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Reporting adverse effects: a practice to be encouraged



Post-marketing surveillance of the adverse effects of drugs is largely based on reporting by healthcare professionals (1). However, in France in particular, healthcare professionals do not frequently report adverse effects to pharmacovigilance centres (2). The reasons stated include lack of time, the administrative procedures involved, lack of feedback, etc. (3).

However, the experience of one general practitioner from the Paris area shows that adverse-effect reporting is feasible for motivated healthcare professionals (3).

Integrating adverse effect reporting into healthcare. This doctor recorded every adverse effect he observed over a one-year period, in 2010, that could have been caused by a drug, medical device or procedure. He classified them as serious or non-serious, and expected or unexpected (3). He assessed the causal link between adverse effects and drugs mainly on the basis of patients' descriptions, timing of events, the drug's pharmacological properties, and sometimes re-introduction of the drug (3).

He collected and reported 163 adverse effects, which corresponds to 2.3 per 100 consultations or visits. Twelve of the adverse effects were serious, and 5 adverse effects were unexpected (3).

By extrapolation, he estimated that more than 5 million adverse effects could be collected by French general practitioners each year, including about 400 000 serious adverse effects and about 150 000 unexpected adverse effects (3). This is a far cry from the 1464 adverse effects (759 of which were serious) reported by French general practitioners to pharmacovigilance centres in 2007.

Genuinely useful, without being time-consuming. The author concluded from his experience that collecting all adverse effects makes it possible "to analyse expected minor adverse effects that can generate anxiety and/or require secondary care, and to reflect on the need for the prescriptions themselves, as part of a global view of the harm/benefit balance of prescribing" (our translation) (3). He affirms that reporting takes little time and is therefore practical for healthcare professionals.

Pharmacovigilance centres have a fundamental role to play in encouraging adverse effect reporting, by providing feedback to healthcare professionals; as of 16 September 2012, the author of the study was still waiting for feedback from his regional pharmacovigilance centre on the reports he submitted in 2010 and 2011 (4).

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Selected references from Prescrire's literature search.

- 1- Prescrire Editorial Staff "Methods for improving the reporting of adverse effects" *Prescrire Int* 2011; **20** (114): 71.
- 2- Prescrire Editorial Staff "Patient reporting improves pharmacovigilance" *Prescrire Int* 2008; **17** (98): 241-242.
- 3- Grange JC "Un an de recueil prospectif systématique et d'analyse des effets indésirables dus aux médicaments, aux dispositifs médicaux ou aux procédures en médecine générale" *Thérapie* 2012; **67** (3): 237-242.
- 4- Grange JC "La déclaration des effets indésirables graves ou inattendus par les médecins généralistes est possible et nécessaire". <http://docteurdu16.blogspot.fr> accessed 17 October 2012: 3 pages.