What Motivates Patients to Report an Adverse Drug Reaction?

TO THE EDITOR: The role of patients in reporting adverse drug reactions (ADRs) is increasingly important.[1,2] The Netherlands Pharmacovigilance Centre Lareb collects and analyzes ADRs reported by health-care professionals, patients, and Marketing Authorization Holders. Lareb has been accepting patient reports since April 1, 2003, and has had favorable experiences with patient reporting.[3]

Little is known about what motivates patients to report an ADR to a pharmacovigilance center. A patient-centered interview regarding patient motives for reporting ADRs has not been previously conducted; thus, a qualitative study was conducted. The aim of our study was to gain insight into the motives of patients who report an ADR to a pharmacovigilance center through qualitative, semistructured interviews with patients who had reported an ADR.

Methods. Adults who reported an ADR to Lareb between September 1 and December 1, 2008, were included. Purposive sampling was used to include patients from different age groups and sexes; patients who had reported serious and nonserious ADRs were included. We chose to include patients using cardiovascular drugs (Anatomical Therapeutic Chemical [ATC] classification C0 up to C10) and those using antibiotics (ATC codes starting with J01), representing chronic and short-term medications, respectively. Interviews were guided by a semistructured topic list. All interviews were audiotaped, transcribed verbatim, and rendered anonymous. The interviews were performed by an academic researcher/ pharmacist and 2 pharmacy students. A content analysis was used for data analysis.[4] The investigators coded the first 8 transcripts independently to identify key themes, using the topic list and additional information from patients as codes. Patients were included until an interview did not provide new information with respect to the research questions. To check the reliability of the coding, all interviews were recoded by a different researcher. The degree of agreement was measured by calculating the Kappa coefficient (κ).[5] All transcripts were analyzed with support of QSR Nvivo (QSR International Pty Ltd, Doncaster, Victoria, Australia) version 8.0.264.0.

Results. A total of 21 semistructured in-depth interviews were carried out. With respect to the coding of the interviews, there was substantial agreement in 12 and almost perfect agreement in 9 interviews (κ between 0.65 and 0.93). The motivations for reporting an ADR could be characterized as either altruistic or personal (Table 1). Almost all patients had multiple motives for reporting.

In patients with altruistic motives, the interests or welfare of others or the public interest was a reason for reporting. Altruistic motives concerned preventing harm to other patients, making the ADR publicly known, increasing medical knowledge, and wanting to improve the patient information leaflet. Personal motives for reporting an ADR included wanting more information about the ADR, indicating that the ADR was too severe not to report, being angry, or wanting confirmation about the ADR. We found no major differences in reasons for reporting between strata of patient characteristics.

Discussion. This study found that some of the personal motives for reporting ADRs, such as wanting more information, could indicate that the information that patients receive from their physician or pharmacist is not always sufficient and that in some cases, patient and health-care professional communication could be improved. This could also be the case for patients who reported because they needed confirmation or recognition of their ADR. It is important that the pharmacovigilance center helps patients feel that they are being taken seriously. The results of this study will be used to develop a questionnaire about patients' motives for reporting ADRs.

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Pregabalin Treatment of Anxiety in Patients with Substance Use Disorders

TO THE EDITOR: Anxiety disorders are common in patients with substance use disorders (SUDs). However, pharmacologic treatment of anxiety can be problematic. While non-benzodiazepines such as selective serotonin-reuptake inhibitors (SSRIs) and serotonin/norepinephrine-reuptake inhibitors (SNRIs) are useful for treating a number of anxiety disorders, many patients do not remit adequately. For these patients, use of benzodiazepines may be necessary. However, clinicians are often reluctant to utilize benzodiazepines for anxiety disorders that coexist with SUDs.

Pregabalin is a novel non-benzodiazepine medication for neuropathic pain and now for fibromyalgia.[1,2] It has been shown to be effective in the treatment of generalized anxiety disorder in European studies.[3] It is a Schedule V controlled substance in the US, due to its limited abuse potential. To date, there have been no reports of its use in patients with SUD. In daily practice, we have used pregabalin augmentation to treat anxiety disorders unresponsive to conventional non-benzodiazepine an-

Table 1. Patient Characteristics and Motivations for Reporting per Stratum

	ATC code J01 (antibiotics)		ATC code C10 (statins)		ATC code C0 (cardiovascular drugs	
Motivations for Reporting per Stratum	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**
Total pts., n	3	2	4	4	4	4
Pts. with serious ADRs, n[a]	2	0	1	2	0	1
Mean age, y (range)	63 (62–64)	37 (20–54)	51.8 (39–63)	63 (52–70)	53.8 (42–60)	57.8 (42–80)
Altruistic motives, number of times mentioned						
Feeling that reporting will lead to more research and knowledge about drugs	1	2	2	3	4	2
Making ADR publicly known for other patients	1	2	3	4	1	1
Withdrawal of drug from market in case of danger for other patients	1					
Less prescriptions of a drug when it has a lot of ADRs						1
Sparing other patients trouble			2	2		1
Feedback to marketing authorization holder through pharmacovigilance center			1			
Change in patient information leaflet needed			1	1	2	
Personal motives, number of times mentioned						
Wanting more information about own ADR	2	1	2	2		1
Wanting to know if complaints are caused by drug (confirmation)	3	1		1		
Concern about own ADR	1			2		1
Severity of the reaction	2		2	2	2	1
Being unsatisfied with information or care provided by health-care professional	1			2	1	
Feeling anger towards marketing authorization holder	1			2		
Wanting to be heard	1			1		
Knowing that health-care professional does not report ADRs		2				
Because the possibility of reporting just exists		1			1	
Unexpectedness of reaction			2			
Reaction occurring after substitution of drug brand					1	
No recognition of ADR by health-care professional/not being taken seriously				1		1

ADR = adverse drug reaction; ATC = Anatomical Therapeutic Chemical; CIOMS = Council for International Organizations of Medical Sciences.
[a]Number of patients with an ADR that was serious according to the criteria of the CIOMS Working Group IV (1998, Geneva).