Pediatric Adverse Drug Events in the Outpatient Setting: 
An 11-Year National Analysis

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WHAT’S KNOWN ON THIS SUBJECT:
“Pharmacologic therapy is used extensively for children in the outpatient setting. Among pediatric inpatients, ADEs have been found to be a frequent complication of medical care.”

WHAT THIS STUDY ADDS:
“ADEs result in a large number of health care visits to outpatient clinics and emergency departments with age-specific variation in the incidence of events and medications implicated.”

FROM ABSTRACT:

OBJECTIVE: Adverse drug events (ADEs) are a common complication of medical care, but few pediatric data are available describing the frequency or epidemiology of these events.

We estimated the national incidence of pediatric ADEs requiring medical treatment, described the pediatric population seeking care for ADEs, and characterized the events in terms of patient symptoms and medications implicated.

METHODS: Data were obtained from the National Center for Health Statistics, which collects information on patient visits to outpatient clinics and emergency departments throughout the United States. We analyzed data for children 0 to 18 years of age seeking medical treatment for an ADE between 1995 and 2005.

RESULTS: The mean annual number of ADE-related visits was 585,922 of which 78% occurred in outpatient clinics and 12% occurred in emergency departments.

Children 0 to 4 years of age had the highest incidence of ADE-related visits, accounting for 43.2% of visits.

The most common symptom manifestations were dermatologic conditions (45.4%) and gastrointestinal symptoms (16.5%).

The medication classes most frequently implicated in an ADE were antimicrobial agents (27.5%), central nervous system agents (6.5%), and hormones (6.1%).

While ADEs related to antimicrobial agents were most common among children 0 to 4 years old and decreased in frequency among older children, ADEs resulting from
central nervous system agents and hormones increased in frequency among children 5 to 11 and 12 to 18 years old.

CONCLUSIONS: ADEs result in a substantial number of health care visits, particularly in outpatient clinics. The incidence of ADEs and medications implicated vary by age, indicating that age-specific approaches for monitoring and preventing ADEs may be most effective.

THESE AUTHORS ALSO NOTE:

About 70% of children seen by medical personnel in an ambulatory setting are given drugs.

In any given week, 56% of US children take at least 1 drug and 26% take 2 or more drugs.

Adverse drug events (ADEs) are defined as injuries resulting from taking a drug for medical intervention.

4.7% of all hospitalizations are the result of ADEs. 6.5% of inpatients suffer an ADE during their hospitalization.

A 1997 pediatric study found that up to 16% of all outpatient prescriptions are associated with an ADE.

This study excluded all visits in which the child was drug dependant or abusing a drug, the use of an illicit substance, drug withdrawal, intentional self-harm, or assault by poisoning. This study only included drugs that were prescribed by a healthcare provider. [Important]

RESULTS

“During the 11-year study period the mean annual number of ADE-related visits was 585,922 with 454,780 visits to outpatient clinics, and 370,763 visits to general practice clinics.”

“The highest proportion of visits was by children 0 to 4 years old who accounted for 43.2% of visits, followed by children 15 to 18 years old who comprised 22.6% of ADE-related visits.”

“In both the clinic and emergency department settings, the greatest proportion of ADE visits were by non-Hispanic white children, those with private insurance, and those residing in the South.”

“Dermatologic conditions were the most common ADE manifestation, present in 45.4% of cases, followed by gastrointestinal symptoms in 16.5% of cases.”
“The medication classes most frequently implicated in an ADE were antimicrobial agents (27.5%), central nervous system agents (6.5%), and hormones (6.1%).”

“Among ADEs related to antimicrobial agents, more than half were the result of a penicillin (40%) or cephalosporin (15%).”

“Adverse events to central nervous system agents were most often related to stimulants (37%) or antidepressants (29%), and the majority of ADEs involving hormones were associated with estrogens and progesterones (73%).”

“There was an increase in ADEs related to central nervous system agents and hormones among older children, with antidepressants and stimulants the most common central nervous system agents (38% and 31%, respectively), and ovarian hormones responsible for the majority of hormone related ADEs (82%).”

DISCUSSION

“On the basis of 11 years of national data on patient visits to US ambulatory health care facilities, we found that ADEs are a common complication of medication use among pediatric outpatients with more than half a million children seeking care annually in the outpatient setting.”

“Of these, 43% occur in children <5 years old.”

“Among children 12 to 18 years of age, we found an increase in the number of ADEs related to central nervous system agents and hormones and synthetic substitutes. The rise in visits related to central nervous system agents likely reflects the increase in medication therapy for depression and other emotional and behavioral disorders during adolescent years.”

“Adverse effects commonly associated with psychotropic medications include headache, agitation and other behavioral disturbances, and gastrointestinal symptoms.”

“Teenaged girls are prescribed contraceptive medications, which are associated with dysmenorrhea, nausea and vomiting, and dermatologic conditions.”

These authors “were careful to exclude all cases which might be related to drug abuse, use of an illicit substance, intentional overdose, or administration of the wrong medication.”

CONCLUSIONS

“ADEs are a common medical complication among children in the outpatient setting and represent a large burden to the health care system, particularly in outpatient clinics.”
COMMENT FROM DAN MURPHY

The number of adverse drug events in US children reported in this study is much lower than the actual number for three reasons (which means the real number is much higher):

1) The authors only reported adverse drug reactions to prescription drugs; over-the-counter drug adverse events were not included in this study.

2) Adverse drug events in which the parent did not bring their child into a doctor’s office, clinic, or emergency department were not counted. In other words, this article only counted adverse drug events that required medical treatment.

3) These authors “were careful to exclude all cases which might be related to drug abuse, use of an illicit substance, intentional overdose, or administration of the wrong medication.”

Therefore, the incredible numbers in this article represent only the “tip of the iceberg.”

VACCINE NOTE FROM DAN MURPHY:

A chart in this article shows vaccine adverse events:

18,702 children report an adverse vaccine event to an outpatient clinic per year
9,360 children report an adverse vaccine event to an emergency dept per year

28,062 total children report adverse vaccine events per year, accounting for 4.8% of the 585,922 yearly total adverse drug events in US children

KEY POINTS FROM DAN MURPHY

1) “Adverse drug events (ADEs) are a common complication of medical care.” In this study, 5% of the children’s adverse event were serious enough to require hospitalization.

2) This study shows that nearly 600,000 children per year (585,922) have to go to the doctor’s office or emergency department for treatment of adverse drug events to prescription medications that were administered and taken properly.

3) 78% of children with an adverse reaction to a prescription drug will go to an outpatient clinic.

4) 12% of children with an adverse reaction to a prescription drug will go to an emergency department.
5) “Children 0 to 4 years of age had the highest incidence of ADE-related visits, accounting for 43.2% of visits.”

6) “The most common symptom manifestations were dermatologic conditions (45.4%) and gastrointestinal symptoms (16.5%).”

7) “The medication classes most frequently implicated in an ADE were antimicrobial agents (27.5%), central nervous system agents (6.5%), and hormones (6.1%).”

8) “Among adverse drug events related to antimicrobial agents, more than half were the result of a penicillin (40%) or cephalosporin (15%).”

9) About 70% of children seen by medical personnel in an ambulatory setting are given drugs. [Wow]

10) In any given week, 56% of US children take at least 1 drug and 26% take 2 or more drugs. [Wow]

11) 4.7% of all hospitalizations are the result of adverse drug events.

12) 6.5% of inpatients suffer adverse drug events during their hospitalization.

13) 16% of all outpatient prescriptions are associated with adverse drug events.

14) “The greatest proportion of adverse drug event visits were by non-Hispanic white children, those with private insurance, and those residing in the South.”

15) “Among children 12 to 18 years of age, we found an increase in the number of adverse drug events related to central nervous system agents and hormones and synthetic substitutes. The rise in visits related to central nervous system agents likely reflects the increase in medication therapy for depression and other emotional and behavioral disorders during adolescent years.”

ADDITIONAL COMMENTS FROM DAN MURPHY

For any medical, governmental or parent group to say that chiropractic may harm children seems crazy when compared to these numbers. This article reminds me of a few proverbs:

“He who is without sin among you, let him throw a stone at her first.”

JOHN 8:7

People who live in glass houses should not throw stones