TRIGGERS OF ACTIVE SURVEILLANCE OF ADVERSE DRUG EVENTS IN HOSPITALIZED NEWBORNS: A PILOT STUDY

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INTRODUCTION

• Infants are more vulnerable to have adverse drug events (ADEs).
• Safety medications have not been properly evaluated in this group.
• Infants have differences in absorption, distribution, metabolism and excretion of drugs.
• The use of drugs is based on the extrapolation of the information used in adults.
INTRODUCTION

• To identify ADEs in health care services:
  - Voluntary reporting
  - Chart Review

• Recent: Trigger method
  A trigger is an occurrence, a clue, a flag that could identify ADEs in a chart review.

AIM

The study aims to use triggers to identify adverse drug events in hospitalized newborns.
METHODOLOGY

Design
- Observational and prospective.

Population
- Newborns admitted at the intensive and semi-intensive care units.
- Which used at least 1 drug until discharge or 29 days of life.

Study locality
- University Hospital.
- Medium complexity care.
- 258 beds.
A list of 50 triggers and a collect data sheet were developed.

A pilot study was conducted to test both.

The triggers were actively sought in the medical charts.

The ADEs detected were analyzed.

Guided by the triggers found previously ADEs were sought.

When a trigger was identified, it was registered.

The trigger’s list and the collect data sheet were reviewed.

A new study was conducted with the reviewed list (48 triggers).
RESULTS

Pilot study:

A pilot study was conducted from Dec 2014 to Jan 2015.

18 newborns were included and followed.

33 triggers were identified 155 times in the charts.

32 ADEs were detected.

18 triggers of 33 detected ADEs.
### RESULTS

Pilot study:

Table 1. Main triggers and main serious ADEs detected

<table>
<thead>
<tr>
<th>Triggers</th>
<th>ADEs detected</th>
<th>Number of ADEs</th>
<th>Drugs involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase in serum creatinine</td>
<td>Decrease of renal function</td>
<td>1</td>
<td>amikacin; penicillin</td>
</tr>
<tr>
<td>Hypotension</td>
<td>Decreased blood pressure</td>
<td>2</td>
<td>phenobarbital</td>
</tr>
<tr>
<td>Prescription of metadon / lorazepam</td>
<td>Withdrawal syndrome</td>
<td>1</td>
<td>fentanyl; midazolam</td>
</tr>
<tr>
<td>Prescription of Naloxone</td>
<td>Chest tightness</td>
<td>1</td>
<td>fentanyl</td>
</tr>
<tr>
<td>Medication suspended</td>
<td>Increase of the blood pressure</td>
<td>2</td>
<td>dobutamine</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>Tachycardia</td>
<td>3</td>
<td>caffeine</td>
</tr>
</tbody>
</table>
New study:

The new study was conducted from Mar to Sep 2015

125 newborns were included and followed

48 triggers screened at the pilot were sought in the charts

272 ADEs were detected

22 triggers of 38 detected ADEs

38 triggers were identified 949 times
### Results

**Table 2. Main triggers and main serious ADEs detected**

<table>
<thead>
<tr>
<th>Triggers</th>
<th>ADEs detected</th>
<th>Number of ADEs</th>
<th>Drugs involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vomit with “coffee grounds” color / Blood in feces</td>
<td>gastrointestinal bleeding</td>
<td>4</td>
<td>caffeine; gentamicin; ampicillin; amikacin</td>
</tr>
<tr>
<td>Necrotizing enterocolitis</td>
<td>necrotizing enterocolitis</td>
<td>2</td>
<td>ibuprofen; caffeine</td>
</tr>
<tr>
<td>Medication suspended</td>
<td>hypersedation; urinary bladder distention; withdrawal syndrome; toxic level serum drug; decrease of the renal function; picc obstruction; oliguria; polyuria; vomit; hyperglycemia.</td>
<td>13</td>
<td>fentanyl; midazolam; tramadol; phenobarbital; ranitidine; ampicillin; gentamicin; furosemide; vancomycin; dopamine; adrenaline; chloral hydrate; glucose 50%</td>
</tr>
</tbody>
</table>
RESULTS

New study:

Cont. Table 2. Main triggers and main serious ADEs detected

<table>
<thead>
<tr>
<th>Triggers</th>
<th>ADEs detected</th>
<th>Number of ADEs</th>
<th>Drugs involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tachycardia</td>
<td>Tachycardia</td>
<td>3</td>
<td>adrenaline; caffeine</td>
</tr>
<tr>
<td>Prescription of metadon / lorazepam</td>
<td>Withdrawal syndrome</td>
<td>6</td>
<td>fentanyl, morphine, midazolam</td>
</tr>
<tr>
<td>Prescription of naloxone</td>
<td>hypersedation; chest tightness</td>
<td>5</td>
<td>fentanyl</td>
</tr>
<tr>
<td>Prescription of flumazenil</td>
<td>Hypersedation</td>
<td>3</td>
<td>midazolam</td>
</tr>
</tbody>
</table>
CONCLUSIONS

1. Triggers are useful for active surveillance to identify Adverse Drug Events.

2. Identification of ADEs is important to improve the safety of hospitalized newborns.
THANK YOU!
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