Pharmacovigilance in Kurdistan, Iraq

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## Two main kinds of adverse effects

<table>
<thead>
<tr>
<th>Type A</th>
<th>Type B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Known pharmacological effects, common, dose-dependent, low morbidity, low mortality.</td>
<td>Unknown pharmacological effects, rare, dose-independent, high morbidity, high mortality.</td>
</tr>
</tbody>
</table>

**Exemples:**
- dryness of mouth (ach)
- drowsiness (sleep pills)
- bleeding (warfarinum)
- tachycardia (adrenergic)
- orthostatism (hypotensives)
- drug interactions (common)

**Exemples:**
- exfoliativ dermatitis
- liver reactions
- asthma attacks
- anapylactic schock
- hematologic effects
- malignancy, cancer
% chance to find adverse effects. Rule of 3.

<table>
<thead>
<tr>
<th>Risk of suffering the adverse effect</th>
<th>1/1.000 eye damage - practolol</th>
<th>1/10.000 Anaphylaxis – penicillin</th>
<th>1/100.000 Aplastic anemia - Chloramphenicol</th>
</tr>
</thead>
<tbody>
<tr>
<td>10,000 patients using the drug</td>
<td>99%</td>
<td>63%</td>
<td>10%</td>
</tr>
<tr>
<td>95% chance to detect one (1) case with an ideal reporting system, requires....</td>
<td>3,000 patients</td>
<td>30,000 patients</td>
<td>300,000 Patients</td>
</tr>
</tbody>
</table>
Illegal medicines

- Illegal medicines is a rapidly growing market
- 10% of all medicines (worldwide) are counterfeit!
- 30% - 40% of medicines in some countries are fake: Useless, dangerous or inferior.
- 50% of all counterfeit medicines come from internet
Problems with illegal drugs and devices

- Reduced amount of active pharmaceutical ingredient (API)
- Wrong API. Potentially life threatening.
- No active ingredient
- They may be potentially life threatening
- They are easily accessible (internet!)
- No checks of QC or QA
- You may have received just anything
- Very limited legal possibilities for compensation
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Which medicines may be dangerous?

• High value medicines
• High demand medicines
• High turnover medicines
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#### Examples of counterfeit drug brand names

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Used for…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reductil</td>
<td>Weight reduction</td>
</tr>
<tr>
<td>Viagra, Cialis</td>
<td>Male impotence</td>
</tr>
<tr>
<td>Plavix</td>
<td>Myocardial infarction, stroke</td>
</tr>
<tr>
<td>Casodex</td>
<td>Prostate cancer</td>
</tr>
<tr>
<td>Lipitor</td>
<td>Hypercholesterolemia</td>
</tr>
<tr>
<td>Seretide</td>
<td>Asthma, Chronic bronchitis</td>
</tr>
<tr>
<td>Sensodyne</td>
<td>Tooth Paste</td>
</tr>
</tbody>
</table>
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Strategies for safer use of D&D

• **Inspections.** Traceability is needed in the chain:
  *Manufacturer – Distribution – Storage – Release*

• **Collaboration.**
  *Customs – Police – Trading systems*

• **Reporting Systems** for adverse effects:
  *Doctors – Hospitals – Regulatory Authorities - WHO*
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The necessity of traceability of drugs

Starting materials from different (international) sources

Manufacturer  Wholesaler  Clinic  Patient
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Strategies for safer use of D&D

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Why is Drug Monitoring so essential? (1)

- Safety for the patients has an increasing priority
- Drugs are increasingly potent and potentially dangerous
- Counterfeit drugs is an increasing global problem
- Drug Authorities have the right to know all about drug effects, since they regulate the drugs. Drug central

- Physicians have the right to know all about the drugs they prescribe
- Interactions between drugs is an increasing problem
- Lawyers have an increasing focus on maltreatment issues and have the legal right to obtain all drug safety information
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Why is Drug Monitoring so essential? (2)

- There is no existing system for reporting adverse drug reactions
- There is no system at the Drug Directorate for receiving reports.
- Minimal or no collaboration with other countries
- Minimal exposure to international bodies, which can help in pharmacovigilance system implementation
- There is no effective PV information-exchange system between physicians and the Drug Directorate
- Pharmaceutical manufacturers in Iraq produce mainly generic drugs, so they depend on information from others.
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Reporting systems to be implemented

- Doctor’s reporting serious adverse reactions to Regional PV Centers (RPVC)
- Reports/Alerts from Drug Directorate (DD) to medical community
- Analysis at RPVC/DD. “Signal Detection”
- Reports from Drug Directorate to WHO Collaboration Centre (a world wide system).
Pharmacovigilance Reporting
The importance of the terminology
Which is the proper term?

- Cardiac Infarction
- Myocardial infarction
- Infarctus cordis
- Heart infarction

We need a common terminology: MedDRA!
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Flow of adverse event ("side effect") reports

Doctor Nurse Pharmacist → Regional PV center

Doctor Nurse Pharmacist → Regional PV center

Doctor Nurse Pharmacist → Regional PV center

PV Center at Drug Directorate

Input from other Drug Directorates

WHO Monitoring Centre (Sweden)

Output to just any customer
A detailed plan for building a pharmacovigilance system has been submitted to relevant authorities.
Thank You !