

Adverse Drug Events Among Pediatric Outpatients

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Background:

- Medications are commonly used in the pediatric ambulatory setting; 72% of pediatric office visits are associated with the continuation or initiation of a drug.
- Medications are the most commonly used form of medical therapy and the single most frequent cause of adverse events.
- Adverse events due to medication errors occur in about 1% of pediatric hospitalizations and less is known about the ambulatory care setting.
- Healthcare disparities are a pervasive national problem, affecting healthcare access, use, and clinical outcomes.
- Relatively little research has examined whether there are increased risks of adverse drug events in vulnerable children in the ambulatory setting, where children receive the majority of medical care.

Objectives:

- To determine rates and types of adverse drug events (ADEs) in the pediatric ambulatory setting.
- To determine whether there are racial/ethnic, socioeconomic, parental linguistic or parental educational disparities in children who experienced a preventable adverse drug event in the pediatric ambulatory care setting.

Methods:

- The study population was a prospective cohort of patients under age 21 seen from July 2002 to April 2003, in Boston, MA at 6 diverse practice sites.
- Data collection methodologies included duplicate prescription review, 2 surveys and chart review.
- All data were reviewed for medication errors including those with the potential for harm (near-misses) and those that actually cause harm (preventable ADEs). In addition, data were reviewed for harm from medications that was not associated with an error (nonpreventable ADEs). (Figure 1)
- Children under age 21 who had an office visit during the study period and received at least one prescription were eligible.
- All prescriptions for oral contraceptives, equipment, and formula were excluded.

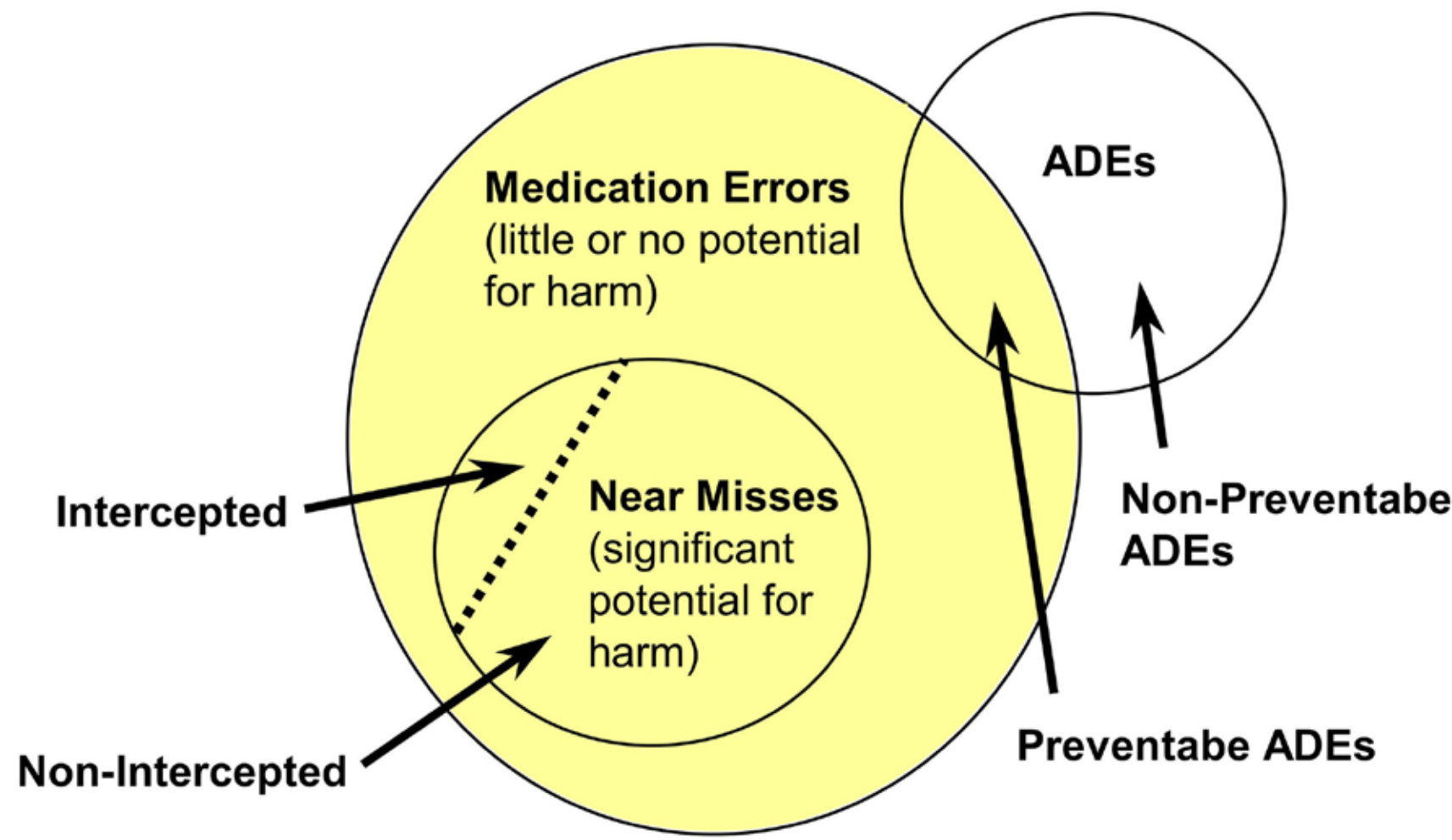


Figure 1. Relationship between adverse drug events (ADEs), near misses, and medication errors.

Results:

- During the study period, 21,209 visits were made by 13,919 patients of whom 3,838 received a prescription. Of these, we analyzed 1,689 patients who had both completed the 10-day survey and had a chart review.
- The children of survey respondents and non-respondents were comparable in terms of gender (50% female in each group), but the children of respondents were slightly younger (29% neonates and infants among respondents compared to 25% among non-respondents, $p=.01$), less likely to be on Medicaid (12% versus 15%, $p=.03$), and less likely to be Hispanic (20% versus 23%, $p=.01$).

Table 1: Characteristics of study sample*		
Characteristics		Total n = 1689 n (%)
Child		
Race	White	815 (49)
	Black	256 (15)
	Hispanic	343 (21)
	Other	239 (14)
Age – yr	Mean (SD)	5.6 (4.5)
Child's Sex	Female	835 (50)
Health Status *	Poor	412 (25)
	Good	1262 (75)
Chronic Condition	No	1168 (70)
	Yes	499 (30)
Insurance Type	Medicaid	727 (43)
	Non Medicaid	962 (57)
Caregiver		
Educational Attainment	≤ 12 yr	501 (30)
	> 12 yr	1153 (70)
	≥ 80,000	465 (36)
Annual income	50,000 < 80,000	200 (16)
	30,000 < 50,000	158 (12)
	≤ 30,000	63 (34)
	At or below	179 (14)
Federal Poverty Level €	Above	1073 (86)
	Proficient	1315 (79)
English Proficiency £	LEP	355 (21)
Utilization		
Practice Site	Teaching Hospital	463 (27)
	Urban Health Centers	409 (24)
	Suburban Practices	814 (48)
No. of prescriptions	1	1316 (78)
	2	304 (18)
	3	51 (3)
	>3	18 (1)

* Percentages may not sum to 100, because of rounding.

¥ Health Status: good is classified as parent report of child's health as excellent or very good.

€ Poverty status was calculated by taking families' annual income and number of family members, comparing them to the 2003 poverty guidelines issued by the HHS, and then classifying families into two groups, either at the Federal Poverty Level (FPL) or above the FPL.

£ English proficient: parent report of speaking English very well.

- We found 283 ADEs that occurred in 242 children, of which 57 were preventable ADEs (rate 3%; 95% CI 3-4) that occurred in 55 children and 226 non-preventable ADEs (rate 13%; 95% CI 11-15) that occurred in 186 children.

Table 2: Rates of ADEs		
	Number (%)	Rate Per 100 Patients (95% CI)
Preventable ADEs	57	3 (3-4)
Severity		
Fatal or life-threatening	0 (0%)	
Serious	8 (14%)	0.5 (0.3-0.6)
Significant	49 (86%)	3 (2-3)
Non-preventable ADEs	226	13 (11-15)
Severity		
Fatal or life-threatening	1 (0.4%)	.06 (.03-.10)
Serious	26 (11%)	1 (1-2)
Significant	199 (88%)	11 (9-13)
Total Near-misses	464	26 (23-29)
Interception		
Non-intercepted	455 (99%)	25 (22-29)
Intercepted	9 (1%)	0.5 (0.4-0.7)
Severity		
Fatal or life-threatening	6 (1%)	0.3 (0.2-0.5)
Serious	58 (13%)	3 (3-4)
Significant	400 (86%)	22 (20-25)

Detection Methods:

- Of the 242 children who had an ADE, 183 (76%) were identified by surveying patients, 47 (19%) by reviewing charts, and 13 (5%) by both means.
- Black and Hispanic parents as well as those who had LEP reported fewer ADEs. Additionally, parents who were wealthy, educated, or visited a suburban practice site were more likely to report an ADE.

Children with Preventable ADEs:

- In univariate analysis, for the 49 children who only experienced a preventable ADE compared to children without ADEs, we found that children of parents who reported they spoke English poorly were twice as likely to have a preventable ADE (OR 2.31, 95%CI 1.01, 5.34) than children of parents who spoke English very well. Similarly, children with less continuity of care (<1 year) were more likely to have a preventable ADE than those with more continuity of care (>1 year) (OR 1.83 95%CI 1.01, 3.34).
- In multivariate analysis, only children with more than one prescription (OR 1.46, 95%CI 1.01, 2.11) were at increased risk of having a preventable ADE.

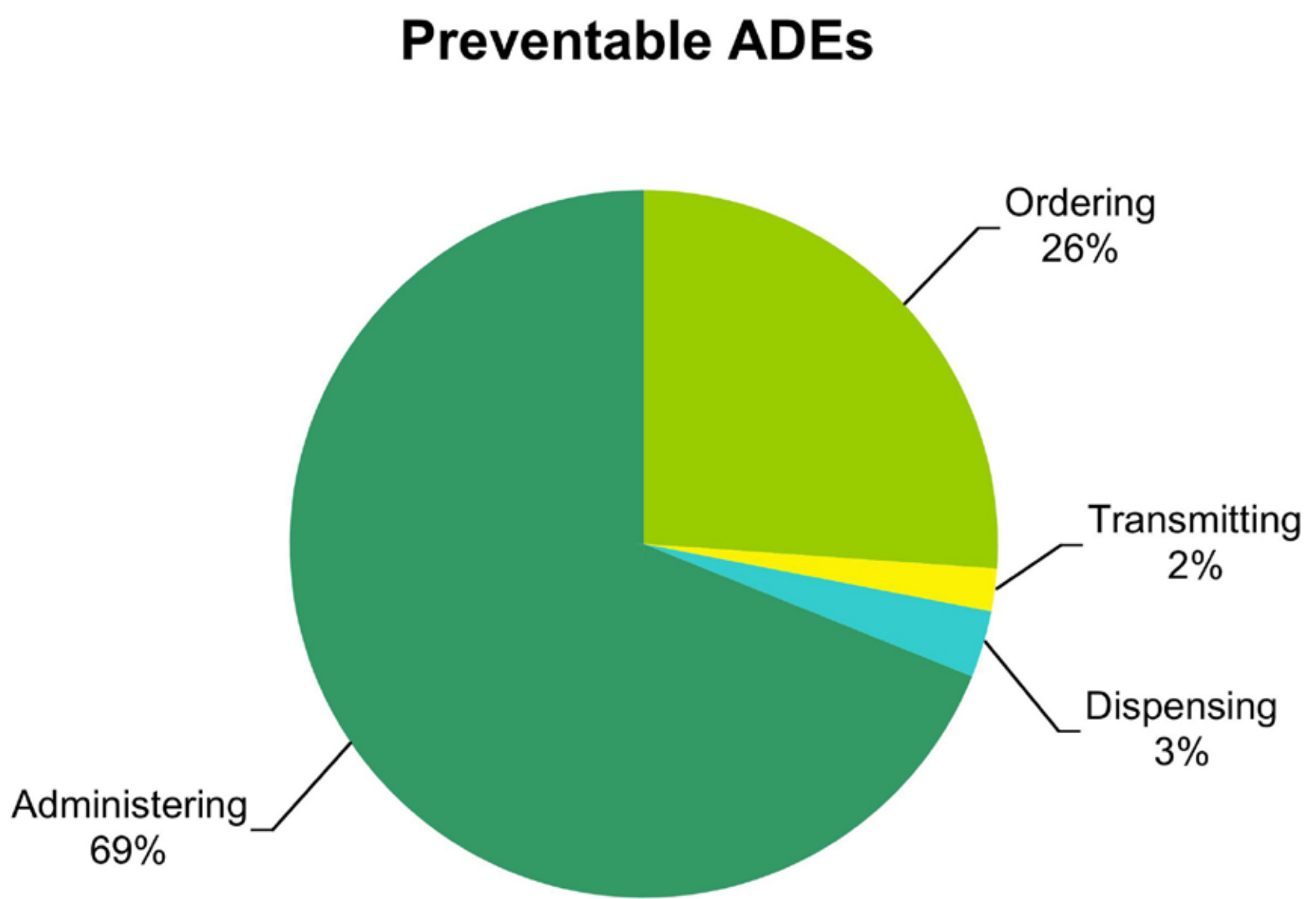


Figure 2. Stages of Preventable ADEs

Conclusions:

- In children seen in the ambulatory care setting, we found that adverse drug events are common and preventable, often occurring at the stage of home administration.
- Minority children, especially those whose parents have LEP, appear to be more likely to experience an error resulting in harm. Additionally, Black and Hispanic parents are relatively less likely to report an ADE.
- Our findings have two important policy implications.
 1. For policymakers and providers who are interested in improving patient safety, better measures are needed to identify preventable ADEs especially among minority parents with limited-English proficiency.
 2. Identification of parent's health literacy and appropriate tailoring of medication-related information are required. Improving physician-patient communication should ultimately lead to decreased preventable adverse drug events.

Acknowledgments:

This project was supported by the Agency for Healthcare Research and Quality (P01-HS11534) and The Commonwealth Fund. Dr. Zandieh is the recipient of the 2006 APA young investigator award.