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Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital

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Aim
To describe the opinions of hospital physicians concerning problems regarding the spontaneous reporting of adverse drug reactions (ADRs) and ways to solve them.

Methods
A qualitative study was carried out. Fifteen focus groups were conducted among physicians working in a tertiary teaching hospital. A total of 208 physicians from different medical specialities participated. The focus group discussions were recorded by three different observers and the transcripts of each session were analysed for issues and themes emerging from the text.

Results
Four types of obstacles to spontaneous reporting were considered particularly important: (i) problems with the ADRs diagnosis; (ii) problems with the usual workload and lack of time; (iii) problems related to the organization and activities of the pharmacovigilance system; (iv) and problems related to potential conflicts. The potential solutions suggested for improving spontaneous reporting were to define the kind of ADRs which should be reported, to facilitate an easy contact and quick access to the hospital pharmacovigilance system, to facilitate information and support for reporting and feedback of pharmacovigilance activities.

Conclusions
The perception of the different obstacles by the hospital physicians is an important factor in determining the causes of the underreporting of ADRs and addressing these obstacles could lead to an improvement in spontaneous reporting. A closer relationship between the doctors and the pharmacovigilance centre is suggested as a means of solving these problems. More information is needed to improve the spontaneous reporting of ADRs in specialized healthcare.

Introduction

The primary focus of a spontaneous reporting system is to detect serious unknown adverse drug reactions (ADRs). All reports of ADRs are reviewed and analysed to generate 'signals' or 'warnings' of serious, yet unrecognized, drug-associated events, that might indicate a public health problem [1]. Improving the number of reports and access to the data facilitates a timely evaluation of aggregates of ADR reports, which are often the first signals of a potential problem. A well-known problem in the spontaneous reporting system is the underreporting of ADRs [2]. Different obstacles to notifying ADRs have been proposed by Inman [3] and have been reported in different studies [4, 5]. The reporting of

ADRs in hospitals is very important because innovative new drugs are usually used, severe ADRs are most likely to be seen in hospitals, ADRs can be detected early on and spontaneous reports can be more accurate. However, there is a poor record of reporting ADRs in hospitals [6]. Thus, the opinions and attitudes of hospital physicians on the problems of spontaneous reporting of ADRs and the ways to solve them are very important. The aim of our study was to assess the perceptions, attitudes and opinions of hospital physicians about problems regarding the spontaneous reporting of ADRs and ways to solve them.

Methods

We chose a qualitative research because this methodological approach could identify the physicians' point of view and would facilitate the development of ideas for possible interventions. The qualitative technique of the study was the focus group methodology [7, 8]. Focus groups were conducted among physicians from different medical specialities in a tertiary teaching hospital. A theoretical sampling model was used and the composition of the groups was 'naturally occurring' (pre-existing groups) aiming for homogeneity within each group. The focus groups consisted of physicians (house staff and residents in training) who work together in the same medical service of the hospital. All the physicians who were contacted agreed to participate in the study. Fifteen focus groups were conducted and 208 physicians from the following medical specialities participated: Internal Medicine, Infectious Diseases, Intensive Care, Cardiology, Haematology, Hepatology, Digestive Diseases, Pneumology, Nephrology, Neurology, Oncology, Dermatology and Rheumatology and other Systemic Diseases.

Focus groups were held over 6 months (from December 2002 to May 2003). Sessions were relaxed and lasted between 1 and 2 h. First of all, each focus group session consisted of a short introduction, undertaken by a clinical pharmacologist specialized in phamacovigilance, describing the objectives of the spontaneous notification system of ADRs and changes in the pharmacovigilance legal rules recently established in Europe and Spain [9, 10]. Then, participants were requested to discuss problems in the spontaneous reporting of ADRs according to their particular point of view and ways to solve these problems. All the focus groups were helped by other clinical pharmacologists whose role was to introduce the topics, ask questions and encourage the participation of all group members. Participants were told that the purpose of the study was not to audit the practice but to understand their perception of the problems of spontaneous reporting and ways to improve it. Open-ended questions were used to generate discussion in both areas: problems and possible solutions. Three different clinical pharmacologists took notes on themes emerging from the discussion and also compared notes to clarify statements and to ensure the transcripts were complete. For each session, content analysis using an open analytic approach was employed to explore and understand the experience of the physicians. This method uses no predetermined categories of analysis and allows incorporation of relevant themes and issues that emerge from the data to guide the coding and facilitate a more detailed understanding of the context and processes related to the problem. This is an inductive and iterative analytical process that seeks out all relevant interpretations and continues until no new information emerges.

Results

A summary of the issues and themes identified in the focus groups is shown in Table 1 (barriers) and Table 2 (solutions).

Potential obstacles to the spontaneous reporting of ADRs

Potential barriers for the spontaneous reporting of ADRs according to the doctors are the following.

The diagnosis of ADRs. Lacking suspicion of an ADR could be a problem, although most of the hospital doctors are used to including them in a differential diagnosis list. There are doctors who believe that it is necessary to confirm ADRs, and they do not report anything if they are not completely sure about the causality assessment of the ADR. A problem in reporting is to establish a causality relationship between several drugs taken by patients and suspicions of adverse reactions. As one physician stated, 'When a patient is taking a lot of drugs, how can we determine which drug is causing the adverse reaction?'. In addition, the doctors sometimes do not have information sources of ADRs and they considered it as a problem in spontaneous reporting.

The organization of the pharmacocovigilance. Although most doctors know about the pharmacovigilance programme, there are some who still do not. Many doctors are not acquainted with the objectives and potential usefulness of this pharmacovigilance programme in the hospitals. Many doctors think that barriers to contact and access to people working in the hospital pharmacovigilance system are an important problem in spontaneous reporting. A lack of yellow cards or forms for reporting is another problem that doctors described. As one physician said, 'I have patients with ADRs, but,

Table 1
Potential obstacles to spontaneous reporting of adverse drug reactions (ADRs)

1	Obstacles related to diagnosis and suspicion of ADRs
	Lack of suspicion
	Uncertain diagnosis (suspicious diagnosis but not confirmed)
	Sources of information and resources for searching for evidence of ADR
2	Obstacles related to organizing hospital pharmacovigilance system
	Ignorance of hospital pharmacovigilance system
	Access to and contact with hospital pharmacovigilance system
	Ignorance of spontaneous reporting ADR utility (objectives, and utility of spontaneous reporting system of ADRs)
	Lack of yellow cards or forms for reporting
	Lack of information and feedback of reported ADR to doctors
3	Obstacles related to clinical activities
	Lack of time and difficulties in filling out records or forms
	Other clinical priorities
	Forgetfulness in reporting ADRs
4	Obstacles related to potential conflicts
	Problems of confidentiality with patients' data
	Problems of legal liability and possible judicial claims
	Problems with publication in medical journals

Table 2
Solutions for overwhelming obstacles to reporting spontaneous adverse drug reactions (ADRs)

1	To define priorities for spontaneous reporting:
	type of drugs
	severity of ADR
	unexpected ADR
2	To facilitate easy contact with and quick access to a hospital pharmacovigilance system:
	use of technology (phones, fax, worldwide web, e-mail . . .)
	use of reminders or advertisements
	availability of yellow cards or forms for reporting
	direct relationship
3	Facilitating information and support for reporting ADRs by means of:
	specific information regarding reported ADRs
	therapeutic consultation about evidence of suspected ADRs and causality assessment of suspected ADRs
4	Feedback information on hospital pharmacovigilance activities:
	periodic summary of reported ADRs in hospital
	periodic summary of specific type of ADR according to interest of different wards
	regular information about ADR warnings

sometimes, I do not have any yellow cards'. An absence of a pharmacovigilance feedback system is seen by many doctors as another barrier to spontaneous reporting and especially for those who are not familiar with the programme. In addition, a further problem is the methodology for identifying warnings. As one physician said, 'I do not know if the process for identifying warnings is reliable'.

The clinical workload. Lack of time, an increase in work and other clinical priorities are important problems manifested by the majority and even more so when doctors have to fill out additional forms or records. Many doctors do not report all ADR cases because they usually see so many ADRs in their practice and they can not report all of them. As many physicians said, 'We see a lot of patients with ADRs', and one physician stated 'I have a lot of work, but I always notify a severe ADR when I see it, although I do not usually notify mild ADRs'. A frequent question posed in this context is 'What kind of ADR should we report?'. Other doctors considered forgetfulness as a problem in reporting,

because when they see a patient with an ADR in their clinical activity, they usually postpone reporting it, and finally they forget it.

The potential conflicts. Obstacles regarding potential conflicts are seen by some doctors as a barrier to reporting. Several doctors thought that the problems of legal liability and possible judicial claims against doctors and the problems of confidentiality with patients' data were obstacles to bear in mind. In addition, a few doctors think problems with publication in medical journals is a barrier to reporting.

Solutions for overcoming obstacles to the spontaneous reporting of ADRs

Suggested solutions by hospital doctors for improving the spontaneous reporting of ADRs are the follows.

Definition of priorities for spontaneous reporting. Doctors believe it is necessary to define priorities for spontaneous reporting in order to select types of more useful reports because they have much work to do and it is impossible to report all their suspicions of ADRs. Physicians think that a selection of spontaneous reporting could be made according to the type of suspected drug or the severity of adverse reactions or unexpected ADRs. Doctors proposed clarifying to a greater degree the ADRs that should be reported to different services according to the treated diseases or drugs used in the different clinical services.

Making access and contact easier with the pharmacovigilance centre. All doctors think that it is necessary to facilitate easy access and a quick contact with a hospital pharmacovigilance group. Different ways proposed to contact someone are by phone, fax or information technologies on the internet (world wide web or e-mail). To facilitate the reporting process, reminders in the form of an advertisement, a poster indicating phone and fax numbers, or other ways to contact people were suggested. The availability of more yellow cards or forms for reporting distributed in different wards was suggested, as well as specific mailboxes for ADR notifications located in different hospital areas.

In addition, other possibilities included having specific doctors to contact in different wards, who would be informed of ADRs seen in each clinical service and who would then report directly to the pharmacovigilance programme. However, doctors considered it necessary to have the physical presence of experts from the pharmacovigilance system to notify them about ADRs, because they can help doctors with advice in filling out forms and doctors can remember much more ADRs. Visiting rounds or periodic sessions to discuss clinical cases was the most direct way suggested to facilitate access and contact for spontaneous reporting. Finally, another possible solution suggested to improve reports of ADRs was a revision of clinical reports when patients are discharged.

Development of information and support activities for reporting ADRs. Facilitating information and support when there is a suspicion of an ADR in specific cases was another solution suggested by some physicians. Support could be to give specific information regarding all reported ADRs, or a therapeutic consultation about evidence of specific suspected ADRs and an opinion about the causality assessment of suspected ADRs or the mailing of an assessment of each notified case.

Feedback of the pharmacovigilance activities. Facilitating general information about hospital pharmacovigilance activities was proposed as a useful way to improve spontaneous reporting. Feedback of the pharmacovigilance activities suggested was: a periodic edition of an ADR bulletin with a periodic summary of ADRs reported in the whole hospital and a discussion of the most interesting cases, or a periodic sessions with a summary of specific types of ADRs according to the interest of the each one of the different medical specialities or different medical wards, or regular information about warnings of ADRs according to the international and national drug agencies.

Discussion

Our study identified various obstacles in the spontaneous reporting of ADRs according to the physicians working in a hospital. Various studies, mainly based on surveys, have assessed the physicians' opinions about the problems in spontaneous reporting of ADRs [4, 5, 11–17]. In our study the most serious problems affecting adverse reaction reporting, according to the doctors, has been the workload of usual clinical activities and lack of time for filling in records, lack of knowledge of the pharmacovigilance system in the hospital, uncertainty of the ADR diagnosis and the potential conflicts derived from reporting ADRs. These results are similar to other studies that have described, as major obstacles to adverse reaction reporting: the lack of time to report due to the workload of clinical activities [4, 5, 11, 14, 15], lack of information about the spontaneous reporting system [4, 12, 14, 15], the unavailability of yellow cards [11–13], uncertainty of ADR causality assessment [14–17] and lack of patient confidentiality [4, 12]. Nev-

ertheless, it is interesting to note that few studies have analysed the problems of spontaneous reporting in hospitals. In fact, only one study has specifically analysed the opinion of the doctors in Irish teaching hospitals based on a survey with a questionnaire [13]. This study identified, as the most important deterrent to reporting, the workload, the uncertainty of how to report, the unavailability of cards, and as major reasons for reporting the severity of ADRs, the implications of new drugs, and the confidence in a diagnosis or an unusual reaction. In other studies, which included doctors' opinions working in primary healthcare and in hospitals, the results have shown that hospital staff are less aware of the purposes of the spontaneous reporting system than their counterparts in general practice [4, 5]. Thus, poor reporting by hospital doctors is a major problem because only a third of reports come from hospital doctors, despite the fact that serious reactions are most likely to be seen in hospitals [6]. It is necessary to emphasize some wrong ideas related to the spontaneous reporting of ADRs that might be easily avoided with appropriate information. For example, many doctors believe that it is necessary to confirm an ADR, and they do not know that it is possible to report it, even though the ADR is only a suspicion.

Biriell and Edwards have explored the positive reasons for reporting ADRs from the point of view of 100 physicians and pharmacists [18]. The principal reasons suggested were the desire to contribute to medical knowledge, a previously unknown ADR, the reaction to new drugs, the evident association between drug and reaction, and the severity of the reaction. However, our study shows an important difference compared with this study, and other studies as well, because hospital doctors were asked about how to solve the obstacles identified for improving spontaneous reporting. A very interesting proposal by hospital doctors to improve reporting was closer contact between them and the pharmacovigilance centre and the feedback of pharmacovigilance activities, as another study has also already reported [18]. Various possibilities were suggested to improve this relationship, which could be through indirect contact by phone, which was also mentioned by a majority of physicians in another study [17], or by using the worldwide web, or more direct contact through periodic sessions of discussing clinical cases, and even visiting patients suspected of having an ADR. The principal implication of the changes suggested by the hospital doctors should be a more hands-on approach from the pharmacovigilance centre to form a closer relationship between hospital doctors and the experts in the pharmacovigilance centre. Experts in pharmacovigilance may be able to help doctors in their clinical activity when they suspect an ADR in particular cases and, furthermore, they can explain the general warnings identified by the system and doctors will probably understand the system better. The consequences might not only be a quantitative increase in the notified ADRs but also an improvement in quality, because there would be more reports of ADRs with new drugs, severe and unexpected. Implementing these measures would probably increase the workload for the pharmacovigilance centre, as well as also requiring an increase in the budget, but it might also increase the efficiency of the system.

The limitations of our study are related to the type of hospital (a large teaching hospital) where the doctors were working and the qualitative methodology that might determine external validity of the types of obstacles identified. However, the need to explore the obstacles to spontaneous reporting with a qualitative methodology has been emphasized because this methodology may be especially useful for the knowledge in imparts of opinions and attitudes and the identification of elements that might be improved in the system of spontaneous notification that leads to a major participation of professionals in the spontaneous reporting system [19]. The present study identifies several barriers and proposes different alternatives to overcome them, which is a first step, but future studies should evaluate the effectiveness of the different strategies proposed to improve spontaneous reporting in hospitals.

In conclusion, the perceptions of the different obstacles by hospital physicians is an important factor in underreporting ADRs and addressing these obstacles could lead to an improvement in spontaneous reporting. A closer relationship between doctors and the pharmacovigilance centre and the feedback of the pharmacovigilance activities in the hospital are suggested as ways of solving these problems. More information is needed to improve spontaneous reporting of adverse reactions in hospitals.

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