Development of a Pediatric Trigger Tool to Identify Adverse Drug Events

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Abbreviations

ADE = Adverse Drug Event
CHAI = Child Health Accountability Initiative
CHCA = Child Health Corporation of America
IHI = Institute for Healthcare Improvement
ME = Medication Error
Outline

1. Why Measure?
2. ADE Trigger Tool Origins
3. Development of a Pediatric ADE Trigger Tool
4. Is the Outcome the Trigger Tool?
5. ADE Trigger Tool Challenges
Why Measure?

Accountability versus Improvement?

↓

For the Child Health Accountability Initiative

Improvement = Measurement Purpose!
A trigger is defined as an “occurrence, prompt, or flag found on review of the medical chart that ‘triggers’ further investigation to determine the presence or absence of an adverse event.

Classen, 1991
Trigger Example:

• Naloxone (Narcan) Trigger:
  “This is a powerful narcotic antagonist. If it has been used, overdosage of narcotics is a frequent finding. If it was used and the patient's condition didn't change, doubt excessive narcotic administration.”

• Review medical record for naloxone use.

• If found, e.g. morphine order, review medical record for ADE associated with naloxone use, e.g. respiratory arrest in child who received morphine.
ADE Trigger Tool Origins

Classen’s (1991) Trigger Tool

- Computerized monitor
  - Sudden medication order stops
  - Antidote ordering
  - Abnormal laboratory values
- Computer identified trigger
- Pharmacist identified ADE

IHI ADE Trigger Tool (Rozich, 2003)

- Chart Review monitor
  - Sudden medication order stops
  - Antidote ordering
  - Abnormal laboratory values
  - Oversedation, rash, transfer
  - Customized to individual institution
- Reviewer identified trigger
- Reviewer identified identified ADE
ADE Trigger Tool Origins

Classen’s (1991) Trigger Tool
36,653 Primarily Adult Patients over 18 months
Trigger Tool → 631 ADEs
Voluntary Report → 92 ADEs
IHI ADE Trigger Tool (2003)
Total: 2,837 Patients in 86 hospitals
    Trigger Tool → 720 ADEs
Subset: 1,040 Patients in 9 hospitals
    Trigger Tool → 274 ADEs
Voluntary Report → 5 ADEs
Purpose:

• Develop and test a pediatric-focused trigger tool.
• Determine the rate of adverse drug events (ADEs) in hospitalized children at 12 freestanding children’s hospitals in the United States.
• Identify characteristics of ADEs in children’s hospitals to provide the basis for developing a strategy to prevent drug-related harm in hospitalized children.
CHAI/CHCA Pediatric ADE Trigger Tool: Phase 1

Antidote Use
• Diphenhydramine
• Vitamin K
• Flumazenil
• Antiemetic
• Naloxone
• Sodium polystyrene
✗ Droperidol
✗ Anti-diarrheals

Abnormal Lab Value
• PTT > 100 seconds
• Rising Serum Creatinine
✗ Hypoglycemia
✗ C. difficile (+) stool
✗ INR > 6
✗ Leukopenia
✗ Thrombocytopenia
✗ ↑ Digoxin
✗ ↑ Lidocaine
✗ ↑ Gentamicin or Tobramycin
✗ ↑ Amikacin
✗ ↑ Vancomycin level

Other
• Oversedation/lethargy/fall/hypotension
• Rash

• Abrupt medication stop
✗ Transfer to higher level of care
CHAI/CHCA Pediatric ADE Trigger Tool: Phase 2

**Antidote Use**
- Diphenhydramine
- Vitamin K
- Flumazenil
- Antiemetic
- Naloxone
- Sodium polystyrene
  - + Laxative or stool softener

**Abnormal Lab Value**
- PTT > 100 seconds
- Rising Serum Creatinine

**Other**
- Oversedation/lethargy/fall/hypotension
- Rash

- + Hyperglycemia
- + Hyperkalemia

- + Abrupt medication stop
- + Called codes
CHAI/CHCA Pediatric ADE Trigger Tool: Phase 2

- 12 Free-Standing Children’s Hospitals
- Training
- Random Chart Selection
  - 4 consecutive two-week periods
  - 20 charts randomly selected each two-week period at each hospital
- Exclusion Criteria
  - Hospital stay <2 days
  - Newborn nursery stay
  - Obstetrics service
  - Day hospital or observation unit
960 Patients in 12 Children’s Hospitals

Trigger Tool → 89 ADEs
Voluntary Report* → 4 ADEs
Total† → 107 ADEs

*All 4 voluntary report ADEs were identified by the Trigger Tool.
†18 additional ADEs not associated with a trigger were identified while using the Trigger Tool.

7.29% of all patients experienced an ADE.

Trigger Tool → 13.1 ADEs/1000 pt-days
Voluntary Report → 0.59 ADEs/1000 pt-days
Total → 15.7 ADEs/1000 pt-days
### Medication-Related Harm in US Children’s Hospitals

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>ADE Detection Method</th>
<th>ADEs per 100 admissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaushal (2001)</td>
<td>1999</td>
<td>Chart Review &amp; Incident Reports</td>
<td>2.3</td>
</tr>
<tr>
<td>Holdsworth (2003)</td>
<td>2000-2001</td>
<td>Chart Review &amp; Staff Interviews</td>
<td>6.4</td>
</tr>
</tbody>
</table>

The rate of adverse drug events experienced by hospitalized children is **higher** than previously reported.
CHAI/CHCA Pediatric ADE Trigger Tool: Phase 2

Trigger Positive Predictive Values

All Triggers → 3.73%

- Polystyrene → 20.0%
- Medication stop → 19.7%
- PTT → 16.7%
- Oversedation → 14.9%
- Codes → 14.3%
- Rash → 12.7%
- Naloxone → 12.1%
- Diphenhydramine → 8.4%
- Serum creatinine → 3.8%
- Hyperkalemia → 3.6%
- Laxative → 2.8%
- Vitamin K → 1.8%
- Antiemetic → 1.5%
- Hyperglycemia → 0.6%
- Flumazenil → 0.0%
CHAI/CHCA Pediatric ADE Trigger Tool: Phase 2

Patient-Level Characteristics

✓ Chronic Diagnoses
✓ Principle Diagnosis
✓ Admission Date
✓ Discharge Date
✓ Gestational Age
✓ Date of Birth
✓ Initial Unit
✓ Communication Barrier
✓ Total Transfers between Units

In addition:
✓ Number of Triggers
✓ Number of ADEs
✓ Total Medications
✓ Total Doses
✓ Time to Review Chart
✓ Chart Reviewer Type
## ADE Characteristics

- ✓ Trigger
- ✓ ADE Date
- ✓ How ADE Identified
- ✓ Unit of ADE Occurrence
- ✓ ADE Outcome
- ✓ Medication Involved
- ✓ Intervention
- ✓ ADE Severity
- ✓ Preventable?
- ✓ Identified Earlier?
- ✓ Mitigated Better?
- ✓ ADE Process
- ✓ Medication Error Type
Conclusions

• The Pediatric ADE Trigger Tool identified more ADEs than voluntary reporting → 22 times more.

• 1 of 15 hospitalized children experienced an ADE.

• 1 of 5 ADEs were preventable.

• Opportunities for Improvement:
  ✓ Narcotics & antibiotic usage
  ✓ Monitoring & prescribing/ordering
An Intervention to Decrease Narcotic-Related Adverse Drug Events in Children’s Hospitals (Sharek, 2008):

- Interventions → Narcotic-related ADE rates ↓ 67%
- Based on Narcotic-Related ADE Trigger Tool
  - Antiemetic use
  - Naloxone use
  - Oversedation, lethargy, falls
  - Abrupt cessation of narcotic
  - Administration of laxatives or enemas
  - Administration of diphenhydramine
  - Intubation/respiratory arrest
  - Combination of ≥3 narcotics ordered

Is the Outcome the Trigger Tool? No!
Measurement Challenges
- What is the gold standard for ADE detection? Sensitivity? Specificity?
- Optimal thresholds?
- Are positive predictive values enough? (Handler, 2007)
- Cost-effectiveness?

How dependent are ADE trigger tools on the operator?
- Phansalkar (2007): 0.23 ADEs identified/admit by pharmacists versus 0.12 ADEs identified/admit by non-pharmacists

Resources to utilize ADE Triggers
- Ferranti (2008): 2 dedicated clinical pharmacists to follow-up 57 automated ADE triggers at an academic medical center
- Jha (1998): voluntary report 5 h/wk → 23 ADEs; chart review 55 h/wk → 398 ADEs; computer monitoring 11 h/wk → 275 ADEs
ADE Trigger Tool Challenges

How do we automate triggers, in particular those not related to medication use or laboratory values? Will natural language triggers work?

- Melton (2005): sensitivity 25% and specificity 99.96%
- Cantor (2007): sensitivity 31% and specificity 98%
- CHLA (2010): testing prohibited abbreviation triggers in EMR

Real-time trigger intervention

- Raschke (1998): Physicians notified for increased ADE risk situations → 53% true positive → 44% unrecognized by MD
- Jha (2008): High-priority ADE alerts → 38% true positive → 11.3% MDs contacted & all unaware of event.
- Duncan (2006): PEWS (Pediatric Early Warning System) → triggers Rapid Response Team
# Pediatric ADE Trigger Tool: Postlude

## Automated ADE Trigger

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Manual or Automated</th>
<th>ADEs per 100 admissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Takata† (2008)</td>
<td>2003-2004</td>
<td>Automated Pediatric ADE Trigger</td>
<td>11.2</td>
</tr>
</tbody>
</table>

*Ferranti, Horvath, Cozart, et al., 2008: Duke Children’s Hospital

†Takata, Takeshima, Waite, 2008: California Pediatric Patient Safety Initiative
CaPPSI Findings, Takata (AJHP 2008): Postlude

- 5 California Children’s Hospitals (CHCF): Pediatric Patient Safety Surveillance System
- Automated ADE Triggers: antidote and lab values
- Patients with Trigger: 53.9%
- Trigger Rate: 2.3 triggers/patients
- Patients with ADE: 9.1%
- Trigger ADE Rate: 11.2 ADEs/100 patients
  - 11 times higher than voluntary ADE rate
- Positive Predictive Value (all triggers):
  - Trigger level: 4.7%
  - Patient level: 16.8%
Patient safe practices are the right thing to do.
References


Stockwell DC, Kane-Gill SL. Developing a patient safety surveillance system to identify adverse events in the intensive care unit. Crit Care Med 2010;38[Suppl.]:S117-S125.

