

# Patient self-reports of potential adverse drug reactions

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**Introduction** The United Kingdom's yellow card system has been extended to enable pharmacists to report directly to the Committee on Safety of Medicines. This system depends on voluntary reporting of suspected reactions by doctors and pharmacists, which in turn requires patients to spontaneously report their symptoms.

Patients' involvement in treatment decisions is increasing,<sup>1</sup> yet their experiences of using medicines are not routinely sought. A systematic approach may be able to identify a truer picture of their experiences of adverse effects and also increase reporting rates.

This study included two "black triangle" drugs, for which all symptoms should be reported to the CSM, and compared the frequency of drug-related symptoms self-reported by patients with those reported to their doctor, documented in medical records and reported to the CSM.

**Methods** A previously piloted questionnaire listing 86 symptoms based on body systems<sup>2</sup> was sent to all patients from 79 medical practices in Grampian who had a prescription dispensed for either tramadol or venlafaxine during January to March 1997 ("black triangle" drugs at the time). This requested respondents to identify any symptoms experienced over the previous year which they thought could be due to the study drug. The questionnaire was sent six months after the dispensing occurred and no reminder was sent to avoid unnecessary anxiety.

The primary care medical records of a sample of patients receiving each of the drugs were examined to determine whether any of these symptoms had been recorded. Data were obtained from the CSM on yellow cards submitted during the corresponding period from the 79 practices.

**Results** The overall response rate was 36 per cent: tramadol 33 per cent (344/1048) and venlafaxine 42 per cent (263/633). Of these 289 (84 per cent) reported at least one symptom they thought attributable to tramadol (median number of symptoms reported 4.5) and 249 (72 per cent) to venlafaxine (median 7). For both

## FOCAL POINTS

- A systematic questionnaire was found to be a feasible method of facilitating patients to report symptoms they perceived to be potential adverse effects of drugs
- Although 89 per cent of patients who had taken tramadol and venlafaxine reported at least one symptom in questionnaires, only 58 per cent of these claimed to have reported their symptoms to their doctor
- Only 22 per cent of symptoms reported by a sample of patients were found to be recorded in medical records and only 23 yellow card reports were submitted to the CSM for the same period
- Low reporting rates to GPs and low recording rates would appear to be contributory factors to low rates of reporting to the CSM

Table 1: Symptoms most commonly reported by patients taking tramadol and venlafaxine

Tramadol		Venlafaxine	
Symptom	Number reporting	Symptom	Number reporting
Dry mouth	112 (32.6%)	Dry mouth	121 (46.0%)
Light-headedness	85 (24.7%)	Increased sweating*	107 (40.7%)
Constipation	84 (24.4%)	Light-headedness	91 (34.6%)
Increased sleep*	70 (20.3%)	Decreased sexual desire	89 (33.8%)
Increased sweating *	69 (20.1%)	Unusual tiredness/weakness	88 (33.5%)

\*One of the 10 symptoms most frequently reported to the CSM

drugs, the five most commonly reported symptoms were all known side effects (see Table 1).

Only 147 (50 per cent) and 166 (67 per cent) of these respondents, respectively, claimed to have informed their doctor about some or all of these symptoms. Of the 50 patients prescribed tramadol whose notes were examined, 66/315 symptoms they reported were recorded (21 per cent); 96/401 symptoms reported by 53 patients to venlafaxine were noted in medical records (24 per cent). This is similar to previous results.<sup>2</sup>

Only seven reports relating to tramadol and 16 to venlafaxine were received by the CSM from the 79 practices over the period of the study.

**Conclusion** Although patient self-reporting of symptoms may result in over-reporting and inaccurate attribution to drug therapy, patient perceptions in this area can contribute to reduced medicine-taking and are therefore important. The study indicates that patients do not report all symptoms they suspect to be adverse

drug reactions to their GP, who in turn does not record all symptoms which are reported. Both factors could contribute to under-reporting to the CSM.<sup>3</sup>

A systematic approach such as described here could provide more information about patients' experiences than are available from the CSM and the questionnaire could be used by pharmacists monitoring therapy to help identify potential ADRs which should be reported.

## References

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*Int J Pharm Pract*  
2001;9(suppl):R35