Development, Testing, and Findings of a Pediatric-Focused Trigger Tool to Identify Medication-Related Harm in US Children’s Hospitals

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What’s Known on This Subject
“Data using the established Harvard Medical Practice Study methodology revealed a 2.3% rate of adverse drug events (ADEs) in the pediatric inpatient population.”

What This Study Adds
“A pediatric-focused ADE trigger tool was built and tested. Use of this more sophisticated detection tool identified an 11.1% rate of ADEs in pediatric inpatients.”

FROM ABSTRACT
OBJECTIVES.
The purposes of this study were to develop a pediatric-focused tool for adverse drug event detection and describe the incidence and characteristics of adverse drug events in children’s hospitals identified by this tool.

METHODS.
A pediatric-specific trigger tool for adverse drug event detection was developed and tested.

All adverse drug events identified using the trigger tool were evaluated for severity, preventability, ability to mitigate, ability to identify the event earlier, and presence of associated occurrence report.

RESULTS.
Review of 960 randomly selected charts from 12 children’s hospitals revealed 2,388 triggers (2.49 per patient) and 107 unique adverse drug events.

Mean adverse drug event rates were 11.1 per 100 patients, 15.7 per 1000 patient-days, and 1.23 per 1,000 medication doses.

Twenty-two percent of all adverse drug events were deemed preventable, 17.8% could have been identified earlier, and 16.8% could have been mitigated more effectively.

Ninety-seven percent of the identified adverse drug events resulted in mild, temporary harm.
Only 3.7% of adverse drug events were identified in existing hospital-based occurrence reports. [Very Important]

The most common adverse drug events identified were pruritis and nausea, the most common medication classes causing adverse drug events were opioid analgesics and antibiotics, and the most common stages of the medication management process associated with preventable adverse drug events were monitoring and prescribing/ordering.

CONCLUSIONS.
Adverse drug event rates in hospitalized children are substantially higher than previously described.

Most adverse drug events resulted in temporary harm, and 22% were classified as preventable.

Only 3.7% were identified by using traditional voluntary reporting methods.

Our pediatric-focused trigger tool is effective at identifying adverse drug events in inpatient pediatric populations.

Abbreviations
AE    adverse event
ADE   adverse drug event

THESE AUTHORS ALSO NOTE:

“The Institute of Medicine concluded that between 44,000 and 98,000 lives are lost per year in US hospitals as a result of error.”

The Harvard Medical Practice Study estimated that 3.7% of all hospitalized patients in a New York State cohort experienced an adverse event (AE) related to medical therapy.

“Recent data from the Harvard group using more sophisticated detection methods revealed a 6.5% rate of adverse drug events (ADEs) alone in the adult inpatient setting, with 33% of these events described as preventable.”

Most importantly, this study used the “trigger method” to identify adverse events to children in hospitals, noting that the “trigger method” identifies adverse events rates as “much as 50 times higher than hospital-based occurrence reporting strategies and identifying adverse rates in high risk populations as high as 112 per 100 patients, with adverse drug events rates of 20 per 100 patients.” [WOW!]

This study was a cross-sectional one that used retrospective chart review in 12 children’s hospitals across the United States.
RESULTS

A total of 960 randomly selected charts from 12 children’s hospitals reflecting a total of 6,806 patient-days were evaluated. The mean length of stay was 7.1 days with a median length of stay of 4 days.

A total of 107 ADEs were identified, resulting in a mean rate of 11.1 ADEs per 100 patients, 15.7 ADEs per 1000 patient-days, and 1.23 ADEs per 1,000 medication doses.

“The medication class that most frequently was associated with an ADE was analgesics/opioids (51%).”

DISCUSSION

“This study, reviewing 960 charts representing a total of 6,806 patient-days from 12 children’s hospitals, is the largest detailed review of ADEs yet published in pediatrics.”

“Our study showed that only 4 of the identified 107 ADEs were identified by the occurrence report system.”

The “trigger” tool used in this study “identified 22 times more ADEs than the frequently used but flawed occurrence report methods.”

CONCLUSIONS

These authors identified an ADE rate of 11.1 per 100 admissions (15.7 per 1000 patient-days).

The “most common class of medications associated with ADEs to be analgesics-opioids (causing 51% of all inpatient ADEs).”

“Twenty-two percent of all identified ADEs were classified as preventable, with 2.8% of ADEs falling into the more severe harm categories F through I.”

[Important]

<table>
<thead>
<tr>
<th>Category Of Harm Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
</tr>
<tr>
<td>F</td>
</tr>
<tr>
<td>G</td>
</tr>
<tr>
<td>H</td>
</tr>
<tr>
<td>I</td>
</tr>
</tbody>
</table>
The primary types of adverse drug reactions noted in this study were:

<table>
<thead>
<tr>
<th>Pruritus</th>
<th>Nausea</th>
<th>Rash</th>
<th>Constipation</th>
<th>Urticaria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vomiting</td>
<td>Hypokalemia</td>
<td>Sedation</td>
<td>Chills</td>
<td>Hives</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>Nausea</td>
<td>Anemia</td>
<td>Clonus</td>
<td>Fever</td>
</tr>
<tr>
<td>Seizures</td>
<td>Stomatitis</td>
<td>Abdominal pain</td>
<td>Altered mental status</td>
<td></td>
</tr>
</tbody>
</table>

KEY POINTS FROM DAN MURPHY

1) Older data, using outdated methods of investigation indicate: “Data using the established Harvard Medical Practice Study methodology revealed a 2.3% rate of adverse drug events (ADEs) in the pediatric inpatient population.”

2) This study, using the “trigger method” of investigation, reveals: “Use of this more sophisticated detection tool identified an 11.1% rate of ADEs in pediatric inpatients.”

3) This study used the “trigger method” to identify adverse events to children in hospitals, noting that the “trigger method” identifies adverse events rates as “much as 50 times higher than hospital-based occurrence reporting strategies and identifying adverse rates in high risk populations as high as 112 per 100 patients, with adverse drug events rates of 20 per 100 patients.” [WOW!]

4) In this study: “Twenty-two percent of all adverse drug events were deemed preventable, 17.8% could have been identified earlier, and 16.8% could have been mitigated more effectively.”

5) Only 3.7% of adverse drug events were identified in existing hospital-based occurrence reports, which constitute traditional voluntary reporting methods. [Very Important: this indicates that traditional methods of reporting hospital adverse drug events only report the “tip of the iceberg.”]

6) “Adverse drug event rates in hospitalized children are substantially higher than previously described.”

7) “The Institute of Medicine concluded that between 44,000 and 98,000 lives are lost per year in US hospitals as a result of error.”

8) “Recent data from the Harvard group using more sophisticated detection methods revealed a 6.5% rate of adverse drug events (ADEs) alone in the adult inpatient setting, with 33% of these events described as preventable.”

9) “The medication class that most frequently was associated with an adverse drug events was analgesics/opioids (51%).”
10) 2.8% of adverse drug events cause severe harm, from one of the following categories: [Important]

A)) Contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
B)) Contributed to or resulted in permanent patient harm
C)) Required intervention to sustain life
D)) Contributed to or resulted in the patient’s death