

Expectations of general practitioners and specialist doctors regarding the feedback received after reporting an adverse drug reaction[†]

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SUMMARY

Objective Aim of this study is to gain insight in experiences and expectations of general practitioners and specialist doctors regarding the feedback information of the Netherlands Pharmacovigilance Centre Lareb.

Method A questionnaire survey was conducted among a random sample of 400 doctors, divided in general practitioners and specialist doctors. Within these groups, a difference was made between those who reported only once and those who are frequent reporters. A structured questionnaire consisted of 23 questions about expectations, experiences, the influence of feedback information and what the doctors would like to change in the feedback from Lareb. A comparison between the groups will give insight in what they think separately and how Lareb can seize on their wishes.

Key findings The response rate was 54.4% ($n = 217$) after one reminder. The respondents are satisfied with the feedback information and regarded the information of good quality. The expectations were higher on information about sources (significance 0.00, caused by specialist doctors who reported once) and co-medication (0.025 caused by all groups). The experiences of the four groups were also very positive. They all find the feedback information of Lareb reliable, scientifically well considered and to the point.

Conclusions General practitioners and specialist doctors are satisfied about the follow-up information and they like to see the same format of information and communication in the future. Copyright © 2007 John Wiley & Sons, Ltd.

KEY WORDS—adverse drug reaction; reporting; feedback information

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INTRODUCTION

The Netherlands Pharmacovigilance Centre Lareb is appointed by the Government as the national centre for the reporting of adverse drug reactions (ADRs)

of registered medicines in the Netherlands. Lareb collects additional information about the reports and stores the information in the Lareb database. Reporters receive confirmation on their report and additional information is provided,¹ indicated as 'feedback information'.

This feedback information is divided in two parts. The first part is a letter with an acknowledgement to the reporter and, if needed, a request for additional information. The second part provides a theoretical framework on the ADR. It contains information on

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whether the ADR is described in the official product information, in the literature and possible other sources. The second part also contains information on the causality of the relation between the drug and the ADR. The causality is examined by a professional of Lareb and includes concomitantly used drugs, the latency period and the occurrence of the ADR after stop or start of the drug.

General practitioners and specialist doctors have an important role in the detection and reporting of suspected ADRs. Communication is of great importance in this process; it stimulates reporters to continue reporting.² Lareb is founded on the voluntarily reporting of ADRs. To evaluate this process Lareb wants to know what the expectations and experiences of the reporters are. Although the reporting rates increase, Lareb wonders if the feedback information meets the expectations of her reporters. It is important to anticipate on their desires to keep the reporters satisfied. Another interesting aspect is to see in what extent physicians use the feedback information in daily practice.

The reasons for reporting are already investigated. The results of this research showed that *community pharmacists* are highly motivated to report ADRs, joined by the knowledge that they are obliged to do so.³ Another investigation on voluntary reporting is performed by Belton *et al.*⁴ They researched voluntary reporting by means of an attitudinal survey among a group of *medical practitioners*. They concluded that a considerable degree of underreporting existed, which might be explained partly by lack of knowledge and misconceptions on spontaneous reporting of ADRs. According to these investigations, a difference exists between medical professionals in reporting of ADRs.

This is an issue in the present research, but the most important focus is to gain insight in the expectations of the reporters. The aim of the present survey was to gain insight in expectations and experiences of general practitioners and specialist doctors towards the feedback information. On one hand, it is interesting to see what is going on in the minds of physicians towards the feedback information. On the other hand, the results are important to implement guidelines for the feedback information to maintain the highest efficiency.

METHODS

A structured, 23-item survey was sent to a random sample of 200 general practitioners and 200 specialist

doctors in the Netherlands in May 2005 with the request to complete and return it within 2 weeks. The group of general practitioners consisted of 100 frequent reporters and 100 physicians who reported only once. The group of specialist doctors consisted of 53 respondents and 147 'once' reporters. The forms could be returned anonymously. A reminder was sent after 3 weeks.

Questionnaire development

The first four questions of the survey covered the opinion of reporters on the quality of the feedback information and whether they used the information in daily practice (see Questionnaire). The following items related to nine points of information were present in the feedback information. The respondents had to choose if they expected information on these nine items and if the provided information met up to their expectations. Then, six questions were asked on the opinion of the respondents towards Lareb. Two questions followed on the moment and content of inquiries by Lareb for additional information. With these questions the respondents were asked to indicate their opinion on a scale from 1 to 7. The last two questions were about the feedback information: whether it stimulates the reporting of ADRs and if any changes in the feedback information were desired. The respondents could choose between 'yes', 'no' and 'slightly'. They could explain their choices on three questions, which provided additional information on their thoughts. Prior to the survey, the questionnaire was piloted by two independent persons, which resulted in adaptation of the phrasing of several questions. After a first analysis of the results, it became clear that the term 'slightly' was too vague. We chose to collect the 'slightly' answers with the 'yes' answers, which resulted in higher expectations of Lareb.

RESULTS

One hundred eighty-four questionnaires were returned on the first mailing. After the reminder, we received another 33 surveys. Thus, a total of 217 of 400 questionnaires were returned, which makes a response rate of 54.3%. The response rate of the more frequently reporting general physicians and specialist doctors was higher than those of the 'once' reporters, as can be seen in Table 1.

Table 1. Response rate of the different type of reporters

	General practitioner (%)	Specialist doctor (%)
'Once-only' reporter	48	54
Frequent reporter	61	74

Expectations and experiences

More than three quarters of the respondents expected information on all nine items mentioned in the questionnaire. The highest (>90%) score was reached on the items 'number of similar reports at Lareb', 'possible mechanism of the ADR' and 'influence of concomitant medication'. A remarkable difference was seen on the four types of reporters on the item 'specification of the sources consulted'. Specialist doctors more often expected information on this item than general physicians.

Figure 1 shows the opinion of the respondents on whether the feedback information they received, met up to their expectations. The information Lareb provided on 'the influence of concomitantly used medication', 'the number of reports at the WHO monitoring Centre' and 'outcome of the ADR' was least appreciated by the respondents. About the feedback information on 'the number of reports in the Lareb database' and 'additional literature references', the respondents were most satisfied.

These answers are not supported by the first question of the survey, which is on the overall quality of the feedback information on a 7-point scale, the lowest indicating the most satisfied reporter. Almost

80% of the respondents gave a '1' or '2' score for the quality of the feedback information.

Opinion of the respondents

The questions about experiences of reporters with Lareb are answered positively. With these questions the reporters indicated their answer on a 7-point scale, 7 standing for the most agreement with the statement. The questions whether feedback information was *judged scientifically well considered, to the point* and of *great value* to the reporter all received a score around 6 points. The opinions on whether the feedback information was being considered *wise/cred, vague* and *arrogant* scored between 1.5 and 2 points.

Need to change?

At the end of the questionnaire the respondents could choose between two options: they would like the feedback information to stay the same or they would like to see it changed. In total, 77% of the respondents want the feedback information to stay the same, versus 13% who would like it to change. Between the different types of reporters, the percentages varied between 72% and 81%. The family doctors, who reported once, were most satisfied with the feedback information as it was, the specialists that reported more often where least satisfied. This question gave the reporters a possibility to argue their thoughts and

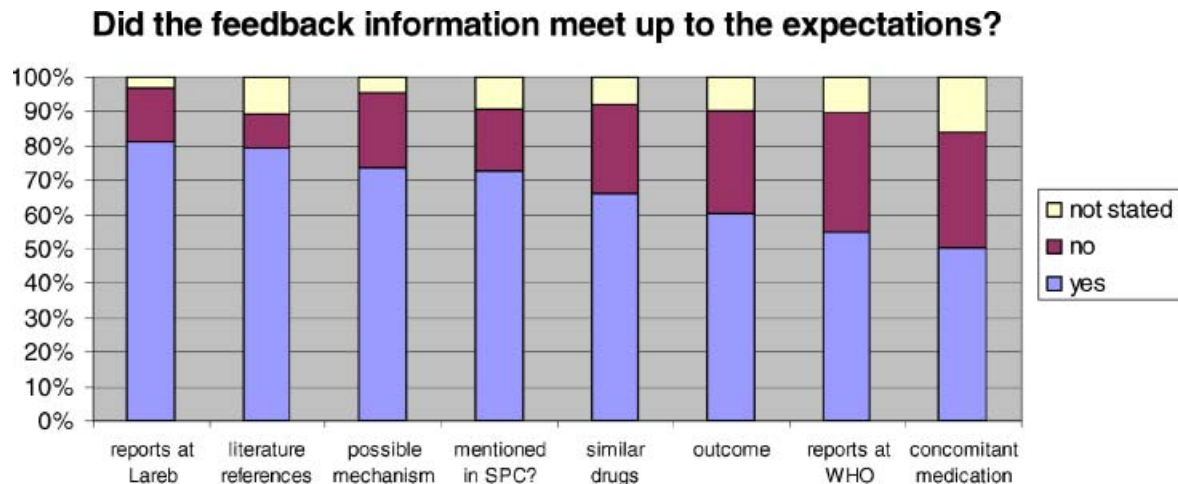


Figure 1. Expectations on points of information

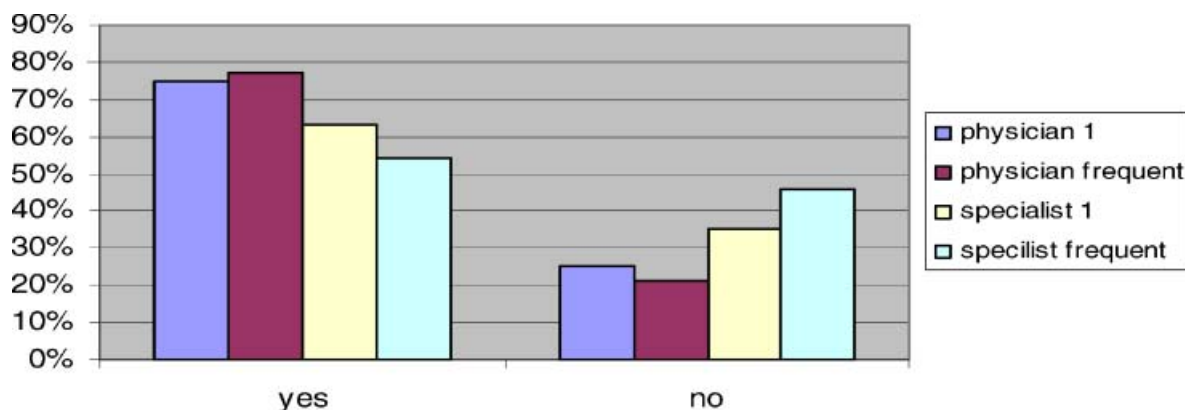


Figure 2. Does the feedback information influence daily practice?

give advice for the future. The most stated comment was that the respondent would like to receive a faster response from Lareb (eight times).

The use of feedback information

The survey stated a question on the influence of the feedback information on the prescription behaviour of the doctors. Figure 2 shows the answers of the respondents in relative numbers. The feedback information is more used by general practitioners, especially those who report more often, than by specialist doctors. The answers on the question 'do you inform your patient about the feedback information' show an equivalent distribution.

DISCUSSION

The greater part of the reporters is satisfied with the provided information and is positive about Lareb. These main results were supported by the following outcomes:

- All nine items present in Lareb's feedback information are topics reporters expect information on.
- The information provided on these nine items did not always meet up to the expectations of the reporters.
- The questions on the opinions of the respondents on the feedback information in general were answered in positive.
- The greater part of the respondents was satisfied with the feedback information and think it has to stay the same. According to the reporters the provided information is stimulating. The greater part thinks it is important to know that Lareb has done something with their report.

KEY POINTS

- Feedback has impact on prescription habits of the reporter
- It is an important stimulus to report ADRs
- Individual Feedback is highly appreciated by health professionals.

- Feedback information has more influence on the 'pharmacotherapeutic' behaviour of general practitioners than on specialist doctors.

CONCLUSION

General practitioners and specialist doctors are generally satisfied with the information provided by Lareb in the feedback information. The information meets their expectations and their experiences with it are positive. The greater part of the respondents wants to keep the feedback information as it is.

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FEEDBACK AFTER ADR REPORTING

QUESTIONNAIRE

Question 1: What do you think of the feedback information of Lareb?

Good Bad

Question 2: Does the information, influence your (pharmaco)therapeutic policy?

- Yes.
- Slightly.
- No.

Question 3: Do you inform your patient about the feedback information of Lareb?

- Yes.
- No.

Question 4: There is a time gap between reporting and receiving feedback information. What do you think of this period of time?

Short Long

Question 5:	Do you expect information about:	Did the information meet your expectations?
1. Number of equivalent reports in the Lareb database.	<input type="checkbox"/> Yes. <input type="checkbox"/> Slightly. <input type="checkbox"/> No, go through to item 2.	<input type="checkbox"/> Yes. <input type="checkbox"/> No.
2. The possible mechanism of the adverse drug reaction.	<input type="checkbox"/> Yes. <input type="checkbox"/> Slightly. <input type="checkbox"/> No, go through to item 3	<input type="checkbox"/> Yes. <input type="checkbox"/> No.
3. Number of equivalent reports in the World Health Organization database.	<input type="checkbox"/> Yes. <input type="checkbox"/> Slightly. <input type="checkbox"/> No, go through to item 4.	<input type="checkbox"/> Yes. <input type="checkbox"/> No.
4. Information about the outcome of the adverse drug reaction.	<input type="checkbox"/> Yes. <input type="checkbox"/> Slightly. <input type="checkbox"/> No, go through to item 5.	<input type="checkbox"/> Yes. <input type="checkbox"/> No.
5. Specification of the sources that were consulted.	<input type="checkbox"/> Yes. <input type="checkbox"/> Slightly. <input type="checkbox"/> No, go through to item 6.	<input type="checkbox"/> Yes. <input type="checkbox"/> No.
6. The appearance of the adverse drug reaction on a equivalent drugs.	<input type="checkbox"/> Yes. <input type="checkbox"/> Slightly. <input type="checkbox"/> No, go through to item 7.	<input type="checkbox"/> Yes. <input type="checkbox"/> No.
7. Whether the adverse drug reaction is mentioned in the official product information or not.	<input type="checkbox"/> Yes. <input type="checkbox"/> Slightly. <input type="checkbox"/> No, go through to item 8.	<input type="checkbox"/> Yes. <input type="checkbox"/> No.
8. References as supplement information.	<input type="checkbox"/> Yes. <input type="checkbox"/> Slightly. <input type="checkbox"/> No, go through to item 9.	<input type="checkbox"/> Yes. <input type="checkbox"/> No.
9. The influence of concomitant-medication on the adverse drug reaction.	<input type="checkbox"/> Yes. <input type="checkbox"/> Slightly. <input type="checkbox"/> No, go through to question 6.	<input type="checkbox"/> Yes. <input type="checkbox"/> No.

Question 5:	Do you expect information about:	Did the information meet your expectations?
1. Number of equivalent reports in the Lareb database.	<input type="checkbox"/> Yes. <input type="checkbox"/> Slightly. <input type="checkbox"/> No, <i>go through to item 2.</i>	<input type="checkbox"/> Yes. <input type="checkbox"/> No.
2. The possible mechanism of the adverse drug reaction.	<input type="checkbox"/> Yes. <input type="checkbox"/> Slightly. <input type="checkbox"/> No, <i>go through to item 3</i>	<input type="checkbox"/> Yes. <input type="checkbox"/> No.
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Question 10: Could you describe in a few words what has to happen with the system of feedback information?

- It must remain the same.
 It must change, could you argument why it must to change:

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Thank you again for your cooperation!