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Online Reporting of Adverse Drug Reactions: A Study from a French Regional Pharmacovigilance Center

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Abstract – Background. In France, online reporting *via* a website is a new method for notifying adverse drug reactions (ADRs). The French Midi-Pyrénées Regional Pharmacovigilance Center (RPVC) set up in July, 2010 a Web-based ADR reporting tool in order to improve ADR reporting rate. **Objectives.** To assess feasibility, use and performances of this new ADR reporting system. To evaluate the main characteristics of these online reports. **Methods.** In a retrospective study, we evaluated characteristics (numbers, ADR reporting and file processing times, type of reporters, suspected drugs, "seriousness" and nature of ADRs) of online notifications reported to the RPVC between July 7th, 2010 (first online notification) and December 31th, 2011. We performed comparisons to a random sample of "conventional" notifications, *i.e.* spontaneously reported to the RPVC *via* traditional tools (post, fax, e-mail or telephone) during the same period. **Results.** The total number of online reports was 312 over the 18-month period. There was a 45% increase in numbers of reports from ambulatory healthcare professionals after the implementation of the new reporting tool. Online reports were transmitted to the French Medicine Agency on average almost one month (26 days) earlier than "conventional" ones. This difference was mainly due to a faster ADR notification process *via* the online form (on average, the reporting period was decreased by 19 days with the new tool). In comparison to "conventional" notifications, online reports came more often from ambulatory healthcare professionals, and involved more frequently neuropsychiatric drugs and neuropsychiatric ADRs. None difference was observed for "seriousness" of ADRs. **Conclusions.** It is feasible to deploy an online ADR reporting system used by health professionals in current practice. We underline the efficiency of this new online reporting tool for increasing ADRs reporting. Moreover, this is the first published study demonstrating that an online reporting tool can help to save time on the ADR reporting period and file processing, which is essential to generate early safety signals.

Mots clés :
effet indésirable médicamenteux ;
notification spontanée ;
déclaration électronique

Résumé – Déclaration en ligne des effets indésirables médicamenteux : étude d'un Centre régional français de pharmacovigilance. Objectifs. Évaluer la faisabilité, l'utilisation et les performances d'un nouveau système de déclaration électronique des effets indésirables médicamenteux (EIM) mis en place en juillet 2010 par le Centre régional de pharmacovigilance (CRPV) de Toulouse. **Méthodes.** Étude rétrospective évaluant les caractéristiques des déclarations en ligne parvenues au CRPV de Toulouse sur une période de 18 mois entre 2010 et 2011, avec comparaison à un échantillon aléatoire de déclarations spontanées « conventionnelles » (courrier postal, fax, e-mail ou téléphone). **Résultats.** Durant la période d'étude, nous avons reçu 312 notifications en ligne et avons observé suite à la mise en place de l'outil une augmentation de 45 % des effectifs de déclarations provenant des professionnels de santé libéraux. Du fait principalement d'une notification plus précoce au CRPV, les déclarations en ligne parvenaient à l'Agence nationale de sécurité du médicament (ANSM) en moyenne 26 jours plus tôt que les déclarations spontanées « conventionnelles ». **Conclusions.** Il est donc possible de mettre en place en pratique courante un système de notification électronique des EIM pour les professionnels de santé. Cette étude met également en évidence un effet positif de la déclaration en ligne sur le taux et la rapidité de notification des EIM.

Abbreviations: see end of article.

* The poster "Online notifications of adverse drug reactions: a study in Midi-Pyrénées Pharmacovigilance Regional Center", D. Abadie, M. Bert, G. Durrieu, J.-L. Montastruc, has been presented to 11th ISoP Annual Meeting, 26-28 October 2011, Istanbul, Turkey.

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1. Introduction

Adverse drug reactions (ADRs) represent a significant cause of morbidity and mortality worldwide, accounting for up to 6.5% of all hospital admissions.[1-4] Many ADRs are identified after approval of drug commercialization because, owing to low sample sizes and short study periods, clinical trials are not adapted to evaluate rare and long latency period ADRs. Consequently, it appears necessary to implement constant surveillance of drugs after they are placed into the market and in this context, pharmacovigilance activities have a prominent place. Spontaneous reporting of ADRs remains the most important method for generating early safety signals. Other advantages of this reporting system lie in its low cost, simplicity of implementation, and the fact that it covers all population and all drugs throughout their whole commercial life.

Nevertheless, under-reporting of ADRs constitutes an important limitation of this monitoring system. Several studies suggest that less than 10% of the ADRs are reported to regulatory authorities.[5,6] Among the variety of obstacles to spontaneous reporting of ADRs, the lack of time for healthcare professionals because of clinical workload due to other healthcare priorities is one of the most discussed.[7] Reducing the time required to report an ADR seems crucial in this context. Developing simpler and faster new ADR reporting tools can constitute an interesting solution to achieve this purpose.

The Midi-Pyrénées Regional Pharmacovigilance Center (RPVC) [South Western, France] set up in July, 2010 a Web-based ADR reporting tool in order to encourage ADR reporting. From this date, it is possible, for both Midi-Pyrénées practitioners and patients, to declare ADRs directly through the website of the Medical Pharmacology Department from Toulouse University Hospital,[8] using an interactive form. This study was performed in order to assess feasibility, use and performances of this new Web-based ADR reporting system. We also aimed to evaluate the main characteristics of these online reports.

2. Methods

The French Pharmacovigilance system is based on a network of 31 RPVCs located in Medical Pharmacology Departments in University Hospitals and coordinated by the French Medicines Agency. RPVCs have to collect and analyze reports of ADRs in their defined geographical area. Particularly, they evaluate for each report the causal relationship between intake of drugs and occurrence of ADRs. Since 1984, they have shared a common database of spontaneously reported ADRs: the French Pharmacovigilance Database (FPVD). In France, prescribers of drugs (physicians, dental surgeons and midwives) and pharmacists are legally required to immediately report ADRs to their RPVC. Other healthcare professionals and more recently patients (decree of June 10th, 2011) can also report ADRs.[9]

We set up in July, 2010 an innovative Web-based ADR reporting tool that offers the possibility to both Midi-Pyrénées practitioners and patients to report ADRs directly online, through the website of the Medical Pharmacology Department from Toulouse University Hospital [*Bulletin d'information de pharmacologie* (BIP31.fr)].[8] BIP31.fr website provides free, updated, validated and independent information on drugs through a quarterly published pharmacological newsletter written by the medical pharmacologists from Toulouse University Hospital. To notify an ADR *via* BIP31 website, only an internet connection is necessary for the reporter to complete the online questionnaire (the connection to the website is free and does not require pre-registration). The form is divided into four subparts, each including several pre-coded fields. The first part is devoted to the patient's characteristics and enables to provide information about his socio-demographic status and his medical history. The second section is devoted to the drugs: the reporter must indicate trade and substance names, indication, dosage, route of administration and intake dates. The third section, devoted to the ADR, comprises a first open test box for the description of the symptoms, precoded fields for dates of the ADR and evolution, and a second open text box for description of ADR evolution. The fourth and final section is devoted to the reporter. He must indicate if he is a health professional (general practitioner, specialist, pharmacist, midwife…) or a patient, his identity and contact details. In order to ensure the quality of the reports, most of the previously described fields are mandatory. As soon as an ADR is reported *via* BIP31.fr, Midi-Pyrénées RPVC is automatically alerted by e-mail and the reporter also receives an electronic acknowledgement.

In order to evaluate the use of this new ADR reporting tool, we first counted the numbers of ADR notifications reported *via* BIP31.fr to Midi-Pyrénées RPVC during an 18-month period, *i.e.* between July 7th, 2010 (first online notification) and December 31th, 2011. To estimate if the new tool enabled to increase ADR reporting, we compared numbers of Midi-Pyrénées ADR reports from ambulatory healthcare professionals before (between July 7th, 2008 and December 31th, 2009) and after (between July 7th, 2010 and December 31th, 2011) the implementation of the new tool. We only focused on ADRs reported by ambulatory healthcare professionals, because other measures intended to increase the ADR reporting rate from hospital health professionals (as regular visits of a clinical research assistant in non-university hospitals) had been implemented by the RPVC during studied periods.[10,11]

We also assessed specific characteristics of online reports received at the RPVC between July 7th, 2010 and December 31th, 2011, by performing comparisons with a similar number random sample of "conventional" notifications, *i.e.* spontaneously reported to the RPVC *via* traditional tools (post, fax, e-mail or telephone) during the same period. Analyzed variables, retrieved from the FPVD, were: ADR reporting and file processing times, workplace of the reporters, suspected drugs, "seriousness" and nature of the ADR. Reporters were divided into 5 categories: university hospital health professionals, non-university hospitals and clinic health professionals,