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Important information regarding reporting of adverse drug reactions: a qualitative study

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Abstract

Objective To give an overview of the views of different types of reporters (patients and healthcare professionals (HCPs)) and assessors of adverse drug reactions (ADRs) on what they consider important information regarding an ADR report.

Methods A semi-structured interview was conducted among reporters and assessors of ADRs in the Netherlands. All interviews were audiotaped and transcribed verbatim. Content analysis was used on the data. All transcripts were coded individually by two researchers. A list was drafted of all elements of information mentioned during the interviews.

Key findings In total 16 interviews were conducted. Elements of information that were explicitly brought up during the interviews were the impact of the ADR on the patient's daily life and information regarding causality. Furthermore, the correctness of reported information was found important by assessors of ADRs. Generally, patient reporting was seen as a very positive development for pharmacovigilance.

Conclusion Patients reported that the severity of ADRs and their impact on daily life were important subjects. In the interviews with HCPs, either reporters or assessors, the focus was mainly on causality. The correctness of the given information is considered by ADR assessors to be very important. Regarding patient reporting the overall view was positive. Because HCPs and patients have different views regarding ADR reporting, in daily practice it is important to receive reports from both groups to assess the true nature of the ADR.

Introduction

A pharmacovigilance centre collects reports of possible adverse drug reactions (ADRs) in order to detect ADRs in the postmarketing phase. In the past the reporting of ADRs was restricted to healthcare professionals (HPCs) in many countries. Nowadays more countries allow patients to report ADRs directly and patient reporting is seen as an increasingly important topic in pharmacovigilance.[1] Patient reporting has also been introduced in the new European pharmacovigilance legislation.[2] This introduction indicates a change in attitude in which the patient's experience is valued.[1]

The contribution of direct patient reporting to pharmacovigilance has been explored in a number of studies.[3,4] Patients' and HCPs' views on ADRs and motives for reporting ADRs can differ. This may result in the reporting of different kinds of information. Little is known about what kind of information different stakeholders in pharmacovigilance actually consider important when it comes to ADR reporting.

The aim of our study is to give an overview of the views of different types of reporters (patients and HCPs) and assessors of ADRs on what they consider important information regarding an ADR report.

Method

This qualitative study used semi-structured interviews to capture reporters' view on what they consider important information regarding an ADR report. Patients, general practitioners, pharmacists and medical specialists were selected

Table 1 Elements of information about an adverse drug reaction (ADR) that were considered important by reporters and assessors

Topic	Elements within a topic
Information about the ADR	ADR, start date, time to onset, treatment, seriousness,[9] other aspects that could have caused the ADR, detailed description of ADR, de- and rechallenge, recurrence, recovery, recovery date, time to recovery, severity, impact of ADR on quality of life
Information about the drug	Suspect drug, indication, RVG code (registration number for drugs), start and stop date, interactions, dosage, pharmaceutical form, actions after ADR, concomitant drugs, contra indication
Information about the patient	Sex, date of birth, body weight, height, medical history, comorbidity, allergy, lifestyle, familial diseases, compliance, metabolism, past drug therapy
Additional information	Test results, letter of resignation, literature, incidence, confounding by indication, opinion of healthcare professional and patient, actions taken by patient, self-management by patient

at random from the database of the Netherland Pharmacovigilance Centre Lareb and asked to participate. In addition, assessors of ADRs employed by the Netherlands Pharmacovigilance Center Lareb, the Dutch Medicines Evaluation Board and the pharmaceutical industry were asked to participate. Out of each group at least two persons were interviewed. Interviews were conducted until the interviews did not provide new information with respect to the research question.

The interview had five sections: (1) information about and work experience of the participant, (2) familiarity with Lareb, (3) elements considered important concerning ADR reporting, (4) differences in HCP and patient reports and (5) the value of patient reports. The interviews were in Dutch and were performed by two researchers (LR and SW). Interviews were translated at the end of the analysis. All interviews were audiotaped and transcribed verbatim. Transcripts were validated by sending a summary of the interview to the participant.[5] Content analysis was used for data analysis. All transcripts were coded individually by two researchers (LR and SW) with the support of QRS NVivo version 9.2.81.0, a program for structuring qualitative data.[6] Cohen's kappa coefficient (κ) was calculated to measure the degree of agreement. We used the following standards for strength of agreement for the κ: 0.01–0.20 = slight, 0.21–0.40 = fair, 0.41–0.60 = moderate, 0.61–0.80 = substantial and 0.81–1.0 = perfect.[7] Some elements that were typical examples of elements found important by patients or HCPs were illustrated by quotes. For this study ethics committee approval was not required, as Dutch legislation does not request this for studies that do not affect the patient's integrity. Participant data were sampled and stored in accordance with privacy regulations. Written informed consent was obtained from all participants prior to the interview.[8]

Results

In total 16 interviews were conducted: nine with reporters (three patients, two pharmacists, two general practitioners, two specialist doctors) and seven with assessors of ADRs. The κ showed substantial agreement in half of the transcripts and perfect agreement in the other half. Table 1[9] summarizes what elements of information about an ADR were considered important by reporters and assessors of ADRs.

Elements of information that were explicitly brought up during the interviews were the impact of the ADR on the patient's daily life and information regarding causality.

The impact, often in combination with its severity, was mentioned by the patients. One patient who reported abdominal pain and a bloated belly associated with the use of pravastatin said: 'I could not keep this up anymore, I could not wear my clothes, not even my underwear, it was all too much for me'. Another patient explained: 'It [the ADR] distracted from other things in life'.

The impact was also mentioned by HCPs. For example, one pharmacist explained the impact of an oily taste in the mouth for one of his patients after the use of amlodipine: 'You are confronted with it the whole day, you cannot even enjoy your meal and it influences your ability to enjoy things'.

Information important for causality assessment was mentioned by all groups; however, it was made less explicit by patients. A general practitioner said: 'I look at other aspects of the patient such as concomitant medication, interactions, medical history. Also age, it is more likely a 70-year-old gets an ADR than a 20-year-old. This is also important information'. Other elements of information considered important involving causality were, for example, the time course of the ADR, test results and patient's medical history.

In addition to the above, assessors of ADRs also found it important that the reported information is 'correct'. This is illustrated by a quote from one of the assessors: 'Yes, I think your first reaction is that you would say you would like as much information as possible. But, when I think about it, I would say I would like the information to be as specific as possible'.

The impact of the ADR on the patient's daily life was less explicitly mentioned in interviews with assessors of ADRs. Assessors working at Lareb found that information about an ADR's impact can be very useful for the writing of proper personalized feedback to the patient, since Lareb writes

personalized feedback to each reporter.[1,10] This aspect was not mentioned by assessors at the Medicines Evaluation Board or the pharmaceutical industry.

Patient reporting

Patient reporting was generally seen as a very positive development for pharmacovigilance. It was thought that patients could give a detailed description of the ADR because it is they who actually experience the ADR. Some interviewees added that additional clinical information from a HCP might be necessary for understanding certain ADRs.

Strengths and limitations

The number of participants involved in this study is limited but, because all parties involved in ADR reporting are included, the authors believe that a clear overview has been obtained of all elements of information that are considered important regarding ADR reporting.

Conclusion

This article gives an overview of the views of reporters (patients and HCPs) and assessors of ADRs on what they consider important information about a reported ADR. Patients reported the severity and impact of ADRs on their daily life to be important subjects. In the interviews with HCPs and assessors the focus was mainly on causality. The correctness of the given information is considered to be very important by ADR assessors. Regarding patient reporting the overall view was positive. Because HCPs and patients have different views regarding ADR reporting, in daily practice it is important to receive reports from both groups in order to assess the true nature of the ADR.

The types of ADR information found in this study will be used for a further quantitative comparison of reports from patients and HCPs.

Declarations

Conflict of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

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