Strategies for the detection of adverse drug reactions – comparison of a hospital clinical-administrative database and spontaneous reporting

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### Context

<table>
<thead>
<tr>
<th>Region</th>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portugal</td>
<td>10,600,000</td>
</tr>
<tr>
<td>Northern Region</td>
<td>3,700,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Region</th>
<th>Health Professionals + Patients</th>
<th>2011</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portugal</td>
<td>Reports</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td>Reports</td>
<td>Rate</td>
<td>Rate</td>
</tr>
<tr>
<td></td>
<td>Portugal</td>
<td>1303 Hp</td>
<td>2289 Hp+175 P</td>
</tr>
<tr>
<td></td>
<td></td>
<td>122</td>
<td>232</td>
</tr>
<tr>
<td>Northern Region</td>
<td>Reports</td>
<td>N</td>
<td>N</td>
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<tr>
<td></td>
<td>Reports</td>
<td>Rate</td>
<td>Rate</td>
</tr>
<tr>
<td></td>
<td>Northern Region</td>
<td>384 Hp</td>
<td>898 Hp+34 P</td>
</tr>
<tr>
<td></td>
<td></td>
<td>104</td>
<td>252</td>
</tr>
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</table>
Important cause of morbidity and mortality that results in additional costs for health services and an extensive burden for the patient

Estimated that are responsible for hospital admissions, for a significant length of stay in the hospital with an increased risk of death in hospitalized patients
Spontaneous reporting

- Widespread, simple and efficient method in early detection of ADR
- Underreporting is a known limitation
  - Underestimation of ADRs
  - Missing of essential information for Drug security monitoring
- Find out other strategies to detect more ADR
Evaluate the potential of a **hospital clinical-administrative database** to detect adverse drug reactions and how it can contribute to the pharmacovigilance system.
**Methods**

Retrospective study, descriptive analysis to characterize ADRs occurred in a central hospital in the North of Portugal (São João Hospital), year 2011

<table>
<thead>
<tr>
<th>Data</th>
<th>Episodes of ADR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northern Pharmacovigilance Centre database (Health Authority)</td>
<td>Spontaneous reports by health professionals of episodes occurred in hospital</td>
</tr>
<tr>
<td>National Hospital Clinical-Administrative database (CAD)</td>
<td>Hospitalization</td>
</tr>
<tr>
<td></td>
<td>Outpatient surgery</td>
</tr>
<tr>
<td></td>
<td>Medical clinic held in hospital</td>
</tr>
</tbody>
</table>
Methods

Clinical administrative data (CAD): National database of patient diagnosis related groups (DRG)

DRG - Inpatients classification in acute care hospitals of the National Health System that includes the patients in similar groups (coded according to ICD-9-CM) with the perspective of resource consumption (hospital expenses with the patient) for hospital reimbursement.
Methods

1. We selected the inpatient episodes with potential ADRs, using a set of codes that are usually related to ADRs:
   - Codes with diagnosis of ADR
   - “E” codes of an external cause of ADR

2. Approximately 11% were randomly selected for revision by trained medical coders (Chart review)
Results

Hospital São João (HSJ)

- 44,613 Inpatient episodes in 2011
- 1438 Inpatient episodes (episodes with either an external cause or a diagnosis of ICD9-CM codes of adverse drug events)
- 1993 ICD9-CM codes of adverse drug events
- Randomly selected
- 177 ICD9-CM codes of adverse drug events
- 153 Inpatient episodes Chart Reviewed
- 242 ADR
- 170 ICD9-CM codes of adverse drug events
- 146 Inpatient episodes

Northern Pharmacovigilance Centre (NPC)

- 384 Reports in 2011
- 244 Reports in hospitals of the north of Portugal
- 52 Reports in Hospital São João
- 200 ADR

Strategies for the detection of adverse drug reactions
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Northern Pharmacovigilance centre – Spontaneous Reports

There were received 52 health professionals reports of ADR episodes that occurred in the São João Hospital, in 2011

After MedDRA coding:

We identified 200 ADRs
Results

Inpatient episodes chart reviewed of CAD

✓ 153 inpatient episodes were reviewed

✓ Of the 177 ICD-9-CM codes identified as potential ADRs, 170 (96%) were actually adverse events related to drugs (ADRs)

After MedDRA coding:

✓ Of the 170 ADRs we identified in fact 242 ADR MedDRA codes

✓ Only one episode chart reviewed was identified in the pharmacovigilance database (spontaneously reported)
Strategies for the detection of adverse drug reactions
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Results

Adverse drug reactions by System Organ Class
Strategies for the detection of adverse drug reactions
Comparison of a hospital clinical-administrative database and spontaneous reports

Results

Suspected drugs by ATC classification

- Chart review of CAD
- Spontaneous Report
Conclusions

✓ Hospital clinical-administrative database can be useful in detecting ADRs as a secondary source of information in pharmacovigilance

✓ The combination of several health databases can give an important contribute to the drug balance benefit-risk
In the future:

• Necessary a national study to validate the utility of hospital CAD in the pharmacovigilance system
• Possibility to use an icon with a web service that after the approval of the medical expert, transfers the ADR information from these hospital databases to the pharmacovigilance database
Thank You!