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Letter to the Editors

Consumers' reports of suspected adverse drug reactions volunteered to a consumer magazine

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In some countries, reporting of adverse drug reactions (ADRs) by patients has been incorporated into spontaneous reporting systems, primarily to increase the number of reports and detect new ADR signals earlier [1]. To date only seven countries have allowed patients to report ADRs: Sweden (since 1978 via KILEN), USA (since 1993), Australia, Canada, Denmark and the Netherlands (since 2003) and the UK (since 2005) [1]. An analysis of ADR reports to the Danish Medicines Agency (DKMA) showed that patients are more likely to report ADRs from the nervous and psychiatric system than are health professionals, that patients' share of reports on serious ADRs was comparable to that of physicians, and that patients provided new and unknown information about ADRs [2]. The use of the internet as a source of information and discussion forum for health matters is rapidly increasing. Therefore we decided to investigate the information about possible ADRs provided by consumers who had easy reporting access via the internet. A consumer magazine provided the opportunity for their readers and others to report ADRs via an open access website. This letter examines whether these reports contributed with information about ADRs not previously described in the product information.

Data were collected from a questionnaire on the website of a consumer magazine during a 2-month period in autumn 2008 (September–October). If patients had experienced ADRs from the use of medicines, they were requested to answer the following questions:

1 To which medicine did you have an ADR?
2 What were you being treated for?
3 What sort of ADRs did you experience?
4 Did you tell anyone about the ADRs you experienced either at the time or later?
5 Did you report your ADRs either via www.borger.dk or to the Danish Medicines Agency?

We analysed the reports with respect to therapeutic groups [Anatomical Therapeutic Chemical (ATC) system] [3] and types of reported ADRs (system organ classes) [4]. The reported ADRs were checked against the official summary of product information (SPC). ADRs not mentioned in the SPC were classified as unlabelled.

Table 1 displays the number of reported ADRs distributed on therapeutic groups and the number of unlabelled ADRs (ATC level 1). Only 11 of the reports (3%) had been reported to the DKMA. In 42% of reports, patients had shared the information about ADRs with a healthcare professional, a family member or a relative. Forty percent of all ADRs were reported for medicines belonging to ATC group N (nervous system). In total, 15% of reported ADRs ($n = 188$) were not mentioned in the official product information. Of these ADRs, the highest share, 34%, was reported for medicines belonging to ATC group N (nervous system disorders). The majority of reported ADRs were of the types 'nervous system disorders' and 'gastrointestinal disorders'.

Open access to other patients' reports as well as the simple structure of the questionnaire may have motivated many patients to report ADRs. Such a data collection method could be used as a rapid data collection instrument in the event of suspected serious or rare ADRs not previously documented. The large number of ADRs reported for psychotropic medicines (ATC group N) could reflect that people with central nervous system problems are more likely to report these symptoms than other people. Although the types of reported ADRs and suspected medicines are in line with results from other countries [1, 2, 5], patients also reported information about previously unlabelled ADRs.

This study has confirmed that patients report rather unspecific symptoms, e.g. indisposition, dizziness and insomnia, as they use lay terminology to describe symptoms differently from terminology used by healthcare professionals. Patients also reported several ADRs such as drowsiness, weight gain and sexual problems, which prescribers may not consider serious but are troublesome to patients and limit the full enjoyment of daily life [1] and which patients find worthy of reporting in a questionnaire.

Table 1

Reports and ADRs of suspected medicines (ATC level 1) by therapeutic group

ATC groups	No. of reports	ADRs N	ADRs %	ADRs/report	Unlabelled ADRs N	Unlabelled ADRs %
Alimentary tract and metabolism (A)	37	90	11	2.4	16	8
Blood and blood-forming organs (B)	3	7	<1	2.3	0	0
Cardiovascular system (C)	41	76	10	1.9	10	5
Dermatological (D)	11	22	3	2	14	7
Genitourinary system and sex hormones (G)	13	25	3	1.9	16	9
Systemic hormonal preparations (H)	9	26	3	2.9	12	6
Anti-infective for systemic use (J)	25	59	7	2.4	15	8
Antineoplastic and immunomodulating agents (L)	14	33	4	2.4	1	<1
Musculoskeletal system (M)	33	53	7	1.6	0	0
Nervous system (N)	116	316	40	2.7	64	34
Antiparasitic products (P)	3	5	<1	1.7	2	1
Respiratory system (R)	26	59	7	2.3	19	10
Sensory organs (S)	2	5	<1	1.5	3	2
Herbal products	7	18	2	2.6	16	9
Total	340	794		2.3	188	100

ADR, adverse drug reaction; ATC, Anatomical Therapeutic Chemical.

The content and quality of the reported data are inappropriate for causality analysis as the reports contained no information about age, sex, diagnosis and concomitant medicines. Hence, the collected ADR data may actually consist of ADRs that patients believe to be possibly drug-related reactions rather than confirmed ADRs, and the value of these data in drug surveillance is limited. Consumer ADR reports might act as whistleblowers of new and previously undetected ADRs, but if the quality of the reports is questionable they bring too much noise rather than valuable information to the pharmacovigilance systems.

Further studies to explore the quality, validity and impact of consumer reports in the pharmacovigilance systems are needed and appropriate systems for patient reports of ADRs should be explored. The unlabelled ADRs should lead to further investigations and possible detection of new ADRs.

Competing interests

None to declare.

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REFERENCES

1 Blenkinsopp A, Wilkie P, Wang M, Routledge PA. Patient reporting of suspected adverse drug reactions: a review of published literature and international experience. Br J Clin Pharmacol 2006; 63: 148–56.

2 Aagaard L, Nielsen LH, Hansen EH. Consumer reporting of adverse drug reactions: a retrospective analysis of the Danish Adverse Drug Reaction Database from 2004 to 2006. Drug Saf 2009; 32: 1067–74.

3 WHO Collaboration Centre for Drug Statistics Methodology. Complete ATC index 2009. Available at: http://www.whocc.no/atcddd/indexdatabase (last accessed 12 May 2009).

4 MedDRA. Available at: http://www.meddramsso.com (last accessed 12 May 2009) [password required].

5 de Langen J, van Hunsel F, Passier A, de Jong-van den Berg L, van Grootheest K. Adverse drug reactions reporting by patients in the Netherlands. Three years of experience. Drug Saf 2008; 31: 515–24.

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