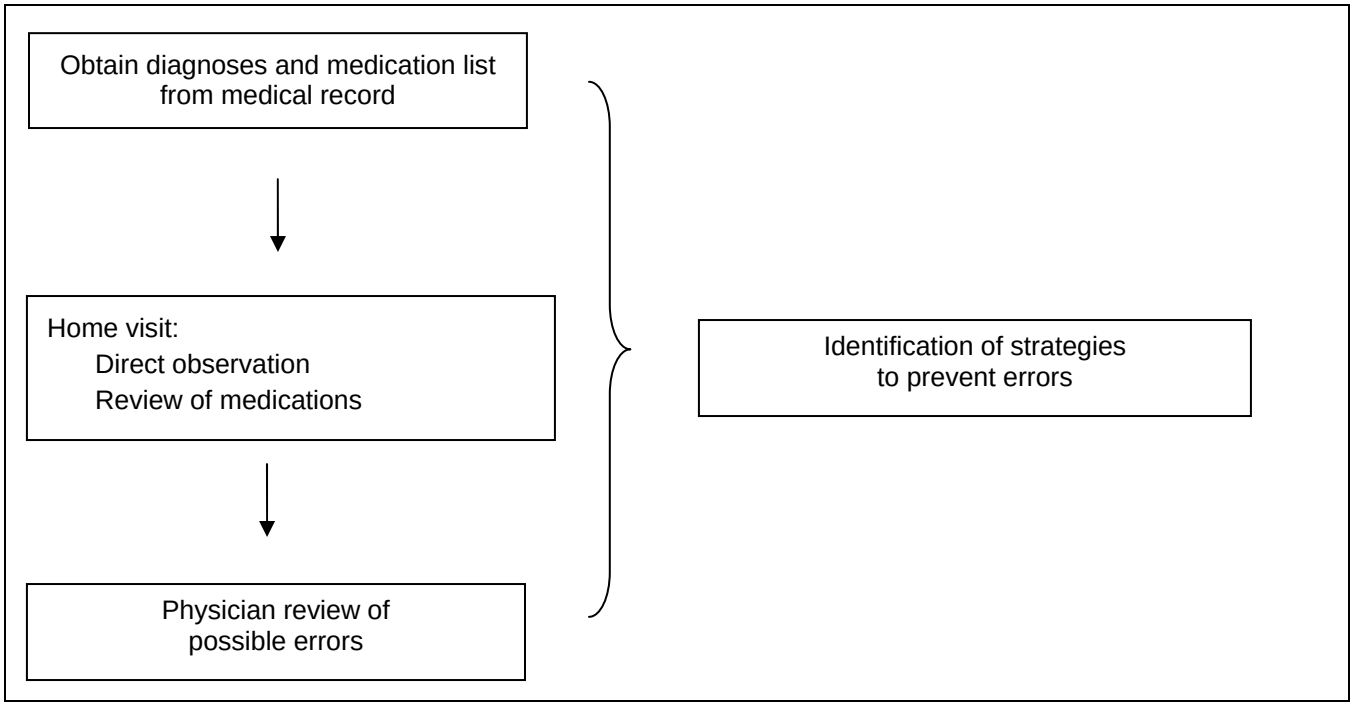

Figure 1. Home visit methods.

The administration of each medication is observed and detailed, and notes are recorded in a study diary. In addition to medication administration, medication preparation—such as pouring nutritional formula into a gastrostomy tube—and related procedures—such as flushing lines or giving medication with food—are observed as described by Flynn and colleagues in the inpatient setting.[10] As in hospital-based studies, observations and documentation are both quantitative and qualitative.[11, 12] Qualitative data include detailed field notes taken in diaries, which are recorded immediately after observation.

Quantitative data include specific details about medication administration, such as which measurement tool is used and what quantity of medication is given. Quantitative data are recorded on the home visit data collection form (Appendix A), along with demographics, allergies, the medication list, dispensing errors, and administration errors. The allergy section and medication list are completed prior to the home visit, using data obtained from the patient's medical record. Any other medications being taken by the child that are not on the medical record medication list are added during the home visit. After direct observation, for each error noted, the type of administration error is recorded on the medication list. The medication label is reviewed, and any dispensing error noted is recorded on the medication list. Pill counts or volumes and fill and expiration dates are recorded. A detailed description of any error noted during the home visit is written on an error reporting form (Appendix B).

Errors that potentially place the patient at risk that are detected by the research nurse but not noticed by the administering parent are intercepted prior to medication administration. The study nurse then contacts the prescribing physician to inform the physician of the error and ask for orders on how to handle the situation.

Medication Review

All medication labels are reviewed for dispensing errors. In addition, to detect missed dose errors, pill counts are taken for pills and volumes for liquid medicines. The percent of doses taken, the primary outcome for this part of the study, is calculated in the following fashion:

$$\text{\% doses taken} = \frac{\text{(\# pills dispensed – \# left in bottle) x 100}}{\text{(\# days between dispense date \& home visit date) (\# doses per day) (\# pills per dose)}}$$

or

$$\text{\% doses taken} = \frac{\text{(volume dispensed – volume in bottle) x 100}}{\text{(\# days between dispense date and home visit date) (\# doses per day) (volume per dose)}}$$

Prior research demonstrates that pill counts are 93 percent sensitive and 52 percent specific at detecting patients who miss more than one in four doses of medication.[46]

In order to assess accuracy of the outpatient medical record medication list compared to which medications the patient is actually taking—which is a Joint Commission goal[47]— the medications the child is taking in the home are compared with the medical record medication list. After observation of medication administration and pill counts, the labels of all medications in the home are compared to a list of home medications obtained from the chart, and the parent is asked about any discrepancies. The primary measure for this portion of the study is percent of home visits where the prescription medication list is accurate. Discrepancies between the medication list and the home medication regimen are not counted as errors because, based on prior research, we expect more than half of medication lists to be inaccurate.[37, 38, 39, 48, 49] However, any discrepancy considered by the study nurse to be potentially dangerous is recorded as a possible error.

In-depth Interviews

In-depth, qualitative interviews are conducted as the final step during home visits. The purpose of the interview is to identify parents' perception of barriers to effective home use of medications for their child(ren) with chronic disease and to describe possible prior medication errors occurring in the clinic or in the home. Parents are also asked for recommendations for systemic changes that would help them to avoid outpatient and home medication errors in the future. Questions were developed from a clinic-based pilot survey of parents of children with chronic conditions and were refined in pilot home visits (Table 3). Interviews are audiotaped, transcribed, and reviewed for themes. Themes are grouped in broad categories that reflect types of medication delivery system failures (e.g., use of the wrong measurement device or failure to complete the entire course of the medication) or categories of error-prevention strategies. Knowledge gaps and misconceptions that may contribute to parents' errors, parents' perceptions of barriers to using medications exactly as prescribed, and parents' recommendations for changes that would facilitate their giving medications exactly as prescribed are carefully considered.

Table 3. Questions for in-depth parent interviews

Repeat questions for each medication:
1. Why does your child take this medication?
2. How much of the medication are you supposed to give and how often?
3. Have you had any trouble giving it?
4. When was the last time, prior to now, that your child took this medication?
5. How often does your child miss medication at home? Why? Tell me more about this.
6. Has your child ever had a problem from the medication that you didn't expect? Tell me more about this.
7. Often, parents make adjustments in how they follow the physician's instructions at home. Some parents might feel that their child doesn't need a particular medication any longer; others might feel that their child is having more problems, and so might increase the dose. Have you ever made any adjustments like that?
8. Often, parents give their child's medication one way, and then realize later on that the doctor had meant for them to give it some other way. Have you ever had that experience?
9. Has your child ever had an error in her care? Tell me more about this.
10. Was there any harm to your child from the error? Any extra medicines or tests?
11. How do you think the error could have been avoided?

Physician Review and Event Classification

All possible medication errors detected during observation, medication label review, and potentially dangerous errors in medication reconciliation are recorded on a standardized error reporting form. This form is an adaptation of forms utilized in outpatient adults and inpatient children, with modifications based on results of the literature review and pilot work[30, 50] (Appendix B). The error reporting form provides space for a detailed description of the incident, including information about any systems failures that may have caused the error and any patient injury that resulted from the error. Additional sections support this description, by naming the system failures that occurred and possible improvements to the system that may have prevented the error.

Possible medication errors are subsequently reviewed by two trained study physicians. Physician reviewers independently classify each possible error in one of the following four categories:

1. A medication error causing injury to the patient (preventable adverse drug event).
2. Medication error that had the potential to cause injury but did not injure the patient (serious medication error without injury).
3. Medication error with little potential for injury.
4. Not a medication error (excluded from the study).

A medication error is an error in drug ordering, dispensing, administering, or monitoring.[30, 32, 51] A serious medication error is a medication error that causes harm or has substantial potential to cause harm.[11] For example, if a mother administers twice the appropriate dose of methotrexate to her 5 year old with leukemia, this is a serious medication error because of the potential for injury, even if it does not cause any harm.

Failure to administer a prescribed medication is considered an error in medication administration.[10] For those incidents categorized as a preventable adverse drug event or a serious medication error without injury, severity of the error is also rated. Severity is rated as:

1. Clinically significant but not serious.
2. Serious. A serious medication error would be a failure to administer pneumocystis pneumonia prophylaxis to a patient with cancer for several weeks, due to confusion about the purpose of the medicine.
3. Life threatening.
4. Fatal.

Pilot Visits

In order to understand the feasibility of these methods, we performed 12 pilot home visits to children with chronic conditions taking at least one daily medication. One challenge we found in scheduling the visits is that home medication administration usually occurs before school or during evening hours for those children enrolled full time in school. One visit took place at 7:00 am, one at 3:00 pm, three at 10 am, and seven between 6:00 and 7:30 pm. Home visits lasted from 15 minutes to 2 hours, with a median duration of 20 minutes. During these 12 home visits, we observed the administration of 23 medications and reviewed the labels of 78 medication bottles.

Reliability

To test the reliability of these methods, two observers observed four medication administrations and reviewed eight medication bottles together during home visits; observers independantly detected the same three errors during the visit.

Interrater reliability of independent classification of events by physicians before coming to consensus was determined and expressed as a kappa statistic. For classification of an event as a preventable adverse drug event, serious error without injury, or error with little potential for harm, interrater reliability for the 16 events captured during the home visits was 0.72 (95 percent, CI 0.4 - 1.0). Interrater reliability for severity was not calculated due to the small sample size.

Preliminary Data

The rate of errors from our pilot work was surprisingly high. In 12 pilot home visits, 16 medication errors were detected, including seven serious medication errors. Errors detected during observation included the use of a twice-a-day medication once a day and carrying EpiPen®s for a nut allergy that were expired. Parents discussed problems with medication use such as using syringes where none of the markings were visible or a child taking and vomiting

twice-concentrated medication for 5 days before the family recognized that the medicine was incorrectly reconstituted.

When assessing an error-detection method, it is also important to consider whether the data collected during home visits will be valuable in developing systems-based improvements. Prior research compared observation to two other commonly used methods—chart review and incident report review—for the detection of medication errors in hospitals and skilled nursing facilities. Direct observation was found to be more efficient and accurate than chart review and incident reports.[10]

Limitations

One concern with the use of observation to measure error rates is the idea that people will avoid making errors when being observed (Hawthorne effect). However, in a study of direct observation of nurses for administration errors, Dean found no difference between observation and no observation periods in the percentage of omitted doses and no change in the error rates with repeated observations.[43] In addition, our literature review demonstrates that parents are frequently unaware that they are making errors and are therefore unable to consciously avoid making errors when being observed. Study nurses are trained in nonintrusive, nonjudgmental methods to avoid altering the normal pattern of home medication use. Our pilot work indicates that error rates, even with observers present, may be high in any case.

Researchers face unique ethical challenges in using direct observation to measure errors.[45] For instance, the researcher normally attempts to avoid altering the environment while observing it. In this setting, if the observer notices a potentially dangerous medication error that is about to negatively affect the patient, the observer is obligated to intercept the error prior to medication administration.

It is possible, however, that given a few more seconds, the parent may have intercepted the error himself or herself. In pilot testing, the research nurse never observed an error that required her intervention. In addition, home visits require a significant time commitment, compared with chart review or telephone survey methods. Nevertheless, in inpatient research, direct observation is considered a better method to detect administration errors.

Conclusion

In the outpatient setting, pediatric home medication errors have not been studied with sufficiently rigorous methods to provide the information needed to guide development of interventions to support self-management of medicines. Existing methods are not adequate to comprehensively capture home medication errors. Building on existing research, we described the use of home visits with observation of medication administration to identify pediatric home medication errors. Reliability of study methods—as measured by interobserver agreement and interrater event classification agreement—in pilot studies was good.

These home visit methods, designed to measure rates of home medication errors among children with chronic conditions, have several other possible applications. The home visit could be expanded to measure rates of errors in medication use among the entire family, rather than just

children with chronic disease. Similarly, other vulnerable populations—such as the elderly, Medicaid patients, or non-English-speaking patients—may benefit from this line of research. These home visit and ethnographic methods may aid those interested in cultural differences in medication use, compliance, and disease care. Health literacy could be evaluated during home visits to assess the relationship between parent health literacy and parent administration errors. Similar methods could also be used to understand medication use by children with chronic disease in schools. These methods may be used to develop and test interventions to prevent systems failures associated with serious medication errors in outpatient children with chronic disease.

In summary, little information is available about pediatric medication errors in the home, where the vast majority of pediatric medications are taken, in part because current research methods are not adequate for the home setting. Building on approaches utilized in outpatient adults and children and on prior inpatient observation studies of nurse administration, we developed home visit methods to detect pediatric home medication errors. These home visit methods may be used to understand and quantify home medication errors in many different patient populations, providing information needed to better support safe medication self-management.

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Appendix A: Home Visit Data Collection Form

To be completed for each home visit even if no possible error is detected.

1. Study ID number ____ ____ ____ ____

2. Date of home visit ____ ____ /____ ____/____ ____

3. Time of home visit ____ ____ : ____ ____

MILITARY TIME

4. Age: ____ ____

5. Weight: ____ ____ ____ pounds **OR** ____ ____ ____ kilograms

6. Height: ____ ____ ____ inches **OR** ____ ____ ____ centimeters

7. Gender: male female

8. Diagnoses at the time of the home visit:

a. _____

b. _____

c. _____

e. _____

f. _____

g. _____

h. _____

i. _____

k. _____

l. _____

m. _____

n. _____

h. _____

9. Persons participating in interview: _____

_____

_____

_____

10. Who administered medication during this visit?

Mother

Father

Child

Grandparent

Sibling

Visiting nurse

Other: _____

Table 11. Allergies to medicines and reaction

Medical record ☐ **NONE**		**Interview** ☐ **NONE**	
Drug	**Reaction**	**Drug**	**Reaction**
A.		A.	
B.		B.	
C.		C.	
D.		D.	
E.		E.	
F.		F.	
G.		G.	
H.		H.	

Med list from chart medication list. Verify against bottle label, note differences, observe medication administration, note errors.

Name	Conc.	Volume of dose or pill strength	Route	Freq. of dose	Fill date	Exp date	Medication label the same? (If no, write in letter from list 12b)	Administration Correct? (If no, write in letter from list 12c)
A.							Y: ____ N: _____	Y: ____ N: _____
B.							Y: ____ N: _____	Y: ____ N: _____
C.							Y: ____ N: _____	Y: ____ N: _____
D.							Y: ____ N: _____	Y: ____ N: _____
E.							Y: ____ N: _____	Y: ____ N: _____
F.							Y: ____ N: _____	Y: ____ N: _____
G.							Y: ____ N: _____	Y: ____ N: _____
H.							Y: ____ N: _____	Y: ____ N: _____
I.							Y: ____ N: _____	Y: ____ N: _____
J.							Y: ____ N: _____	Y: ____ N: _____
K.							Y: ____ N: _____	Y: ____ N: _____
L.							Y: ____ N: _____	Y: ____ N: _____
M.							Y: ____ N: _____	Y: ____ N: _____

Med list from chart medication list. Verify against bottle label, note differences, observe medication administration, note errors. (continued)

Name	Conc.	Volume of dose or pill strength	Route	Freq. of dose	Fill date	Exp date	Medication label the same? (If no, write in letter from list 12b)	Administration Correct? (If no, write in letter from list 12c)
N.							Y: ____ N: _____	Y: ____ N: _____
O.							Y: ____ N: _____	Y: ____ N:_____
P.							Y: ____ N: _____	Y: ____ N:_____
Q.							Y: ____ N: _____	Y: ____ N:_____
R.							Y: ____ N: _____	Y: ____ N:_____
S.							Y: ____ N: _____	Y: ____ N:_____
T.							Y: ____ N: _____	Y: ____ N:_____

12b. Label Differences:

a. No longer takes
b. Different concentration
c. Different volume
d. Different route
e. Different frequency
f. Different indication
g. Additional med not listed in medical record med list

12c. Administration differences

a. Administration
b. Wrong frequency
c. Wrong route
d. Wrong instrument (e.g., tablespoon instead of teaspoon)
e. Unable to see lines on syringe
f. Overdose
g. Underdose

Pill Count

a. Too many pills
b. Too few pills
c. Volume too small
d. Volume too large
e. Medication expired
f. Drug interaction

13. Was a possible error found? Yes____ No ____

If yes, please list the event # and complete an error- reporting form for each different event.

____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____

____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____

____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____

____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____

Appendix B: Error Report Form

Only to be completed for index cases with possible errors

If a single index visit has more than one error, a separate form should be completed for each possible error

DESCRIPTION OF EVENTS INVOLVED IN ERROR

Please include period leading up to, during, and following the error. It is important to emphasize data that would help determine if: 1) an error in care occurred; 2) the error reached the patient or was intercepted before reaching the patient; and 3) the error injured the patient.

Brief Description of error _____

Date of error_____

Detailed Description of error

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

What was the final outcome of the error? _____

_____

_____

_____

_____

_____

DETAILS OF ERROR

2. Person primarily responsible for the error:

☐$_1$Oncologist ☐$_2$ Fellow ☐$_3$ Other physician ☐$_4$ Nurse practitioner

☐$_5$ Physician assistant ☐$_6$ Nurse ☐$_7$ Pharmacist ☐$_8$ Patient or family

☐$_9$ None ☐$_{10}$ Unable to determine ☐$_{11}$Other_____

3. At what level in the process did the *primary* failure occur? ____

4. Additional levels where failure occurred?

PROCESS LEVELS

1. Pharmacy prepares/dispenses
2. Medication administration
3. Monitoring for side effects
4. Other_____
5. Unable to determine

5. Was anyone notified of the error? (may select more than one)

☐$_1$Physician ☐$_2$ Fellow ☐$_3$ Nurse ☐$_4$ Physician assistant

☐$_5$ Pharmacist ☐$_6$ Patient or family ☐$_7$ None ☐$_8$ Unable to determine

☐$_9$ Other_____

6. Who initially discovered the error?

☐$_1$Physician ☐$_2$ Fellow ☐$_3$ Nurse ☐$_4$ Physician assistant

☐$_5$ Pharmacist ☐$_6$ Patient or family ☐$_7$ Secretary

☐$_8$ None ☐$_9$ Unable to determine ☐$_{10}$Other_____

OUTCOMES OF ERROR

7. Was any additional vital sign monitoring performed because of the error?

☐$_0$ No ☐$_1$ Yes

8. Was any additional medication given because of the error?

☐$_0$ No ☐$_1$ Yes

9. Was any additional blood work performed because of the error?

☐$_0$ No ☐$_1$ Yes

10. Was any additional radiologic test performed because of the error?

☐$_0$ No ☐$_1$ Yes

11. Was any additional invasive procedure (other than blood work and radiologic tests) performed because of the error?

☐$_0$ No ☐$_1$ Yes

12. Was any additional clinic visit made because of the error?

☐$_0$ No ☐$_1$ Yes

13. Was any additional outpatient consult made because of the error?

☐$_0$ No ☐$_1$ Yes

14. Was any additional emergency room visit made because of the error?

☐$_0$ No ☐$_1$ Yes

15. Was the patient admitted to the hospital because of the error?

☐$_0$ No ☐$_1$ Yes

16. Was the patient admitted to the intensive care unit because of the error?

☐$_0$ No ☐$_1$ Yes

17. Did the error injure the patient?

☐$_0$ No (*If no, please stop here)* ☐$_1$ Yes

Drug A

18. Name of drug involved _____

19. Dose of drug _____

20. Unit of drug dose:

☐$_1$ Drops ☐$_2$ Grams ☐$_3$ Kilograms ☐$_4$ International Units

☐$_5$ Liters ☐$_6$ Micrograms ☐$_7$ Milligrams ☐$_8$ Milliliters

☐$_9$ Units ☐$_{10}$ Other_____

21. Route of drug ordered:

☐$_1$ Central venous access ☐$_2$ Intramuscular ☐$_3$ Topical ☐$_4$ Oral

☐$_5$ Intravenous ☐$_6$ Subcutaneous ☐$_7$ Sublingual

☐$_8$ Other _____

22. Frequency of drug ordered_____

23. # doses received in the 24 hours previous _____

24. # doses received in last week _____

Drug B

Please complete only if there were more than one medication involved in the error being described. ***If there were two different medications involved in different errors complete a separate event identification form.***

25. Name of drug involved _____

26. Dose of drug _____

27. Unit of drug dose:

☐$_1$ Drops ☐$_2$ Grams ☐$_3$ Kilograms ☐$_4$ International Units

☐$_5$ Liters ☐$_6$ Micrograms ☐$_7$ Milligrams ☐$_8$ Milliliters

☐$_9$ Units ☐$_{10}$ Other_____

28. Route of drug ordered:

☐$_1$ Central venous access ☐$_2$ Intramuscular ☐$_3$ Topical ☐$_4$ Oral

☐$_5$ Intravenous ☐$_6$ Subcutaneous ☐$_7$ Sublingual

☐$_8$ Other _____

29. Frequency of drug ordered_____

30. # doses received in the 24 hours previous _____

31. # doses received in last week _____

Drug C

Please complete only if there were more than two medications involved in the error being described. ***If there were two different medications involved in different errors complete a separate event identification form.***

32. Name of drug involved _____

33. Dose of drug _____

34. Unit of drug dose:

☐$_1$ Drops ☐$_2$ Grams ☐$_3$ Kilograms ☐$_4$ International Units

☐$_5$ Liters ☐$_6$ Micrograms ☐$_7$ Milligrams ☐$_8$ Milliliters

☐$_9$ Units ☐$_{10}$ Other_____

35. Route of drug ordered:

☐$_1$ Central venous access ☐$_2$ Intramuscular ☐$_3$ Topical ☐$_4$ Oral

☐$_5$ Intravenous ☐$_6$ Subcutaneous ☐$_7$ Sublingual

☐$_8$ Other _____

36. Frequency of drug ordered_____

37. # doses received in the 24 hours previous _____

38. # doses received in last week _____