Medication Errors in the Home: A Multisite Study of Children With Cancer

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KEY WORDS

antineoplastic agents, medical errors, medication errors, patient safety, pediatric cancer, quality improvement

ABBREVIATIONS

CI—confidence interval

S-TOFHLA—short test of functional health literacy in adults

Dr Walsh conceptualized and designed the study; contributed to the acquisition, analysis, and interpretation of data; performed statistical analysis; obtained funding; drafted the manuscript; critically revised the manuscript for intellectual content; and approved the final manuscript as submitted. Dr Roblin contributed to the concept and design of the study, as well as critical revision of the manuscript for intellectual content, and approved the final manuscript as submitted. Dr Weingart contributed to the acquisition of data, analysis and interpretation of data, administrative and material support, critical revision of the manuscript for intellectual content, and approved the final manuscript as submitted. Ms Houlahan contributed to the acquisition of data, critical revision of the manuscript for intellectual content, and approved the final manuscript as submitted. Dr Degar contributed to the analysis and interpretation of data, critical revision of the manuscript for intellectual content, and approved the final manuscript as submitted. Dr Billett contributed to the analysis and interpretation of data, critical revision of the manuscript for intellectual content, and approved the final manuscript as submitted. Dr Keuker contributed to the analysis and interpretation of data, administrative and technical support, critical revision of the manuscript for intellectual content, and approved the final manuscript as submitted. Ms Biggins contributed to the acquisition of data, analysis and interpretation of data, administrative support, drafting of the manuscript, and approved the final manuscript as submitted. Mr Li contributed to the acquisition of data, administrative support, critical revision of the manuscript for intellectual content, and approved the final manuscript as submitted. Dr Wasilewski contributed to the acquisition of data, administrative and material support, critical revision of the manuscript for

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WHAT'S KNOWN ON THIS SUBJECT: Children are taking more medications than ever before. Medication errors in the hospital are common. Less is known about the medication errors that occur in children's homes, and there are no studies that examine the entire process.

WHAT THIS STUDY ADDS: We reviewed 963 medications in the homes of children with cancer at 3 sites. We found 3.6 errors with injury and 36 errors with potential for injury per 100 patients. Interventions should target common and dangerous errors at home.

abstract

FREE

OBJECTIVE: As home medication use increases, medications previously managed by nurses are now managed by patients and their families. Our objective was to describe the types of errors occurring in the home medication management of children with cancer.

METHODS: In a prospective observational study at 3 pediatric oncology clinics in the northeastern and southeastern United States, patients undergoing chemotherapy and their parents were recruited from November 2007 through April 2011. We reviewed medical records and checked prescription doses. A trained nurse visited the home, reviewed medication bottles, and observed administration. Two physicians independently made judgments regarding whether an error occurred and its severity. Overall rates of errors were weighted to account for clustering within sites.

RESULTS: We reviewed 963 medications and observed 242 medication administrations in the homes of 92 patients. We found 72 medication errors. Four errors led to significant patient injury. An additional 40 errors had potential for injury: 2 were life-threatening, 13 were serious, and 25 were significant. Error rates varied between study sites (40–121 errors per 100 patients); the weighted overall rate was 70.2 errors per 100 patients (95% confidence interval [CI]: 58.9–81.6). The weighted rate of errors with injury was 3.6 (95% CI: 1.7–5.5) per 100 patients and with potential to injure the patient was 36.3 (95% CI: 29.3–43.3) per 100 patients. Nonchemotherapy medications were more often involved in an error than chemotherapy.

CONCLUSIONS: Medication errors were common in this multisite study of outpatient pediatric cancer care. Rates of preventable medication-related injuries in this outpatient population were comparable or higher than those found in studies of hospitalized patients. *Pediatrics* 2013;131: e1405–e1414

Americans are taking more medications at home than ever before.[1,2] From 2002 to 2005, the number of children taking medication at home increased in all major drug classes.[3] Due to improving survival rates for premature infants and those with congenital anomalies, increasing treatment of cancer with oral agents, and increasing survival rates for patients with cancer and other serious illnesses, the number of children requiring ambulatory care is increasing.[4,5] In the inpatient setting, where nurses administer medications, errors are common.[6–10] Less is known about error rates in the outpatient setting, where medications are administered by patients and their families.[11]

Literature on outpatient care does not provide a complete understanding of how medicines are used at home. Several studies rely on retrospective, large database analyses, which provide limited information on causality and risk factors.[12–14] Medical record reviews capture only errors documented in the record.[15–17] Some studies rely on patient or parent reports of medication errors.[18,19] However, parents may inaccurately report doses given or be unaware of the errors they make. Other studies ask parents to demonstrate proper dosing of home medications while in the clinic.[20–22] These approaches assess only part of the entire process of home medication use and are subject to sampling bias. A comprehensive investigation of the spectrum of errors in medication use at home, assessing frequency and severity, is needed to identify vulnerabilities, target education, and design interventions.[23]

Our previous multisite study of medical records demonstrated that children with cancer are particularly vulnerable to home medication errors.[17] Ten percent to 40% of oral chemotherapy doses are missed at home.[5,24] Errors in the use of home medications for cancer treatment can be dangerous; underdosing may result in failure to treat the cancer, and overdoses can be fatal. We have developed direct observational methods to identify and describe medication errors occurring in the home.[11,25] In the current study, our objective was to describe types of medication errors that occur in the homes of children with cancer. We performed a prospective study at 3 sites in which we reviewed medical records and bottle labels, and directly observed medication use in the home.

METHODS

Study Sites

We identified 3 study sites with different clinical settings in the northeastern and southeastern United States. All study sites had academic affiliations. The visit numbers varied from 2000 patients a year and 40 prescribers to 50 patients a year and 5 prescribers. All 3 sites used electronic health records for drug ordering. Physicians and nurses at each site performed medication reconciliation at each visit for all medications. The study protocol was approved by the institutional review board at each site.

Subjects

Parents (the word parent throughout this article refers to the parent or guardian) and their child, from infants through 20 years old, taking daily home medications and undergoing chemotherapy for cancer were eligible for the study. A research assistant approached potential participants by telephone or in the clinic and informed them that the study concerned how children with cancer take medications at home to identify problems that can occur. At 1 study site, visits were performed in English or Spanish. At the other sites, visits were performed in English only. Patients living more than a 2-hour drive away from the clinic were excluded; numbers of patients living >2 hours away varied by site from zero to 20% of patients.

Demographic Characteristics

We abstracted the patient's age, diagnoses, and insurance status from the medical record. Parents were asked for their race/ethnicity and highest educational level. We used the short test of functional health literacy in adults (S-TOFHLA) and a single-item health literacy screener to assess parent health literacy.[26,27]

Medical Record Review

Before the home visit, we reviewed the most recent clinic visit note. At 1 site, we reviewed a home medication calendar, which clinicians and families routinely used as the most up-to-date source of information on the patient's current medication regimen. At the other sites, the medication list and clinic note were used to ascertain the patient's current regimen. We confirmed each dose by using the patient's current weight and height and checked allergy lists. Doses >10% different from the recommended dose were considered errors.[13,25] When multiple references existed, including cancer treatment protocols, we considered the maximum and minimum dose referenced to represent the normal range. To be conservative in our estimates, giving as much credit as possible to prescribers, doses outside of normal limits that were considered clinically reasonable by physician reviewers (based on reviewers' experiences) were not considered errors.[25]

Home Visits

Methods of direct observation were developed from hospital-based methods to detect errors[8,28–30] and were refined based on pilot testing, as described elsewhere.[11] Home visits were scheduled at times when the patient

took the most medications and when the person who normally administered the medications was available. Because these times were usually in the morning, daytime, or evening (rather than late at night), it was not difficult for study staff to visit the homes at these times. The home visit included a medication review, brief parent interview, and direct observation of medication administration by a trained research nurse. We visited each child only 1 time.

Medication Review

A medication was defined as any over-the-counter, prescription drug, or any herbal supplement. We reviewed all of the patient's medication bottles, including as-needed medications; recorded the name, strength, use instructions (including dosage and frequency), expiration date; and reviewed the bottle contents. Pill counts were not valuable in our pilot study and were therefore not performed.[11]

Brief Parent Interview

The research nurse asked the parent how each medication was used and how many doses had been missed in the last 7 days. When she found a difference between the current medication regimen, the bottle label, and how the medication was used, she asked the parent to explain. The medical record was rereviewed, and the patient's oncologist was consulted as needed for clarification. For example, if a parent gave a different amount of chemotherapy than recorded in the medication list but explained that the oncologist called yesterday to change the dose, and this change was confirmed by the medical record, it was not counted as an error.

Direct Observation

The research nurse directly observed medication preparation and administration. The parent and patient were asked to administer daily and as-needed medications exactly as they would normally do so. With 2 independent nurses in the home, interobserver reliability for the detection of errors during home visits was good (κ = 0.89 [95% confidence interval (CI): 0.67–1.0]).[11] During the home visit, information was gathered about the home environment, such as the use of support tools (eg, pill boxes).

A written protocol outlined procedures for dealing with dangerous errors, concerns regarding child abuse or neglect, and spontaneous parental reports of depression. At each site, a clinician was available by page at all times.

Nurse Training

To ensure consistency between sites, nurses received didactic training, including a review of the literature and examples of possible errors (eg, errors of omission and commission). We created training and test videos of simulated home visits and accompanying labeled medication bottles containing common errors from pilot visits. Nurses identified 100% of the errors on the test video before going on home visits.

Event Description and Classification

The research nurse noted potential errors on an error-reporting form. The nurse also noted whether the clinician or parent seemed aware of the error, based on observation and medical record review. For example, in our previous research, nurses or parents may not have realized that the dose of chemotherapy changed and may have unknowingly administered the wrong dose.[17] At other times, parents are aware of an error. For example, a parent may report that the medication bottle was labeled incorrectly, but they use it correctly or a parent may discover they have been giving the medication dose incorrectly and fix it. Pairs of pediatricians, including at least 1 oncologist (Drs Billett, Degard, and Walsh) trained in error identification and analysis, made independent judgments about whether an error had occurred and its severity, as in previous well-established methods.[6,8,9,16–18,31] A medication error was defined as an error in drug ordering, dispensing, administering, or monitoring.[6,8,25] Severity was rated as life-threatening, serious, significant, or trivial.[6,15–17] Significant injury included minor pain, such as headache, worsening of constipation, or vomiting. Serious injury was serious pain or injury that was not life- threatening. The κ value for the interrater reliability of independent judgments of whether an error had occurred was 0.94 (95% CI: 0.87–1.0) and its severity was 0.71 (95% CI: 0.54–0.88). For each error, physician reviewers selected, from a list of 50 interventions proposed in the literature or used in clinical practice, interventions most likely to prevent the error, as in previous research.[32] One physician (Dr Walsh) qualitatively developed types of errors.

Analyses

The primary outcome was the total number of medication errors identified. We compared patients who declined to participate with those recruited but not visited and with those we visited by using χ^2 tests for categorical data (diagnosis and insurance) and analysis of variance for continuous data (age). The rate of errors per patient was calculated for each study site. To account for clustering between study sites, we calculated a weighted rate of errors for the overall group, with 95% CIs. Medications were categorized as chemotherapy (medications intended to treat cancer), supportive medications (eg, antiemetics), and other medications (eg, albuterol for asthma). For each site, we calculated the rate of errors per medication, weighted by individual

patient to account for variations in the number of errors per patient within sites. We performed bivariate analyses for the whole group and for each study site by using χ^2 or Fischer's exact tests to test the association between demographic characteristics and the risk of having a medication error at home. The S-TOFHLA is scored on a scale of 0–36 where scores of 23–36 are adequate, 17–22 are marginal and under 22 are inadequate health literacy.

RESULTS

We invited 167 eligible families to participate; 118 consented, and 92 home visits were completed. This 71% recruitment rate is similar to or better than other home visit studies.[33,34] Reasons for declining participation included no time and the desire to keep the home free of medical personnel. Families consented but were not visited because we were unable to schedule a visit after at least 3 telephone calls or the patient completed treatment before we could schedule a visit. The age was similar between those who declined, consented but not visited, and those visited: 6.5 years, 7 years, and 7 years, respectively ($P = .6$). The number of patients with private insurance was similar among the 3 groups: 70%, 75%, and 76% ($P = .8$). The number of patients with leukemia was also similar: 67%, 70%, and 78% ($P = .8$).

Demographic Characteristics

In our 92 home visits, we reviewed 963 medications and observed 242 administrations. Most of the patients visited (78%) had leukemia (Table 1). They took a median of 10 medications at home (range: 3–26). The mother was usually primarily responsible for administering home medications (87%). Parents were well educated: 57% completed a bachelor's degree and 97% scored in the adequate range (67–100) on the S-TOFHLA, a measure of health literacy.

TABLE 1 Demographic Characteristics of Home Visit Study Patients and Their Parents

Characteristic	No. or Range ($N = 92$)	Percent
Subject child, female gender	39	42
Subject child's insurance		
Private	70	76
Public	22	24
Subject child's cancer diagnosis		
Leukemia	72	78
Lymphoma	8	9
Brain tumor	7	8
Other	5	5
Subject child's age		
Median	7 y	—
Range	14 mo–19 y	
Person primarily responsible for administering medications		
Mother	80	87
Father	5	5
Nurse	0	0
Aunts	1	1
Child (self-administration)	6	7
Parent's race		
Black	7	8
White	80	87
Asian/Pacific Islander	5	5
Parent's ethnicity		
Hispanic	11	12
Non-Hispanic	81	88
Parent's highest educational level		
No high school degree	3	3
High school diploma/GED	13	14
Some college, trade school, associate's	23	25
Four-year college diploma	36	39
Advanced degree	17	19
Parent's primary language		
English	79	86
Spanish	6	7
Other	7	8
Parent's S-TOFHLA score		
Median	96	—
Range (low–high)	36–100	
"How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?"[a]		
Never	62	70
Rarely	16	18
Sometimes	9	10
Often	1	1
Always	1	1
Support tools used at home to help in medication use[b]		
Calendar	52	57
Pill box	27	29
Pill cutter/crusher	5	5
Alarm reminder	6	7
None	9	10

GED, general equivalency degree.

[a] Three study subjects did not answer this question.

[b] More than 1 answer was accepted for this question.

Behavior During Observation

When asked if they did anything to prepare for the home visit, 94% of parents reported that they did not. To the statement: "There is nothing different today about how I gave my child's medicine," 68% strongly agreed, 3% agreed, 9% were neutral, and 20%

strongly disagreed. Some adjusted the time of administration to coincide with the home visit. To the statement: "During the home visit, my child took his/her medications just as he/she usually does," 80% strongly agreed, 17% agreed, and 3% were neutral.

Types of Errors

We found 72 medication errors, including 4 that resulted in injury and 40 with potential for injury (Table 2). All errors with injury were significant. One parent did not taper a psychiatric medication as instructed, and the patient suffered severe agitation. Two parents underdosed or failed to fill prescriptions for antacids; both patients experienced prolonged untreated chest and abdominal pain. One patient was administered repeated significant underdoses (<20% of the appropriate dose) of acetaminophen, with resulting failure to relieve pain. The research nurse worked with each child's oncologist to rectify these errors, when possible.

Of those errors with potential for injury, 2 were life-threatening, 13 were serious, and 25 were significant. The 2 life-threatening errors were: (1) a methotrexate bottle labeled to give 8 tablets daily rather than weekly; and (2) a parent observed administering a large underdose (50% of the prescribed dose) of trimethoprim-sulfamethoxazole for *Pneumocystis* prophylaxis.

Error rates varied between study sites (40.0–120.6 errors per 100 patients); the weighted overall rate was 70.2 errors per 100 patients (95% CI: 58.9–81.6) (Table 3). The rate of errors per 100 medications, weighted for differing rates of errors in individual patients, also varied between sites, from 3.0 to 15.0 per 100 medications reviewed. Nonchemotherapy medications were more often involved in an error than chemotherapy.

Drug administration was the most common stage of medication use in which an error occurred (63.5% of errors) (Table 4). These sometimes occurred when parents failed to increase or decrease medication doses as instructed by the oncologist or failed to communicate changes in dose to other caregivers at home. We also found missed doses (by parent report or based on review of bottle contents) and failure to fill prescriptions. There were several errors in which parents selected the wrong dose of acetaminophen for their child. We found no measurement errors. Of note, of the 47 parents we observed administering chemotherapy, only 5 wore gloves when handling these agents to avoid toxicity.[35,36] These were not counted as errors because the patient took the medication correctly.

We frequently reviewed medication bottles where, because of changes in dose, the medication label no longer reflected the current dose of the medicine. For example, a mercaptopurine bottle was labeled "2 tablets orally at bedtime," but the child was taking one-half tablet at bedtime at the time of the home visit. Errors occurred when parents gave the medication according to the label, rather than instructed, or when parents disregarded the medication label when it was correct. Of the 58 medications for which the label did not reflect the current dose, 11 were associated with a medication error.

During home visits, 47% of patients experienced at least 1 error: 32% had 1 error ($n = 29$), 8% had 2 errors ($n = 7$), and 8% had ≥3 errors ($n = 7$). In bivariate analyses, race, ethnicity, insurance, health literacy, and use of support tools were not associated with increased risk for having a medication error, but the study was not adequately powered to detect these relationships (Appendix). Multiple logistic regression analyses were not performed because we identified no significant ($P < .05$) bivariate associations.

Physician reviewers judged that improved communication about medication use between families and physicians could have prevented 36% of errors. Clinicians were unaware of 82% of the errors we detected, and parents were unaware of 56%. Parents were aware of some errors because they discovered the error around the time of the home visit or because the error was in

TABLE 2 Number and Rates of Medication Errors for Children With Cancer Visited at Home

Medication Error	Site A	Site B	Site C	Total
Home visits	34	40	18	92
No. of medication errors[a]	41	16	15	72
Crude rate per 100 patients	120.6	40.0	83.3	78.3
95% CI	92.2–148.7	28.8–51.2	58.7–107.9	—
Adjusted rate per 100 patients	—	—	—	70.2
95% CI	—	—	—	58.9–81.6
No. of errors with potential to injure (potential ADEs)	26	7	7	40
Life-threatening	1	1	0	2
Serious	8	3	2	13
Significant	17	3	5	25
Crude rate per 100 patients	76.5	17.5	38.9	43.5
95% CI	58.6–94.0	10.4–24.6	24.6–53.2	—
Adjusted rate per 100 patients	—	—	—	36.3
95% CI	—	—	—	29.3–43.3
Errors with injury (preventable ADEs)[b]	2	2	0	4
Crude rate per 100 patients	5.9	5.0	0	4.3
95% CI	1.8–10	1.5–8.5		—
Adjusted rate per 100 patients	—	—	—	3.6
95% CI	—	—	—	1.7–5.5

[a] Medication errors include all errors with injury, errors with potential to injure, and clinically trivial errors.

[b] All injuries (preventable adverse drug events [ADEs]) were rated significant by physician reviewers; none was serious or life-threatening.

TABLE 3 Rates and Numbers of Errors by Medication and Errors in Chemotherapy, Supportive Medications for Safe Administration of Chemotherapy, and Other Medications

Medication	Site A	Site B	Site C
Total medications reviewed	335	510	118
Median medications per child (range)	10 (3–26)	12 (5–23)	7 (3–13)
Administrations observed	96	105	41
Crude error rate per 100 medications	12	3	13
Adjusted error rate per 100 medications[a]	9.6 (7.5–11.7)	3.0 (0.9–4.1)	15.0 (11.4–18.6)
Chemotherapy medications	72	74	43
Chemotherapy errors	8	2	4
Supportive medications	32	45	13
Supportive medication errors[b]	2	0	1
Antibiotics, antiviral agents, antifungal	56	70	19
Antibiotics, antiviral agents, antifungal errors	11	4	4
Gastrointestinal medications	62	119	3
Gastrointestinal medication errors	1	4	1
NSAIDS and local anesthetics	22	45	3
NSAIDs and local anesthetic errors	3	0	1
Narcotics	19	51	8
Narcotic errors	2	2	1
Respiratory medications	8	5	1
Respiratory medication errors	3	0	0
Antiepileptic/neurologic medications	9	36	7
Antiepileptic/neurologic medications errors	0	0	0
Allergy medication	16	11	8
Allergy medication errors	3	1	2
Vitamins	13	14	0
Vitamin errors	1	0	0
Topical agent	7	8	1
Topical agent errors	1	0	0
Behavior/mental health medications	8	9	8
Behavior/mental health medication errors	4	2	1
Other medications	11	23	1
Other medication errors	1	1	0

Supportive medications included antiemetic agents and other medications included methylphenidate for attention-deficit disorder or medications for *Pneumocystis* prophylaxis. NSAIDs, nonsteroidal antiinflammatory drugs.

[a] The adjusted rate per medication was weighted to account for clustering by individual patient.

[b] Supportive medications were those required to support safe chemotherapy use.

medication labeling, such as an incorrect label where parents ignore the label and give the medicine correctly. In cases in which parents were unaware of errors, they had often misunderstood medication preparation or dosage instructions that unknowingly introduced mistakes.

DISCUSSION

Medication errors were common in this study of children and adolescents with cancer, with almost 1 in 2 patients exposed to ≥1 error in medications used at home. Administration errors accounted for the majority of the errors detected, most often due to the parent administering the wrong dose or missing scheduled doses of medication. The rate of injuries due to error in our study (3.6 per 100 patients) was high.

To our knowledge, this is the first multisite study of errors in medication use in the homes of pediatric oncology patients. Consistent with previous multisite research,[17] there was variation in error rates between sites. This finding may reflect actual differences in error rates or inconsistent detection of errors during the home visit or medical record review.

Compared with previous medical record review studies, we found a higher rate of errors. In a previous multisite study of medical records, we found that 19% of pediatric oncology clinic visits involved a medication error.[17] Gandhi et al[15] found that 2% of pediatric oncology clinic visits and 3% of adult visits involved an error. Taylor et al[20] observed parents measuring chemotherapy in the clinic and found mistakes in 10%; we found fewer errors. By using medical record review, bottle review, and direct observation in the home, we were able to identify a broad range of error types that occur in outpatient pediatric oncology care.

Although we detected only 4 injuries due to medication errors, the rate of injury (3.6 per 100 patients) is higher than expected. In hospitalized adults, Bates et al found that 1.8% of admissions had a preventable injury due to medication use. In hospitalized children, rates of preventable medication-related injuries ranged from 0.5% to 3.8%.[9,37] Children with cancer in our study in the home setting had a comparable or higher rate of medication-related preventable injuries than hospitalized children in other studies.

In our study, parent administration errors were often caused by miscommunication between parents and clinicians or between in-home caregivers regarding changes in oral chemotherapy dose. Frequent changes in dose, which caused the bottle label to be outdated, were often a root cause of parent errors. Many errors occurred in nonchemotherapy medication. Given that children with cancer see their oncologist more frequently than their primary care physician, oncologists may need to inquire more about nonchemotherapy medication use.

Given the variety of error types detected in our study, multiple support tools will likely to necessary to prevent errors in home medication use in children with cancer. Failure modes and effects analysis methods have been used to understand sources of errors in oral chemotherapy use.[38,39] Some communication-based errors may be prevented by using strategies developed in hospitals around

TABLE 4 Types of Errors Detected in Children With Cancer

Error Type	Frequency		Example (Severity Rating of Example)
	N	%	
Administration: wrong dose or frequency	20	28	Parents failed to reduce home oral chemotherapy dose to 50% dose as instructed by physician. They did not realize they were supposed to do so. (Error with potential for injury; serious)
Label wrong	13	18	Child on narcotic that is prescribed 3 times a day as needed. Medication label written as take every 6 h. (Error with potential for injury; significant)
Missed doses	14	19	Patient prescribed antibiotic for urinary tract infection. During home visit several months later, more than one-half of the antibiotic remained in bottle. (Error with potential for injury; significant)
Prescribing error	9	12.5	Clinician prescribed standard dose rather than the indicated high dose chemotherapy. (Error with potential for injury; serious)
Using expired medication	9	12.5	Family using stool softener that expired several months before home visit. (Error; clinically trivial)
Other	4	6	Pharmacy told mother the prescription requires prior authorization; parent did not understand and did not get medication or request previous authorization. (Error potential for injury; significant)
Administration: wrong technique	3	4	Parent gives albuterol prediluted bullets with saline bullets. Takes too long to administer so only gives when child is sleeping. (Error with potential for injury; significant)

Administration of wrong dose or frequency, missed doses, using expired medication, and administration using wrong technique were all considered types of administration errors.

handoffs. In adult patients with chronic disease, pharmacist case-management involving health information technology has been used to support home medication use.[40,41]

Although this study used a multisite prospective approach, it is important to consider a few limitations. First, our methodology is unlikely to have detected all errors, and this study was focused on capturing errors, rather than focusing on adverse drug events. Administration errors that occurred when we were not in the home would not have been detected according to our direct observation methods. The use of direct observation is an excellent approach to "allow comparison between what people say and what they actually do,"[42] but our presence in the home may have changed behavior. If parents changed their behavior, the effect would most likely be to reduce the number of errors detected. The population we studied was well educated, which may have also led to an underestimate of the error rate. Second, due to the laborious nature of home visits, our sample size of 92 patients was smaller than other studies of medical errors that used medical record review. We did review a large number of medications (n = 963) and found many errors (n = 72). Finally, generalizability of the results of this study to other pediatric oncology clinics requires additional study. This study focused on children cared for at medium and large academic health centers. The patients in this study were treated with chemotherapy and support medications according to cancer treatment protocols, including children's oncology group protocols and others, which may reduce variability across oncology clinics. The use of antibiotics and other medications may have more variability across sites.

CONCLUSIONS

In this multisite study of medication errors in the homes of children with cancer, we found that errors were common, with a rate of 3.6 injuries due to medication error per 100 patients. Parent administration errors were often due to communication failures. As the use of oral chemotherapy rises, responsibility for the management of these toxic medications shifts from nurses to parents and patients. Although significant resources are aimed at reducing inpatient medication errors, we found that children with cancer in the outpatient setting were also at very high risk for preventable injuries due to medication use.

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APPENDIX: BIVARIATE ANALYSES FOR INSURANCE, HEALTH LITERACY, USE OF SUPPORT TOOLS, AND RACE/ETHNICITY

APPENDIX TABLE 1 No. of Patients With Private or Public Health Insurance Who Have at Least 1 or No Errors

Medication Error	Private Insurance	Public Insurance	Total
At least 1 error	30	12	42
No errors	40	10	50
Total	70	22	92

APPENDIX TABLE 2 No. of Patients With Inadequate, Marginal, and Adequate Health Literacy Who Have at Least 1 or No Errors

Medication Error	Inadequate (0–59)	Marginal (60–74)	Adequate (75–100)	Total[a]
At least 1 error	0	3	39	42
No errors	1	1	47	49
Total	1	4	86	91

[a] One parent who had no errors at home declined to complete the S-TOFHLA.

APPENDIX TABLE 3 No. of Patients Using Support Tools at Home or No Support Tools Who Have at Least 1 or No Errors at Home

Medication Error	No Support Tool	Any Support Tool	Total
At least 1 error	1	41	42
No errors	4	46	50
Total	5	87	92

APPENDIX TABLE 4 No. of Patients, by Race, Who Have at Least 1 or No Errors at Home

Medication Error	Asian	Black or African American	White	Total
At least 1 error	3	2	37	42
No errors	2	5	43	50
Total	5	7	80	92

APPENDIX TABLE 5 No. of Patients, by Ethnicity, Who Have at Least 1 or No Errors at Home

Medication Error	Hispanic	Non-Hispanic	Total
At least 1 error	5	37	42
No errors	6	44	50
Total	11	81	92