Incidence of Adverse Drug Events in an Academic Hospital: A Prospective Cohort Study

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Incidence of adverse drug events in an academic hospital: a prospective cohort study

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Abstract

Objective. To determine the incidence of adverse drug events (ADEs) and assess their severity and preventability.


Setting. A 900-bed tertiary academic hospital.
Background

• The incidence of Adverse drug events (ADEs) in hospitals is unknown in Saudi Arabia.

• No database available to study this outcome.
Study Objectives

• To determine the incidence of adverse drug events (ADEs) and assess their severity and preventability.
Methodology Challenges

- Database may not be the best option to address the study aim.
- Current electronic information is not sufficient.
- Data collector need training.
Methods

- **Design:** A prospective cohort study.

- **Setting:** A 900-bed tertiary academic hospital.

- **Participants:** A total of 977 patients admitted to two medical, one surgical and two intensive care units over four months.
Methods-cont

• **Main Outcome Measures:**

• **Primary Outcomes:** the incidence of ADEs, preventability of ADEs, potential ADEs and medication errors. A physician and a clinical pharmacist independently determined the likelihood that incidents were caused by medications and judged severity and preventability.

• **Secondary Outcomes:** Factors associated with ADEs and potential ADEs.
Results
<table>
<thead>
<tr>
<th>Variable</th>
<th>Number (%)</th>
<th>Mean (±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>-</td>
<td>48.9(20.4)</td>
</tr>
<tr>
<td>Female</td>
<td>638(65)</td>
<td>-</td>
</tr>
<tr>
<td>Length of stay, days</td>
<td>-</td>
<td>10.1(9)</td>
</tr>
<tr>
<td>Number of medications on admission</td>
<td>-</td>
<td>3(3.4)</td>
</tr>
<tr>
<td>Comorbidities (charlson’s index weight)</td>
<td>-</td>
<td>1.1(1.2)</td>
</tr>
<tr>
<td>Wards:</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Medicine</td>
<td>496(51)</td>
<td>-</td>
</tr>
<tr>
<td>Surgery</td>
<td>306(31)</td>
<td>-</td>
</tr>
<tr>
<td>ICUs</td>
<td>175(18)</td>
<td>-</td>
</tr>
</tbody>
</table>
Incidents Classification Flow Chart

Study included 977 admitted patients over four months

Incidents identified by chart reviewers
361 (261 patients)

Incidents accepted by reviewers
281 (207 patients)

Incidents rejected by reviewers
80 (54 patients)

Adverse drug events (ADEs)
83 (68 patients)

Medication errors
223 (172 patients)

Non-preventable ADEs
58

Preventable ADEs
25

Risk to cause harm (Potential ADEs)
132 (117 patients)

No risk to cause harm
66 (55 patients)

Intercepted
48

Non-intercepted
84
### Table 2. Numbers and rates of ADEs and potential ADEs

<table>
<thead>
<tr>
<th>Category</th>
<th>N = 281</th>
<th>Incidence*</th>
<th>95% CI</th>
<th>Crude rate¥</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ADEs</td>
<td>83</td>
<td>8.7</td>
<td>6.9-10.6</td>
<td>8.5</td>
<td>6.8-10.4</td>
</tr>
<tr>
<td>Preventable ADEs</td>
<td>25</td>
<td>2.6</td>
<td>1.7-3.7</td>
<td>2.6</td>
<td>1.6-3.7</td>
</tr>
<tr>
<td>Non-preventable ADEs</td>
<td>58</td>
<td>6</td>
<td>4.6-7.7</td>
<td>6</td>
<td>4.5-7.6</td>
</tr>
<tr>
<td>Total Potential ADEs</td>
<td>132</td>
<td>13.8</td>
<td>11.5-16.2</td>
<td>13.5</td>
<td>11.3-15.9</td>
</tr>
<tr>
<td>Intercepted potential ADEs</td>
<td>48</td>
<td>5</td>
<td>3.7-6.5</td>
<td>4.9</td>
<td>3.6-6.5</td>
</tr>
<tr>
<td>Non-intercepted potential ADEs</td>
<td>84</td>
<td>8.8</td>
<td>7.0-10.8</td>
<td>8.6</td>
<td>6.9-10.5</td>
</tr>
<tr>
<td>Medication Errors(^a)</td>
<td>66</td>
<td>6.9</td>
<td>5.3-8.7</td>
<td>6.8</td>
<td>5.2-8.5</td>
</tr>
</tbody>
</table>

*per 1000 patient-days, ¥ per 100 admissions
## Incidents classification according to the stage of medication use process

<table>
<thead>
<tr>
<th></th>
<th>Ordering N (%)</th>
<th>Transcription N (%)</th>
<th>Dispensing N (%)</th>
<th>Administration N (%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventable ADEs</td>
<td>24 (96)</td>
<td>0</td>
<td>1 (4)</td>
<td>0</td>
<td>25 (100%)</td>
</tr>
<tr>
<td>Intercepted Potential ADEs</td>
<td>37 (77)</td>
<td>3 (6)</td>
<td>7 (15)</td>
<td>1 (2)</td>
<td>48 (100)</td>
</tr>
<tr>
<td>Nonintercepted Potential ADEs</td>
<td>62 (74)</td>
<td>2 (2)</td>
<td>20 (24)</td>
<td>0</td>
<td>84 (100)</td>
</tr>
<tr>
<td>Medication Errors&lt;sup&gt;a&lt;/sup&gt;</td>
<td>48 (72.7)</td>
<td>2 (3)</td>
<td>15 (22.7)</td>
<td>1 (1.5)</td>
<td>66 (100)</td>
</tr>
<tr>
<td>All above events</td>
<td>171 (76.7)</td>
<td>7 (3.1)</td>
<td>43 (19.3)</td>
<td>2 (0.9)</td>
<td>223 (100)</td>
</tr>
</tbody>
</table>
Table 4. Factors associated with ADEs and potential ADEs

<table>
<thead>
<tr>
<th>Factors</th>
<th>ADEs</th>
<th>Potential ADEs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Crude OR (95% CI)</td>
<td>P value*</td>
</tr>
<tr>
<td>Age</td>
<td>1.015 (1.001-1.030)</td>
<td>0.042</td>
</tr>
<tr>
<td>Male(^a)</td>
<td>1.606 (0.889-2.900)</td>
<td>0.116</td>
</tr>
<tr>
<td>ICUs(^b)</td>
<td>2.250 (1.176-4.306)</td>
<td>0.014</td>
</tr>
<tr>
<td>Surgical ward(^b)</td>
<td>0.304 (0.109-0.845)</td>
<td>0.022</td>
</tr>
<tr>
<td>Number of medications on admission</td>
<td>1.210 (1.097-1.335)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Comorbidity</td>
<td>1.626 (1.240-2.132)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Study Conclusion

• The incidence of ADEs in a Saudi hospital was 8.5 per 100 admissions. Preventable ADEs most commonly occurred in the ordering stage; therefore, interventions to reduce ADEs should target the ordering stage.
Challenges

• Consistency between data collectors.
• Case review and time constrains of clinicians.
• Data management and analysis.
• Support from nurses, administrators, and pharmacy.
• Fund.
• Time for data collection.
Possible Improvements

• Can we do the study with different methods of lower cost?
Question I

- Identifying the incidence of Adverse Drug Events is best accomplished through:
  - A- Prospective design.
  - B- Retrospective design.
  - C- Analyzing patient reported incidence.
  - D- The use of discharge summary.
  - E- Using trigger tools.
Question II

- Challenges for non-database studies include:
  - A- Need for fund.
  - B- Inconsistency in data collection.
  - C- Longer time for data collection.
  - D- Support is needed from various departments.
  - E- All of the above.