

Direct Patient Reporting of Adverse Drug Reactions: a 15-country survey

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Why do it? Patients' reports add value

- They are more **direct** and give more and **better context** than indirect reports from professionals
- They commonly describe the **impact on people's lives**, which clinicians rarely note
- Indirect and direct reports **complement** each other, generating **multicultural** knowledge
- **Knowledge** of ADRs and their importance **accumulates faster**
- Patients become **active participants** in their care
- Patients **learn** how to **manage their medicines** and to **communicate better** with professionals

An example

- In 2002 a BBC TV programme on the antidepressant Seroxat (paroxetine), led to thousands of phone calls and emails from viewers about their experiences.
- The words that consumers used were much clearer than those in ADR reports from doctors; the regulatory agency's rigid coding system had also obscured meaning and caused errors.

[Medawar C, Herxheimer A. A comparison of adverse drug reaction reports from professionals and users, relating to risk of dependence and suicidal behaviour with paroxetine. *Int J Risk & Safety in Medicine* 2003/2004; 16: 3-17.]

A 15-country snapshot

- In autumn 2009 Health Action International Europe undertook a brief survey, funded by the EU Exec. Agency for Health & Consumers
- Experts in regulatory agencies and NGOs in 15 countries were interviewed by phone, email or in person
- 8 countries **accept** direct patient reporting:
NL DK I S UK N B USA
- 7 countries **don't accept** it:
CH D EIR F SF P ES

Diverse national experiences: NL

- **Lareb**, an independent foundation, does all pharmacovigilance work for the Dutch regulatory authority, collecting patient reports since 2003
- The 2,500 patients' reports for 3 years were compared with those from professionals. Patients reported more life-threatening ADRs and more disability; they more often noted outcomes and non-recovery.
- 70% of cases were followed up
- People are altruistic and cooperate willingly
- The Lareb board now includes 3 patient representatives

Diverse national experiences: DK

- Patient reporting began in 2003
- The Danish Medicines Agency gets several hundred reports a year from patients
- A PhD thesis comparing reports from professionals and patients has noted differences especially in neurological ADRs
- Reports published in the media have stimulated consumer reporting
- 20 cases of severe kidney toxicity from gadolinium radiological contrast medium led to a national Action Plan in 2009 to reduce barriers to reporting

Diverse national experiences: Italy

- Since 2004 patients can download an ADR reporting form from the regulatory agency website, complete it and send it to their health district's pharmacovigilance centre
- Direct letters too have led to regulatory action, eg on light sensitivity to topical ketoprofen and on the packaging of paracetamol for children
- The consumer organisation *Altroconsumo* says: *'If adequately stimulated, patients respond in great numbers and provide accurate and detailed reports.'*

Diverse national experiences: **Sweden**

- KILEN, a voluntary organisation, has worked on issues of dependence, side effects and injuries related to medicines, particularly psychotropic drugs. In 1997 it established a database to enable consumers to share such experiences. In 2000 it held the 1st International conference on Consumer Reports on Medicines.
- In 2008 the Medical Products Agency added an interactive section to its website for people to report ADRs on the site.
- The first 400 reports received were compared with those from professionals; more of them concerned psychiatric disorders and drugs.

Diverse national experiences: UK

- In 2005 a small pilot scheme for patient reporting of ADRs was launched. After a disappointing response the NHS commissioned a broad evaluation of patient reporting. The results will be published this year.
- In 2008 more efforts were made to make people aware of patient reporting and to increase the number of reports. By late 2009 the MHRA received about 100 reports a month.
- The reports have contributed some useful signals, insights and quality of life experiences.

Diverse national experiences: F, D

- **F** Patients are not encouraged to report ADRs. People who send a report to their pharmacovigilance centre are asked for medical validation, but few want to discuss a problem with someone who may have caused it.
A joint project of the regulatory agency (AFSSAPS) with patient organisations was partly successful but not a satisfactory model. A decree enabling patients to report ADRs should be published by April 2010
- **D** Allowing direct reporting by consumers has not been publicly discussed. The regulators require medical validation.

Conclusion

The European Commission's plan to allow and encourage spontaneous patient reporting is welcome.

To be taken seriously is a human right

Reporting should be possible not only via a web portal but also by e-mail, telephone and letter.

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Suggestions for discussion

- 1. Does your organisation support direct patient reporting? If not, why?
- 2. Which initiatives/measures could contribute to raise awareness of direct patient reporting in country, at national level?
- 3. Which formats should be available for direct patient reporting?
- 4. How could data retrieved from direct patient reporting feed future activities aimed at consumer/patient health literacy?