Communication on medication errors
What does the patient need to know?

François Houÿez & Rob Camp
European Organisation for Rare Diseases (EURORDIS)
Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Drug Information Association, Inc. ("DIA"), its directors, officers, employees, volunteers, members, chapters, councils, Special Interest Area Communities or affiliates, or any organisation with which the presenter is employed or affiliated.

These PowerPoint slides are the intellectual property of the individual presenter and are protected under the copyright laws of the United States of America and other countries. Used by permission. All rights reserved. Drug Information Association, DIA and DIA logo are registered trademarks or trademarks of Drug Information Association Inc. All other trademarks are the property of their respective owners.
All in all, how worried are you about suffering a serious medical error?

Eurobarometer n° 2421
2/09 to 6/10/2005
amongst 29,153 EU25 citizens + accessing countries
One case

Plasma donation at hospital

3 beds, 1 doctor, 1 nurse

Sodium chloride and sodium citrate injected

After 45 minutes: sudden weakness. Emergency doctor called in

Put in hyperbaric chamber as air bubble hypothesised

Exact cause not immediately identified
In fact

- Nurse realised she had mixed up sodium chloride and sodium citrate.

- But was too afraid to report: “I knew I had done something wrong, but I could not tell.”

- A new provider for sodium chloride and sodium citrate had just delivered bags that were new to all staff.

- Before, sodium chloride and sodium citrate bags differed by colour and connector. This wasn’t the case anymore with the new ones.

- 3 similar cases already reported in past 2 years but no formal action.

- Nurse, doctor and blood donation organisation to court (October 2014).
Second case

High dose neuroleptic treatment prescribed to overweight patient

Treatment in fact given to his neighbour, an underweight patient

Nurse immediately realised her error and called doctor

Doctor recommended to monitor blood pressure and didn’t prescribe gastric lavage (by phone, did not come to see the patient)

Patient died
In fact

After realising her error, the nurse did exactly the right thing.

She called both the casualty doctor and the hospital administrator, not hiding or denying anything.

She was taken into custody with immediate professional disqualification.

Now nurse to court.
These cases raise different points:

- Confusing product presentations
- Product changes with no training and safety measures no longer prioritised (via colours and shapes)
- Decision chain (institution - prescriber - nurse)
- Information chain (previous cases)
- Professional attitude (hiding versus reporting)
- No matter what you do, you end up in court

- How were relatives informed of what happened?
To properly inform the patient and/or the relatives

- This responsibility should be clearly given to someone
- The person who made the error - probably not the best option
- Not only for fatalities, but any kind of medication error
- If consequences are long-lasting, how to follow up with the victim?
- Proper information and follow up of the victim/relatives will not prevent media to report on error
How detailed should the information be?

**Scope**
- Omission error
- Dose error
- Strength/concentration error
- Medicine name error
- Presentation error
- Administration route error
- Administration output error
- Administration duration error
- Administration time error
- Patient ID error
- Used by date error
- Defective medicine

**Scope**
- Treatment follow-up, clinical follow-up
  - Drug-drug interaction
  - Food intake and medicine intake
  - Known allergy
  - Contraindication
  - Non-validated indication
  - Clinical state not compatible with medicine
  - Treatment duplication
  - …
How detailed should the information be?

**Seriousness of the error**

- Event with potential error only
- Error, but medicine not taken
- Error, but no consequence for the patient
- Error with monitoring of the patient and no harm

**Seriousness of the error**

- Error with subsequent treatment or medical intervention and transient harm
- Error with hospitalisation or with prolonged hospital stay and transient harm
- Error with permanent harm
- Life-threatening error
- Fatal error
<table>
<thead>
<tr>
<th>Mechanism of error</th>
<th>Compensation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication issue</td>
<td>How the consequences of the error will be handled by the health care providers</td>
</tr>
<tr>
<td>Medicine name issue</td>
<td>Social services that can help (home care until good health resumes…)</td>
</tr>
<tr>
<td>Package or labelling issue</td>
<td>When existing, how to benefit from <strong>the medication error compensation fund</strong></td>
</tr>
<tr>
<td>Design or storage issue</td>
<td></td>
</tr>
<tr>
<td>Information error</td>
<td></td>
</tr>
<tr>
<td>Human factors</td>
<td></td>
</tr>
<tr>
<td>…</td>
<td></td>
</tr>
</tbody>
</table>
A multi-thematic survey

- Off-label use of medicines
- Pharmacovigilance and the impact of the legislation
- Medication errors
- NATC treatments
  - Natural, Alternative, Traditional, Complementary
- Medicines used by EURORDIS members
“Acting on the treatment information you have”: large survey among patients

- DITA task force survey on Treatment information in rare diseases 2016
- Funded by an operating grant from the public health programme
- Questionnaire in 13 languages
- INSERM IRB approval July 2015
- Field work 15 February - 31 May 2016
- 1,965 responses collected
  - Of which 1,453 valid (more than 75% completion score)
    - Of which 1,401 with agreement to participate
      - Of which 1,350 reports on medicines
      - Other on medical devices, food supplements….
- Asking respondents to have their package leaflet by them
Results: all

Can you contact your health care team between visits (incl. nights, weekends)?

- Yes: 57%
- No: 35%
- I don't know: 8%

If yes:

- Prescription medicine
  - Prescribed: 92%
  - Non-prescribed: 8%

- Prescription medicine
  - Prescribed: 1225
  - Non-prescribed: 113

Can you contact your health care team between visits (incl. nights, weekends)?

If yes:

- Phone only: 41.0%
- Phone and email: 35.6%
- Email only: 20.5%
- Other: 1.5%
- Self: 0.6%
- App: 0.4%
- An IT connector: 0.4%
Is the presentation (packaging, name, documents) confusing?

- Yes: 27%
- No: 73%

1005 respondents to confusing information question
## Examples (40 of the 271)

<table>
<thead>
<tr>
<th>Country</th>
<th>FYROM (Macedonia)</th>
</tr>
</thead>
<tbody>
<tr>
<td>methotrexate</td>
<td>Package leaflet is reduced to 5-6 sentences, there is no information</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gylenia® (fingolimod)</td>
<td>Package leaflet too long. Would like to see updates marked</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>Belgium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esbriet® (perfenidone)</td>
<td>Packaging and aspect of the drug has changed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>Croatia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florinef® (flucrocortisone acetate)</td>
<td>The instructions are only in German</td>
</tr>
<tr>
<td>Motilium® (domperidone)</td>
<td>The instructions are only in German</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levothyroxin</td>
<td>The pharmacist's label often covers the dose strength</td>
</tr>
<tr>
<td>ursodeoxycholic acid</td>
<td>The information is about a completely different disease</td>
</tr>
<tr>
<td>Lodotra® (prednisone)</td>
<td>I am not sure what some of the side effects mean</td>
</tr>
</tbody>
</table>
### Examples (2)

<table>
<thead>
<tr>
<th>Country</th>
<th>Sweden</th>
<th>France</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mnesis® (idebenone)</td>
<td>Text in Italian and I live in Sweden</td>
<td>Nice pictos! There is phone number supposedly for any problem I could have, but then they say they can’t respond to individual patients.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>Spain</th>
</tr>
</thead>
<tbody>
<tr>
<td>sirolimus</td>
<td>At the hospital pharmacy they only give me the pills, never the box or PL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>Belgium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kentera 3.9mg/24h Transdermal patch oxybutynine</td>
<td>The device is difficult to apply and removes easily because without protective edges without active substance. Plastic protections to be removed before applying it are not easily graspable</td>
</tr>
</tbody>
</table>
How to communicate on medication errors…
Recommendations to prevent them?

- **Web-RADR two-way communication mobile app**
  - Where users can list medicines of interest to them and receive regulatory information
  - Same idea for other health apps?

- **DHCP letters on medication errors**
  - Annual meetings with patients’ organisations
  - Copy systematically sent to relevant patients’ groups

- **How to involve the dispensing pharmacists?**

- **Patients’ registries for the surveillance of medicines**
  - First time users register and receive updated information

- **Use videos (youtube and others)**
Potential Interaction

Ledipasvir/Sofosbuvir

Antacids
69% of hospitals have some form of patient engagement initiative.

14% of hospitals say their patient engagement strategy is making a major difference in the quality of care or outcomes.

34% that say the difference is moderate.

For 38% of hospitals, a web-based patient portal was the primary tool used to drive patient engagement compared to secure e-mail at 14%, electronic health records at 9% (scheduling) and 8% (reminders).

- Mayo Clinic, Cleveland Clinic

Objective app qualities: engagement, functionality, aesthetics, and information quality (JMR)