Pharmacovigilance Systems

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WHO Programme for International Drug Monitoring

How it started

Thalidomide 1961

WHO Programme for International Drug Monitoring (PIDM) 1968

- World Health Assembly Resolution 16.36
- INVITES Member States to arrange for a systematic collection of information on serious adverse drug reactions observed during the development of a drug and, in particular, after its release for general use.
Over 170 countries and territories are part of the WHO Programme for International Drug Monitoring (as full or associate members).
Pharmacovigilance data flow: how it works in a country

- **Adverse Event (AE) observed (Dx or Vx)**
- **AE is reported**
- Sometimes the report is sent to the PHP or the national pharmacovigilance centre

**Levels:**
- **National Regulatory Authority**
- **National Pharmacovigilance Centre**
- **WHO global database of Individual Case Safety Reports, VigiBase**
- **Public Health Programme (PHP) [PHP]**

*Note: The document includes a flowchart illustrating the data flow from reporting an adverse event to regulatory decisions.*
VigiBase: WHO global database of individual case safety reports

- Contains over 30 million reports of adverse drug reactions/adverse events following immunization
- Currently 152 countries and territories contribute to the database
How reports of medication errors reach the WHO database of Individual Case Safety Reports, VigiBase
Number of ICSRs with a medication error in VigiBase

- A total of 1,162,041 ICSRs reporting a medication error in VigiBase (4% of all ICSRs)
- Reports originate from 107 countries
- 6% of ICSRs for medication errors originate from LMICs
Reports of medication errors in VigiBase: Originating countries – top reporting countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of ICSRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland</td>
<td>2,526</td>
</tr>
<tr>
<td>Mexico</td>
<td>2,558</td>
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<tr>
<td>Morocco</td>
<td>2,609</td>
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<tr>
<td>Greece</td>
<td>3,167</td>
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<tr>
<td>Sweden</td>
<td>3,924</td>
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<tr>
<td>Netherlands</td>
<td>4,073</td>
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<tr>
<td>Egypt</td>
<td>4,203</td>
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<tr>
<td>Switzerland</td>
<td>4,700</td>
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<tr>
<td>Italy</td>
<td>7,126</td>
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<tr>
<td>Australia</td>
<td>8,561</td>
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<tr>
<td>Spain</td>
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<td>India</td>
<td>10,125</td>
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<tr>
<td>Canada</td>
<td>13,217</td>
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<td>Korea (the Republic of)</td>
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<td>Germany</td>
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<tr>
<td>France</td>
<td>29,846</td>
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<td>United Kingdom of Great Britain</td>
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<td>Brazil</td>
<td>35,877</td>
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<tr>
<td>United States of America</td>
<td>903,552</td>
</tr>
</tbody>
</table>
MedDRA Dictionary

• Medical Dictionary for Regulatory Activities
• The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) developed MedDRA
• A rich and highly specific standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans.
• Translated in many languages
• Standardised MedDRA Queries: SMQs: validated, predetermined sets of MedDRA terms grouped together after extensive review, testing, analysis and expert discussion. There is an SMQ related to medication errors.
Standard MedDRA Queries (Narrow): Medication errors

Over 90 preferred terms in Narrow SMQ for medication errors
Most frequently reported Medication error, preferred MedDRA term in VigiBase:

- **PT: Inappropriate schedule of product administration** (20%)
- **PT: Wrong technique in product usage process** (18%)
- **PT: Incorrect dose administered** (15%)
- **PT: Product storage error** (10%)
- **PT: Medication error** (8%)
- **PT: Expired product administered** (7%)
- **PT: Incorrect route of product administration** (6%)
- **PT: Product administration error** (6%)
- **PT: Accidental exposure to product** (5%)
- **PT: Incorrect product administration duration** (5%)
Tools exist, but are we using them optimally?

• We know that many ME occur – but all are not reported to the WHO global database

• How do we link patient safety and PV databases so that
  • A global repository of MEs to help study:
    • types of medication errors
    • products prone to medication errors
    • mitigation strategies that are needed
    • the impact of the strategies: trends over time
Acknowledgements

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https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance