Medication errors detected among spontaneously reported ADRs to HALMED

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For public health
Aim of the study

The objective of the study was to:

✔ identify,

✔ evaluate and

✔ describe medication errors (MEs)

among the spontaneously reported ADRs to the Croatian Agency for Medicinal Products and Medical Devices (HALMED).
Method

- A retrospective observational study was performed on the first 200 spontaneously reported ADRs in 2013

The previously validated “P-method”¹ was employed to systematically detect MEs in individual case safety reports (ICSR) sent to the Croatian Pharmacovigilance Centre (PVC) at HALMED

ME that lead to ADR identified by reporter as well as ME suspected by assessor are described

Additionally, ME were categorized according to „Good practice guide on recording, coding, reporting and assessment of medication errors”: 

- medication errors associated with adverse reaction(s),
- medication errors without harm,
- intercepted medication errors and
- potential medication errors
Results

- **Gender:** 75 M, 125 F
- **Age:** 51.7 ± 23.7 (range 8 months to 93 years)
- **Comorbidities:** 1.6 ± 1.1 (range 0-6)
- **Number of medicines:** 2.5 ± 1.8 (range 1-13)
- **45 ME with ADRs**
- **94 ME**
- **200 ICSRs**
Medication errors

- Number of ICSR with medication errors associated with adverse reaction according to primary source or assessor

26 ICSR = 1 ME with harm
5 ICSR = 2 ME with harm
3 ICSR = 3 ME with harm

ICSRs with ADRs caused by Medication errors (34)
Not assessable for Medication errors (6)
Out of 71 (35.5%) spontaneously reported serious ADRs, 14 (19.7%) were caused by medication errors.
Number of ICSRs with medication errors associated with ADRs according to primary source

In Only 3 ICSR out of 34 (9 %) with ADR/ADRs suspected to be caused by Medication Errors the primary source has clearly stated that a medication error has occurred.
The two most commonly identified preventability criteria for ADR occurrence were:

- "Incorrect dose" 28.3%;
- "Documented hypersensitivity to administered drug" reported in 17.4% of MEs associated with ADRs.

Among MEs without harm:

- "Labelled drug-drug interaction" (32.7%) was the most commonly identified type of ME.
THE PERCENTAGE OF MEDICATION ERRORS AMONG THE DIFFERENT MEDICINES
Good practice guide on recording, coding, reporting and assessment of medication errors
Good practice guide on recording, coding, reporting and assessment of medication errors

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Flag G.K.10.r</th>
<th>Reaction E.I.2.1b</th>
<th>Sender’s comment H.4</th>
<th>Sender’s diagnosis H.3.r.1.b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported as medication error, sender agrees</td>
<td>✓</td>
<td>✓</td>
<td>As applicable</td>
<td></td>
</tr>
<tr>
<td>Reported as medication error, sender assessment provides alternative ‘diagnosis’</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not explicitly reported as medication error but information and assessment of case leads to suspicion that a medication error was involved</td>
<td>At discretion</td>
<td>MedDRA PTC: Do not infer</td>
<td>Disclaimer* may be used as an option</td>
<td>✓</td>
</tr>
</tbody>
</table>

*Disclaimer as referred to in chapter 5.7.1.
Discussion and Conclusion (cont.)

- High number of additional cases should be followed up
- Additional burden to NCAs, MAHs, HCPs...
- Process of identifying ME is **very sensitive** and relationship between reporter and national pharmacovigilance center should be taken into account
- Not all follow up are successful¹

Discussion and Conclusion (cont.)

Improving number of cases with medication errors associated with adverse reaction reported by primary source:

- Education of reporters
- Improving reporting forms (decision tree)
- Liability for Medication errors by HCPs
For safe and effective medicines.

www.halmed.hr