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

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

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Disclaimer

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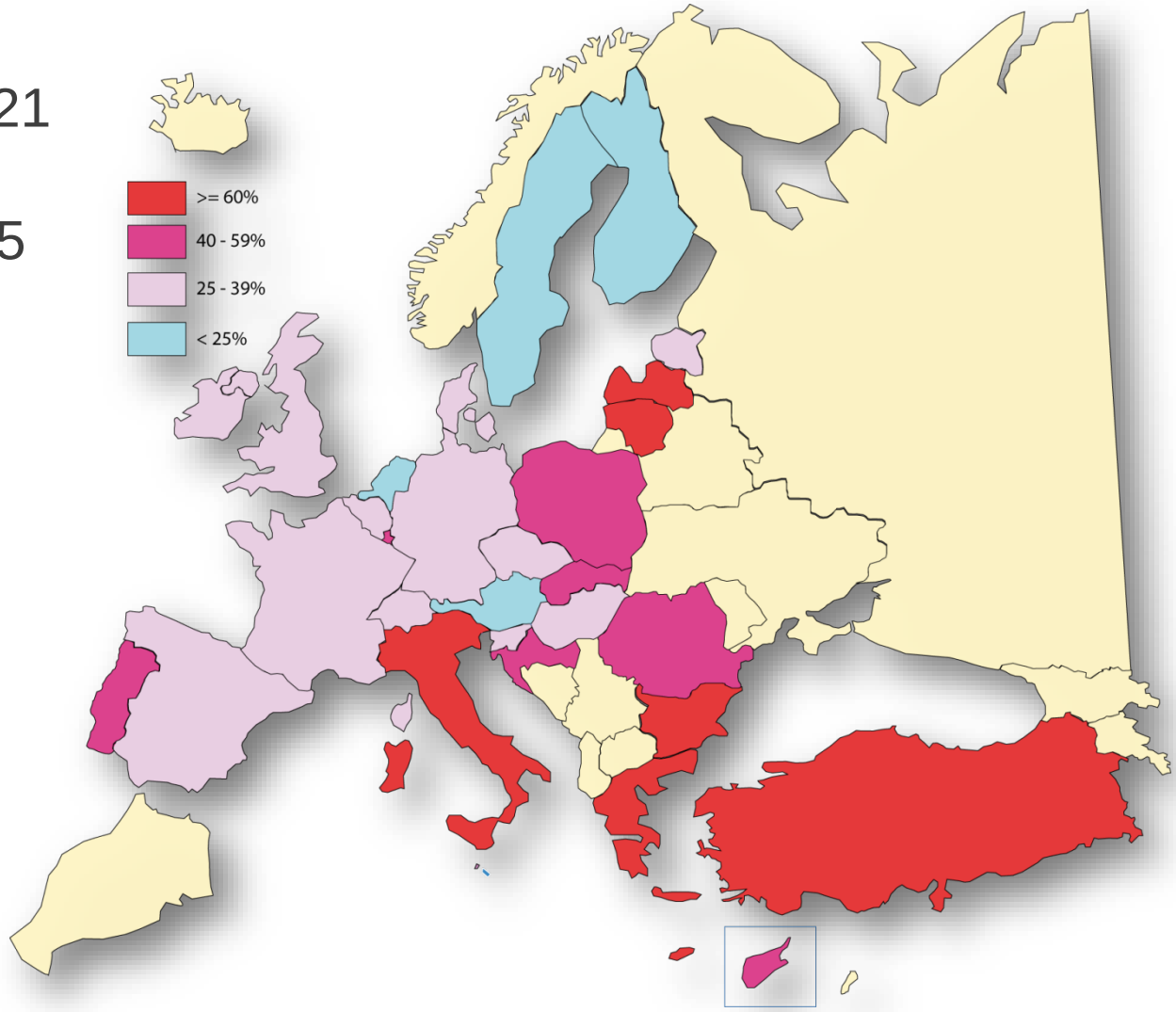
All in all, how worried are you about suffering a serious medical error?

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



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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 to 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 raises 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

How detailed should the information be?

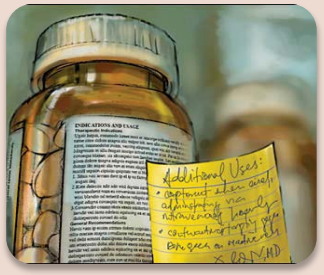
Mechanism of error

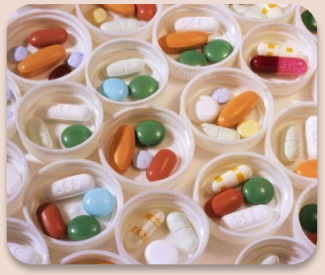
- Communication issue
- Medicine name issue
- Package or labelling issue
- Design or storage issue
- Information error
- Human factors
- …

Compensation

- How the consequences of the error will be handled by the health care providers
- Social services that can help (home care until good health resumes…)
- When existing, how to benefit from **the medication error compensation fund**
- …

A multi-thematic survey





Member of EURORDIS Rare Diseases Europe

Off-label use of medicines

Pharmaco-vigilance and the impact of the legislation

Medication errors

NATC treatments
Natural, Alternative, Traditional, Complementary

Medicines used by EURORDIS members

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"*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

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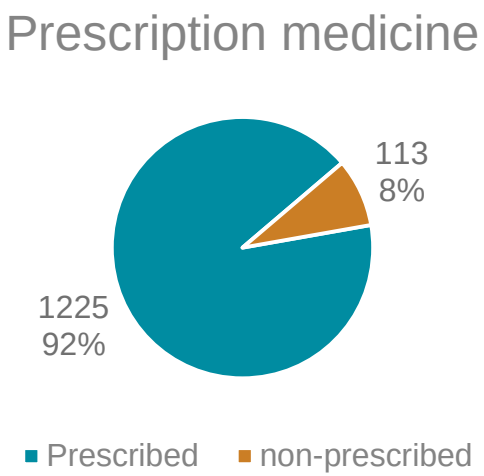
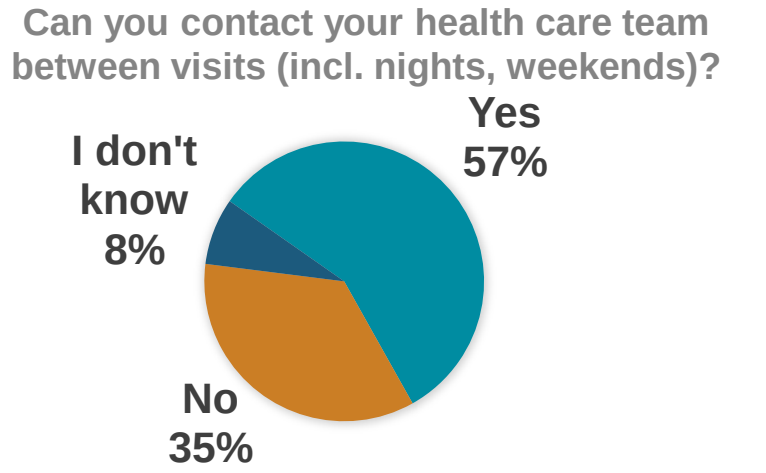
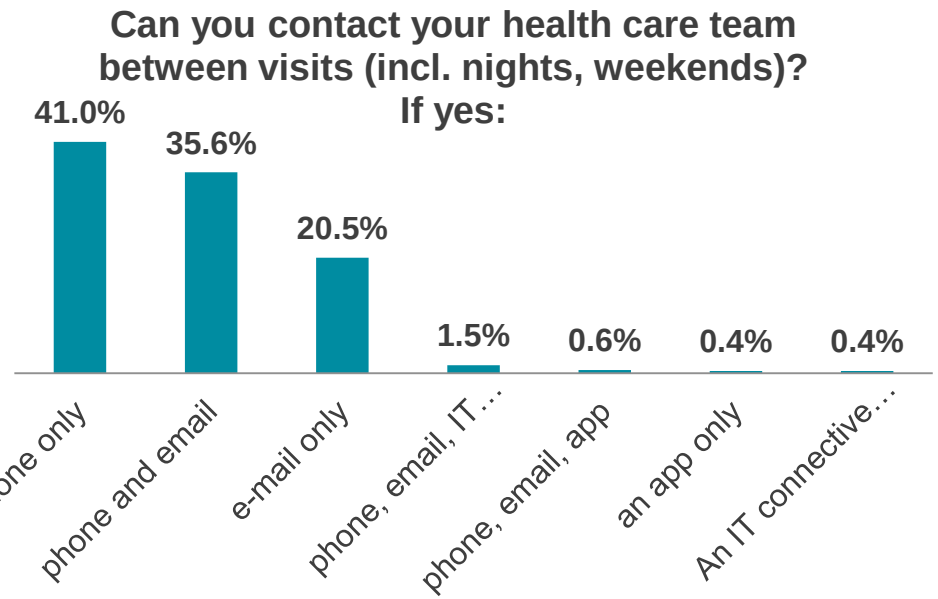
Results: all







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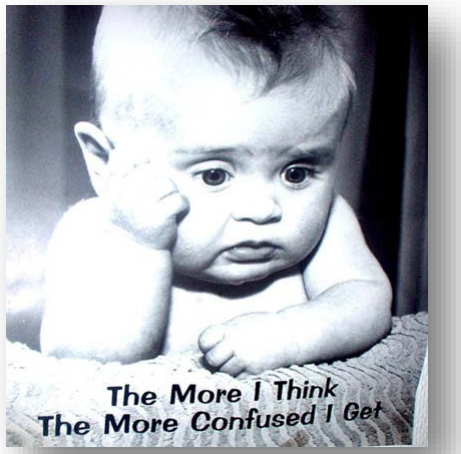
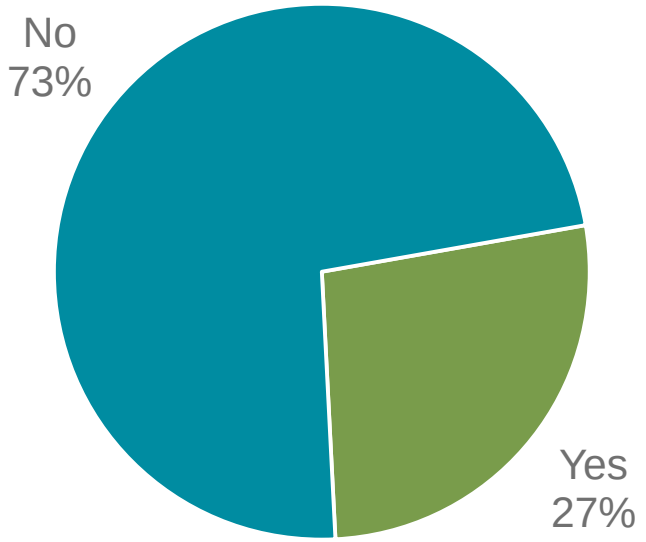
1005 respondents to confusing information question

Is the presentation (packaging, name, documents) confusing?





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Examples (40 of the 271)

Country	FYROM (Macedonia)
methotrexate	Package leaflet is reduced to 5-6 sentences, there is no information

Country	Belgium
Esbriet® (perfenidone)	Packaging and aspect of the drug has changed

Country	Croatia
Florinef® (flucrocortisone acetate)	The instructions are only in German
Motilium® (domperidone)	The instructions are only in German

Country	Ireland
Gylenia® (fingolimod)	Package leaflet too long. Would like to see updates marked

Country	United Kingdom
Levothyroxin	The pharmacist's label often covers the dose strength
ursodeoxycholic acid	The information is about a completely different disease
Lodotra® (prednisone)	I am not sure what some of the side effects mean

Examples (2)

Country	Sweden
Mnesis® (idebenone)	Text in Italian and I live in Sweden

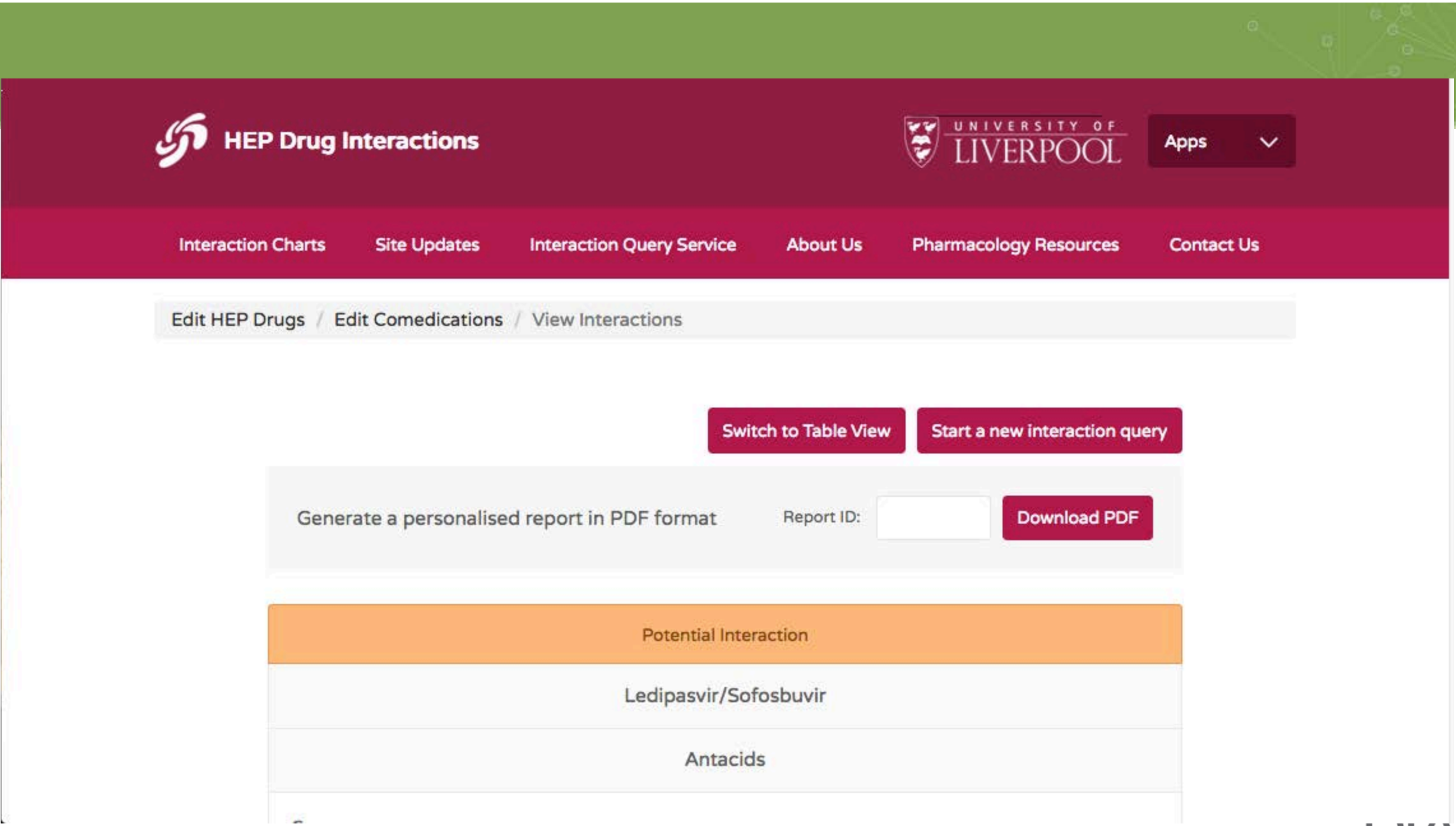
Country	Spain
sirolimus	At the hospital pharmacy they only give me the pills, never the box or PL

Country	France
Sandostatine Lp30 (octreotide)	Nice pictos! There is phone number supposedly for any problem I could have, but then they say they can't respond to individual patients.

Country	Belgium
Kentera 3.9mg/24h Transdermal patch oxybutynine	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

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)



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Communication examples

- 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
  - 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)*