

Experiences with Adverse Drug Reaction Reporting by Patients

An 11-Country Survey

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Abstract

Background: Patients are important stakeholders in pharmacovigilance; however, little formal evaluation has been undertaken of existing patient reporting schemes within and outside Europe. If patient reporting is to be recognized as beneficial for pharmacovigilance and further optimized, methodology and best practice must be internationally shared and promoted.

Objective: This study aims to review the methods of patient reporting of adverse drug reactions (ADRs) in 11 countries worldwide and to compare different aspects of their experiences.

Methods: A survey based on telephone interviews, e-mail discussions and field visits of existing practices in consumer and patient reporting of ADRs was performed in the second half of 2010.

Results: The start dates of the patient reporting schemes vary from 1964 (Australia) to 2010 (Norway). The number of patient reports per country varies widely. Most countries would ideally spend more resources on making the public aware of the possibility that patients can report ADRs.

Most countries have three different ways for patients to report ADRs – a paper form, an electronic form on a website or by telephone. The level of sophistication of the electronic forms varies.

The route of handling of patients' and healthcare professionals' ADR reports is the same for most countries. Personalized feedback on the reported association for each report is only given by four organizations. All countries have guidelines for the identification of patients in the database and most undertake checks for duplicate reports. In all countries, with the exception of Norway, it is possible to ask patients for follow-up. None of the organizations seek medical confirmation for each patient report. There is a difference between countries that do a causality assessment for each incoming ADR report and countries that only do a causality assessment of reports when they

are looking at a potential signal. All countries assess the seriousness of reports, mostly by using the criteria of the CIOMS committee.

In all countries, patient reports are used for signal detection purposes and in publications about ADRs. The Netherlands and the UK are actively evaluating their patient reporting schemes. None of the organizations hired additional staff when they started with patient reporting.

Conclusions: This study provides a comprehensive review on the methods used in patient reporting of ADRs. Although there are some differences in the way various countries handle patient reports of ADRs, the importance of giving the public the opportunity to report and the additional scientific value of the collected data is widely recognized by the countries who participated in this survey.

Background

Existing pharmacovigilance systems and activities have proven to be useful in identifying patient safety issues,^[1] although there is scope for optimizing and improving their use.^[2,3] Allowing patients to report adverse drug reactions (ADRs) directly to the competent authorities is seen by the European Commission as a way to improve pharmacovigilance.^[4] The introduction of patient reporting in pharmacovigilance indicates a change in attitude in which the patient's experience is valued.^[5,6]

Patients have been allowed to report ADRs directly since the start of their pharmacovigilance schemes in a number of countries, for example in the US, Canada, Australia and New Zealand. More recently, there has been an increase in the number of countries who encourage patients to report ADRs,^[7] however, little formal evaluation has been undertaken of existing patient reporting schemes within and outside Europe.^[5-11]

There are also many countries that do not yet have schemes for direct patient reporting of ADRs. For Europe, the European Parliament legislative resolution of 22 September 2010 on pharmacovigilance of medicinal products for human use (Regulation [EC] No 726/2004) will allow patients to report drug concerns directly to the competent authorities.^[4,12,13]

The real benefits and place in pharmacovigilance of direct patient reporting of ADRs is still debated.^[3,6] However, experiences with patient re-

porting from different countries seem to be favourable.^[6] Studies on patient reporting indicate that new^[9,14] or different types^[8] of ADRs can be identified and described by patients themselves. Contrary to earlier concerns, the quality of patient reports is generally good,^[5,15] however, if patient reporting is to be recognized as beneficial for pharmacovigilance and is to be further optimized, methodology and best practice must be internationally shared and promoted. Comparative analysis between patient reporting schemes will help identify key methods for consumer reporting.

This study aims to review the methods of patient reporting of ADRs in 11 countries worldwide and to compare different aspects of their experiences.

This survey was performed as part of the 'Monitoring Medicines' project,^[16] which aims to optimize drug safety monitoring to enhance patient safety and achieve better health outcomes. The knowledge gained from this survey, as well as following projects, will be taken into account when developing a method and tool for patient reporting that aims at being applicable on a global scale for countries that do not have pharmacovigilance schemes for patient reporting yet.

Methods

A survey based on telephone interviews, discussions, field visits of existing consumer practices and patient reports of ADRs was performed.

Selection of Countries and Organizations

Countries in which specific systems for direct patient reporting of adverse reactions, or other drug-related problems, are operational were identified through a study of the published literature. A structured literature search was conducted using MEDLINE, using both MeSH terms and text search. Keywords used were 'consumer participation', 'adverse drug reaction reporting systems', 'patient reporting adverse drug reactions' and 'patient reporting pharmacovigilance'.

A MEDLINE filter was used to search publications from the last 10 years (from 3 August 2000 to 3 October 2010). Studies were included only when they contained data on spontaneous ADR reporting by patients. Studies of intensive monitoring, or other forms of monitoring where the patient does not report ADRs directly, were excluded.

We checked if known key publications were included with this search. Initial selection of publications was made on the basis of the title of the publication and keywords. Abstracts of the remaining identified studies were then assessed for relevance to the scope of the review ($n = 50$ in total). The full paper was obtained for each study being considered for inclusion in the review. The reference list of each paper was checked to identify any further relevant studies. No studies were excluded on the grounds of quality, and several review articles were included. We also searched the journals *Drug Safety and Pharmacoepidemiology* and *Drug Safety* for abstracts concerning patient reporting of ADRs from the International Society of Pharmacovigilance and International Society for Pharmacoepidemiology conferences from 2005 until 2010.

In addition, Internet searching (Google) and key contacts were used to identify further information on patient reporting of ADRs. In the English-language ADR newsletter that the Netherlands Pharmacovigilance Centre Lareb distributes worldwide through the web-based forum for those working at national centres in the WHO Programme (VigiMed),^[17] pharmacovigilance centres that collect patient reports were asked to respond and share their experiences.^[18]

The systems of five European and six non-European countries were then purposively selected

for detailed review. The selection was aimed at documenting differences in approaches and the impact of such differences. We aimed at presenting a review that was detailed enough to provide background information for an assessment of the benefits and disadvantages of various approaches to direct patient reporting. Selection was also based on a country's patient-reporting structure. Because more published information was found for European than non-European countries, not all EU countries who accept patient reporting were selected, to keep the review 'balanced'.

All organizations that were selected for the review accepted to participate in this study. The countries and organizations that were selected for this review and the methods of information collection per country are shown in table I.

Australia was the only country for which two organizations were included: the National Pharmacovigilance Centre [part of the Therapeutic Goods Administration (TGA)] and the Adverse Medicine Events (AME) Line.

Interviews

A structured interview guide (see Appendix 1, Supplemental Digital Content, <http://links.adis-online.com/DSZ/A58>) was used to obtain information from the selected organizations. The interview guide was divided into five main topics, namely:

- information about the organization in different countries;
- collection of ADR reports from patients;
- handling of patients' ADR reports;
- use of patient reports;
- pharmacovigilance centre's recommendations on patient reporting of ADRs.

All organizations were interviewed, either by telephone or in a face-to-face interview. The oral interviews lasted between 36 minutes and 1 hour and 50 minutes. For each interview, we asked permission to audio-tape the interview for transcription, with the exception of the interview with the US FDA, who provided their own transcription of the interview. Recordings were only used for this study. The FDA in the Philippines and the TGA in Australia were the only organizations to give written answers to the questions without

Table 1. The countries and organizations that were selected for this review and the methods of information collection per country

Country	Organization (website)	Method of information collection
Australia	Therapeutic Goods Administration [TGA] (http://www.tga.gov.au/) Adverse Medicines Events [AME] Line (http://www.mater.org.au/ame/)	E-mail correspondence Telephone interview, e-mail correspondence
Canada	Health Canada (http://www.hc-sc.gc.ca/index-eng.php)	Telephone interview, e-mail correspondence
Denmark	Danish Medicines Agency [DMA] (http://www.dkma.dk/)	Face-to-face interview, field visit
Netherlands	Netherlands Pharmacovigilance Centre Lareb (http://www.lareb.nl) ^a	Face-to-face interview, field visit
New Zealand	Centre for Adverse Reactions Monitoring [CARM] pharmacovigilance centre (http://carm.otago.ac.nz/start.asp)	Telephone interview, e-mail correspondence
Norway	Norwegian Medicines Agency (http://www.legemiddelverket.no)	Telephone interview, e-mail correspondence
Malaysia	Malaysian Adverse Drug Reactions Advisory Committee [MADRAC] (http://portal.bpfk.gov.my/)	Telephone interview, e-mail correspondence
Philippines	Food and Drug Administration (http://uhmis1.doh.gov.ph/adverse/revised_ADR_form_march_2011.pdf)	E-mail correspondence and the report 'Review of Consumer Reporting in Medicines Surveillance System – International experiences and the pilot implementation in the Philippines' (report on the evaluation of the pilot of patient reporting in the Philippines)
Sweden	Medical Products Agency (http://www.lakemedelsverket.se/)	Face-to-face interview, field visit
UK	Medicines and Healthcare products Regulatory Agency [MHRA] (http://www.mhra.gov.uk/)	Face-to-face interview, e-mail correspondence, field visit
US	US FDA (http://www.fda.gov/Safety/MedWatch/)	Telephone interview, e-mail correspondence

a Three of the authors are employed by the Netherlands Pharmacovigilance Centre Lareb.

WPRO = Western Pacific Regional Office.

a telephone or face-to face interview. The Philippines provided an evaluation of their pilot patient reporting project as background documentation (Philippines FDA, personal communication). In addition, field visits were conducted to obtain more detailed information about patient reporting schemes in the UK, Sweden, Denmark and the Netherlands. Interviews and field visits were conducted in the second half of 2010.

Data Analysis

Information from the transcribed interviews was categorized according to the questions in the interview guide. The cutting and pasting of the information was done manually. A preliminary report of the survey was sent to all participants for feedback, and the report was then revised and further condensed.

Results

The results are presented in different topics, as follows: information on the organization; collection

of ADR reports from patients; handling of patient ADR reports; utilization of patients' reports; and pharmacovigilance centres' recommendations on patient reporting of ADRs.

Information on the Organization

The pharmacovigilance centres operating a spontaneous ADR reporting system are generally part of the drug regulatory authority and are usually funded (partially) by user fees paid by the pharmaceutical industry or relevant government health department. The pharmacovigilance centres in the Netherlands and New Zealand are independent organizations that run the national spontaneous reporting system on behalf of the drug regulatory authority. In Australia, in addition to the TGA, the AME Line was interviewed. The AME Line is funded by the government through the National Prescribing Service and assists patients by collecting relevant information and passing this information on to the TGA.

All organizations collect reports from both patients and healthcare professionals. There are

only two pharmacovigilance centres that have a formalized agreement with other organizations to receive ADR reports forwarded by them – the Netherlands Pharmacovigilance Centre Lareb and the TGA in Australia.

Some pharmacovigilance centres accept reports about quality defects or medication errors; in other countries these are forwarded to separate organizations or departments.

Reports on unregistered products are accepted in most countries, but not all; Norway, for instance, accepts only reports on drugs that are registered in Norway.

Start of the Patient Reporting Schemes and Motives for Collecting Patient Reports

In table II, the start dates of the patient reporting schemes are listed for each country. Countries that started patient reporting more recently did this for reasons such as ‘empowerment of patients’, ‘taking patients seriously’, ‘EU initiatives’ or ‘partially solving the problem of underreporting’. For the Philippines and Malaysia a pilot programme with patient reporting was funded by the WHO and started in 2008 and 2007, respectively.

Number of Patient Reports in the Adverse Drug Reaction (ADR) Databases

Table II presents quantitative details about patient reporting for each country.

Promotion of the Reporting System

All organizations have a website with information about the reporting scheme for patients, with the exception of the Philippines. Other methods of making the public aware of the reporting scheme are flyers/leaflets or posters (distributed mostly through community pharmacies), television advertisements or targeting patients through patient organizations. There are some countries that have not actively promoted the patients’ reporting scheme, for example New Zealand and Sweden, because of a lack of resources relating to both public relations as well as for handling of the reports. Most countries would ideally spend more resources on making the public aware of patient ADR reporting schemes. In addition, campaigns aimed at reaching the general public have not

always been hugely successful and some organizations expressed that they believe the awareness of the public about their access to the reporting scheme is still low.

Collection of ADR Reports from Patients

Methods of Reporting

As shown in table III, most countries have three different ways for patients to report ADRs: a paper form (that can be sent by mail or faxed), an electronic form on a website or by telephone. Patients in the Netherlands, Denmark and Norway can only report electronically; electronic forms are not available in the Philippines and Malaysia. In Malaysia, consumers can report by e-mail if they prefer and there is a downloadable form available on the website.

Electronic Reporting Forms

As shown in table IV, all available electronic reporting forms allow patients to use free text in describing the reaction. Some forms have no mandatory fields and allow user-friendly patient reporting. In some countries, e.g. Norway, the UK and the Netherlands, the electronic forms are more sophisticated and allow checks for completeness and importation of data directly to a database. These forms are mostly based on an International Conference on Harmonisation E2B XML^[20] standard for exchanging information. Predefined lists of ADRs are generally not used in the reporting forms, with the exception of some forms used to report ADRs associated with pandemic influenza vaccines during 2009–10. Drop-down lists are also used in some electronic forms to help the patient choose the correct suspect and concomitant drugs; these drop-down lists are based on the country’s own drug dictionaries.

Differences in Reporting Forms

Most countries use different forms for patients and healthcare professionals, although the content of the forms is approximately the same. Some countries choose to have a more ‘open’ form for patients, with more free text, whereas other countries prefer a very structured patient reporting form.

Table II. Start of consumer reporting schemes and quantitative details about consumer reporting per country^{a,b}

Country	Start of consumer reporting schemes	Total number of reports	Number of consumer reports
Australia	1964 (AME Line since 2003)	TGA total: >240 000 2009: 13 298	TGA total: 6323 2009: 1307
Canada	1965	2009: 26 061	2009: 8428 (32.3% of total)
Denmark	July 2003	2009: 5000	2009: 1500
Netherlands	1 April 2003	2009: 9989 In 2009, 7138 additional reports were received on the swine flu vaccine	2009: 1566 In 2009, 5981 additional reports were received from consumers on the swine flu vaccine
New Zealand	1965	ND	1–2% of all reports in the database are from consumers
Norway	1 March 2010	ND	Until 11 July 2010: 115 30 consumer reports per month (14% of total)
Malaysia	The pilot was started in 2007	2005–10: 18 000 (not more than 10% came in through the pharmaceutical industry)	Since 2007, about 80 consumer reports were received in total
Philippines	The pilot was started in 2008	ND	21 reports were received during the 4-month pilot period from August–November 2008 From 27 October 2009–30 April 2010: 131 reports
Sweden	June 2008	Approximately 4000 healthcare professionals' reports per year 2009: 6000 reports due to the influenza vaccine	A few hundred reports until the influenza pandemic in 2009. As at the beginning of February 2010, more than 2000 reports
UK	2005	ND	To the end of 2009: 10 284 (excluding pandemic reports). 18% of ADR reports were submitted by patients ^[19]
US	1969	2009: 580 904 reports, of which 490 835 were entered in the FDA Adverse Event Reporting System database	2009: 272 989 (57%) In 2000, there were 46 249 reports submitted by consumers, increasing to 272 989 in 2009. ^a Since 2006, the FDA has received more reports from consumers than physicians and pharmacists, but less than the total reports submitted by all healthcare professionals

a Some countries do not make a distinction in their statistics between reports received directly by patients and healthcare professionals or reports received from these groups through the pharmaceutical industry. For countries such as Canada and the US, a large part of their patient reports are received through the pharmaceutical industry.

b For most countries, the overall number of (patient) reports for 2009 (and the first part of 2010) was exceptionally high, mostly due to reports about the new H1N1-influenza A (swine flu) vaccine.

AME = Adverse Medicine Events; **ND** = no data; **TGA** = Therapeutic Goods Administration.

Handling of Patient ADR Reports

As shown in table V, the route of handling of patients' and healthcare professionals' ADR reports is the same for most countries. All organizations code the ADRs before storing the reports in their database with either MedDRA[®]^[21] or WHO Adverse Reactions Terminology (WHO-ART) terminologies.^[22]

Table VI shows how patient and healthcare professionals' reports are shared with international databases.

Feedback

Personalized feedback on the reported association between the drug and reported ADR for each report is only given in the Netherlands,^[23] New Zealand^[24] and Malaysia, and in Australia by the AME Line (see table VII for details). The other countries only send a letter of confirmation upon receiving the report and/or information about what will happen to the report.

The Medicines and Healthcare products Regulatory Agency (MHRA) in the UK automatically

Table III. Method of adverse drug reaction report collection per country

Country	Telephone	Electronic forms	Paper forms
Australia	✓	✓	✓
Canada	✓	✓	✓
Denmark		✓	
Malaysia	✓		✓
Netherlands		✓	
New Zealand	✓	✓	✓
Norway		✓	
Philippines	✓		✓
Sweden		✓	✓
UK	✓	✓	✓
US	✓	✓	✓

✓ indicates method of reporting available.

generates an acknowledgement letter to all reporters that provides a unique reference number for the case, as well as links to Drug Analysis Prints^[25] on their website, and their electronic monthly bulletin, Drug Safety Update.^[26]

Identification of Patients in the Database, and Checks for Duplicate Reports

All countries need some basic information about the patient, drug and suspected ADR to be able to include the report in their database. In the EU, requirements for the basic information on patient identification are described in Volume 9A

guidance of the European Commission.^[27] Some of the organizations have made these required fields mandatory in the electronic reporting forms.

Several countries ask for the patients' contact details, such as addresses, telephone numbers or e-mail-addresses. This information can be used to contact the patient for follow-up information or to send them feedback. The information that is collected and stored in the database also depends upon privacy laws in the different countries; the Norwegian Medicines Agency has no way of contacting patients.

In all countries it is possible for non-healthcare professionals to report for others. For example, parents can report for their children and vice versa.

All countries, with the exception of Malaysia, have some kind of system for checking for duplicates. This can be an automated system upon entry of ADR reports in the database that checks certain characteristics of the reports (combined with manual checks), such as the system used at the Netherlands Pharmacovigilance Centre Lareb, or a manual check when reviewing potential signals, such as in the UK or Sweden. The US FDA uses a data mining algorithm to remove duplicates; there is no systematic way to identify duplicates at the point of entry. An algorithm is also used in Australia to check for duplicate reports.

Table IV. Specifications for electronic reporting forms^a

Country	Use of free-text in form	Mandatory fields in form	Forms automatically imported in database	Drop-down lists for selection of ADRs used in form	Drop-down list for selection of (co-) medication used
Australia (TGA)	Available	Available	Unknown	Not available	Not available
Australia (AME-Line)	Available	Not available	Not available	Not available	Not available
Canada	Available	Available	Not available	Not available	Not available
Denmark	Available	Available	Not available ^b	Not available	Available
Netherlands	Available	Available	Available	Not available	Available
New Zealand	Available	Not available	Not available	Not available	Not available
Norway	Available	Available	Available	Not available	Available
Sweden	Available	Available	Available	Not available	Not available
UK	Available	Available	Available	Available	Available
US	Available	Available	Unknown	Not available	Not available

a Electronic patient reporting forms were not available for Malaysia and the Philippines.

b At the time of the interview, the forms were not automatically imported in the database; in the new system that the Danish Medicines Agency uses, this will have changed.

ADRs = adverse drug reactions; **AME** = Adverse Medicines Events; **TGA** = Therapeutic Goods Administration.

Table V. Differences in the route of handling for patients' and healthcare professionals' reports

Country	Same route of handling	Different route of handling
Australia	✓ ^a	
Canada	✓	
Denmark	✓	
Malaysia	✓	
Netherlands	✓	
New Zealand	✓	
Norway		✓ ^b
Philippines		✓ ^c
Sweden		✓ ^d
UK	✓	
US	✓	

a In Australia, reports from the AME Line are forwarded to the Therapeutic Goods Administration where they are kept in the national database; from there the route of handling is the same. The AME Line keeps a record of the information they receive in their own database.

b Patients report directly to the Norwegian Medicines Agency through an electronic reporting form, while healthcare professionals report to regional centres on paper.

c The Philippines did not forward the patient reports they received during their pilot period to the national adverse drug reaction database.

d In Sweden, patient reports also come in directly to the Pharmacovigilance Department at the Medical Products Agency and are stored in the designated database (Kondis). The database used for healthcare professional reports (SWEDIS) is quite old, and at the start of the patient reporting scheme the Medical Products Agency chose not to add the patient reports to this database for technical reasons.

AME = Adverse Medicines Events; ✓ indicates whether route of handling was the same or different.

Follow-up Information and Medical Confirmation

In all countries it is possible to ask patients for follow-up, with the exception of Norway, where patients can contact the Norwegian Medicines Agency if they actively want to give follow-up information. In the UK, patients are specifically asked on the reporting form if they wish to be contacted for follow-up information. Also in the UK, patients can elect to have a copy of the ADR report sent to their GP or any other healthcare professional.

In all countries, with the exception of Norway, it is possible to ask the patient for permission to contact their healthcare professional. This can

either occur by having the patient fill in their healthcare professional's contact information on the reporting form and checking a consent box on the form confirming that they agree to this, or by contacting the patient later to ask for permission.

None of the organizations seek medical confirmation for each patient report. Mostly, healthcare professionals are only contacted in very serious cases or when the organization is looking into a potential new signal.

Causality Assessment and Seriousness of ADRs

There is a difference between countries that do a causality assessment for each incoming ADR report (the Netherlands, New Zealand, Malaysia and the Philippines) and countries that only do a causality assessment of reports when they are looking at a potential signal (Canada, the UK, Denmark, Sweden and the US). The TGA in Australia does a causality assessment for serious reactions. In Norway, only reports from healthcare professionals are assessed for causality (in the regional centres) and not the patient reports. The Naranjo algorithm^[28] and the causality assessment model of the WHO^[29] are most frequently used to assess causality.

Table VI. Sharing of reports with international databases

Country	WHO database		EudraVigilance database	
	consumer reports	HCP report	consumer reports	HCP reports
Australia	✓	✓		
Canada	✓	✓		
Denmark ^a	✓	✓	✓	✓
Malaysia	✓	✓		
Netherlands	✓	✓	✓	✓
New Zealand	✓	✓		
Norway ^a	✓	✓		✓
Philippines	✓	✓		
Sweden ^b		✓		✓
UK		✓		✓
US	✓	✓		

a Denmark and Norway share only serious reports with the EudraVigilance database.

b Sweden does not currently have an export function to share consumer reports with the WHO or EudraVigilance database.

HCP = healthcare professional; ✓ indicates sharing of reports with the database.

Table VII. Feedback given to patients and healthcare professionals

Country	Patients	Healthcare professionals	Feedback provided
Australia TGA			
Australia AME Line	✓		Information on the causality of a reported reaction and management of a suspected ADR via telephone, and, in some cases, further written information about the reported association, can be forwarded to the reporter
Canada			
Denmark			
Malaysia	✓	✓	Healthcare professionals receive a summary of any previous reports of the association sent to the National Pharmaceutical Control Bureau. Consumers receive information about the investigation into the report, including what the incidence rate is and if the adverse effect is usual or not
Netherlands	✓	✓	Personalized feedback about the reported drug-ADR association. Feedback typically consists of information about the ADR from the Summary of Product Characteristics, literature sources and information about previous reports in the Lareb database (latencies, drug withdrawal, outcome, causality). In addition, in some cases feedback includes information about the number of reports and disproportionality of an association in the WHO database
New Zealand	✓	✓	Feedback typically consists of the centre's causality assessment, the number of similar reports in New Zealand and/or the WHO, plus any other additional information such as at-risk groups and prevention issues that may be relevant or topical
Norway		✓	Personalized feedback on the reported drug-ADR association
Philippines			
Sweden			
UK			
US			

ADR=adverse drug reaction; **AME**=Adverse Medicines Events; **TGA**=Therapeutic Goods Administration; ✓ indicates answered 'yes'; feedback is given to patients and/or healthcare professionals.

All countries assess the seriousness of reports, mostly by using the criteria of the CIOMS committee.^[30] In the UK, the MHRA allocate an in-house classification known as 'dictionary serious' to individual preferred terms within the MedDRA[®] following assessment by medically qualified staff within the MHRA.^[10] Patients are asked some specific questions about the seriousness of their suspected ADR, which are not asked of healthcare professionals. The reporting form for patients also includes questions regarding the impact of the suspected ADR on daily life.

Utilization of Patient Reports

Using Patients' Reports for Signal Detection

In all countries, patient reports are used for signal detection purposes and in publications about ADRs. The Netherlands and the UK have published about their experiences with patient reporting and signal detection.^[31-33] In the UK,

patient reports have contributed to a number of safety signals including varenicline and aggression, scopolamine and visual hallucinations, and a food interaction between amlodipine and grapefruit juice.^[34] The Philippines have examples of issues they picked up with their limited number of patient reports, such as the discovery of counterfeit drugs (Philippines FDA, personal communication).

The use of patient reports in signal detection has been hindered in Sweden by the separate databases they use and the fact that they cannot easily make listings at the moment. Despite this, the Swedish Medical Products Agency has used patient reports, for example, in the signal evaluation in the case of a herbal product that caused liver problems.^[35]

Making Information from Patients' Reports Available

Most countries also publish information about the reports they receive on their website. For ex-

ample, the Netherlands Pharmacovigilance Centre Lareb has an online ADR database on their website and Canada provide some of the data from the Canada Vigilance database on their website.^[36,37] The UK MHRA does not have an online database but provides 'Drug Analysis Prints'^[25] on their website, which detail all spontaneous 'suspected' ADR reports received for a given drug substance in the UK.

Workload

None of the organizations hired additional staff when they started patient reporting. Patient reports can take more time to process, code and assess than healthcare professionals' reports but this does not necessarily have to be the case. The Netherlands and Norway only allow patients to report electronically and the reports are automatically imported into the database, saving the organizations time and ensuring completeness of data, which makes assessment easier. In the UK, the processing of patient reports takes the same amount of time as the healthcare professionals' reports. Patients do write a little more on average^[10] but is not a problem for the online reports, which are also automatically imported into the database.

There is no special training for the assessment of patient reports other than the 'normal' pharmacovigilance training that staff receive at the organizations that were interviewed. Some organizations, such as the Netherlands Pharmacovigilance Centre Lareb, do a 'triage' with incoming reports so that the reports that adhere to certain criteria (for example, serious reports, high-signal value, suspect drug is a New Chemical Entity) are assessed by 'senior' assessors.

Pitfalls with Patient Reporting

None of the countries that were interviewed have experienced major pitfalls with patient reporting. Litigation is not an issue for most countries. Canada and the US have experience with patient reports being completed by lawyers but this was not mentioned as a major issue. In addition, the AME Line has some experience with reports driven by litigation in patients using the drug zolpidem.^[38] Almost all countries have experi-

ence with increased reporting after media attention about safety issues or after the new influenza A (H1N1) vaccination campaign in 2009/2010. Increased reporting after media attention is not always seen as negative as it also increases awareness of the reporting scheme to the public.

Pharmacovigilance Centres' Recommendations on Patient Reporting of ADRs

Table VIII provides the main recommendations on patient reporting of ADRs expressed by the pharmacovigilance centres in this study.

Discussion

A report on collective experiences in Europe published in 2010 suggested that patient reporting provides many benefits for pharmacovigilance, including involvement of the patient in their treatment.^[7] This survey provides detailed information about the patient reporting schemes in pharmacovigilance centres in 11 countries worldwide and gives insight into the way patient reports are handled and used by pharmacovigilance centres.

Value of Patients' Reports in Signal Detection

Almost all countries in this review used patient reports in addition to reports from healthcare professionals for their signal detection strategies. Comparisons of patients' and healthcare professionals' reports from Denmark,^[8] the Netherlands^[9,31] and the UK^[32,33] found that patients can provide a valuable contribution to signal detection. In the Netherlands, the proportion of patient reports contributing to generate signals was equal to the proportion of patient reports in the database. Apparently the presence of patient reports did not hamper the selection of signals in the Netherlands.^[31] In the UK, combining patients and healthcare professionals' reports generated more potential signals than healthcare professionals' reports alone. Some potential signals in the dataset with only healthcare professionals' reports were lost when patient reports were added, but fewer than those gained. The addition of patient reports to the dataset identi-

fied 47 new 'serious' reactions not previously included in the Summary of Product Characteristics.^[11,32,33] The impact of consumer reports on signal detection in the database of a pharmaceutical company was determined by Hammond et al.^[39] using a disproportionality analysis. It was concluded from this study that adverse event reports submitted by consumers can help significantly in the early detection of safety signals.

The fact that not all countries share their patient reports with the WHO and/or the EudraVigilance database has the consequence that these reports are not taken into account if these databases are used for signal detection purposes.

Public Awareness of Patient Reporting Schemes

The awareness that patients can report ADRs is still thought to be low in most countries. For example, the majority of patients in the UK are unaware that they are able to report ADRs.^[19,40]

Engaging the public in pharmacovigilance is seen as an important issue by the participants in this review. However, patient reporting is not actively promoted in all countries where a reporting scheme for patients is in place, mainly because the organizations are lacking resources to organize large publicity campaigns and/or to handle a large number of reports in addition to healthcare professional reports.

Furthermore, not all patients in the various countries may have the same general knowledge about their medication and ADRs that may influence how active they are with reporting. In a study from Malaysia, community pharmacists were not aware of the direct patient reporting scheme and were sceptical about its success. Lack of awareness and patients' limited knowledge about their medications were viewed as barriers to patient reporting.^[41] In a recent UK study, 10.5% of respondents who had previously reported an ADR to the MHRA suggested that greater publicity and promotion of the reporting scheme by healthcare professionals, plus wider availability and accessibility of the reporting forms, were required.^[42] Another study from the UK discussed that patient opinions of the pharma-

covigilance centre, their expectations of what will happen to the information in their report and how these expectations are handled are of great interest in sustaining patient interest in reporting, given that the motivation to report is primarily altruistic.^[43] An emphasis on the benefits of reporters to other medicine users could be used to further motivate reporting from other patients.^[43] The use of social media as a way to increase spontaneous reporting has recently been discussed;^[44,45] however, this method may also have its disadvantages.^[44] Using multiple media for disseminating information about a reporting scheme seems important to reach a wide audience.^[19]

Practical Experiences

There are some differences between pharmacovigilance centres in the way (patient) reports are handled. For instance in the UK, the MHRA have tried to incorporate the impact on daily life into their patient reporting form by asking "How bad was the suspected side effect".^[46] Most other countries only asked patients if the reaction led to one of regulatory authority's criteria for seriousness. Regulatory or medical seriousness may differ from patients' views on what constitutes a serious problem.^[47]

Also in the UK, a copy of the patient's ADR report can be sent to the patient's general practitioner or any other healthcare professional if the patient enters their contact details. This practice is not used by most other pharmacovigilance centres.

There are only a limited number of countries who provide personalized feedback to patients. The desire for personalized feedback from patient reporters in the UK was high in a study on patients' views and experiences of making ADR reports to the MHRA.^[28] Almost one-third of all respondents to the study expected feedback from the MHRA and more than 60% would have liked feedback.^[42] In a study from the Netherlands, 44.8% of patients who reported did so because they wanted some kind of additional information from the pharmacovigilance centre.^[23]

There is experience in some countries with reducing workload for pharmacovigilance centres by using structured, electronic reporting forms

Table VIII. Recommendations on patient adverse drug reaction (ADR) reporting per pharmacovigilance centre

Country	General recommendations	Practical recommendations	Promotion of the system
Australia	Consumer reports provide a valuable addition to the data available for the monitoring of medicines safety, and should be encouraged. The TGA feels that a consumer is just as capable as a healthcare professional of providing information about a drug and a suspected reaction to that drug. It is the role of the pharmacovigilance experts within national monitoring centres to interpret these data and to code the data in the national database in a uniform way		
Canada	Information from consumers can be different from healthcare professionals. The programme looks at the information received, not the source		
Denmark			Better marketing. Maybe there is a tendency to underestimate the need of the public for this new opportunity. Proactively, citizens should be given the skills to report, maybe through dialogue with patient organizations. Patient organizations could be a partner advocating for patient reporting
Malaysia		Having an electronic form for consumer reporting would also be a way of making consumers report more easily	You have to promote well your consumer reporting system, and think of the best way to reach the audience. Lack of funding can be a difficulty here
Netherlands	The past years of experience with patient reporting have taught us that patient reports contribute substantially to the reporting of ADRs, both in quantity and quality. Reports from users of drugs are generally well documented reports with valuable information. The different point of view from patients compared with healthcare professionals is an interesting starting point for obtaining valuable information	Working with an electronic patient reporting form based on an E2B format is feasible and has certain advantages; it is not time consuming, basic information has to be filled in by using mandatory fields and the form is automatically imported into the database. In this way, a lot of reports can be quickly processed with limited staff	
New Zealand	Consumer reports complement the pharmacovigilance database in addition to healthcare professionals' reports		
Norway		The Norwegian Medicines Agency has taken a lot of effort to reduce the amount of handling for individual reports. They think this is important because human resources demand money and even in rich countries money must be prioritized right. It is important to make a system that is simple to handle	

Continued next page

Table VIII. Contd

Country	General recommendations	Practical recommendations	Promotion of the system
Philippines		<p>Also, it is important to look to international standards such as E2B and universal designs of forms, especially if you are designing an electronic reporting form</p> <p>A comprehensive reporting form should be used</p> <p>The consumer should be encouraged to submit the report directly to the pharmacovigilance centre by post, hotline or online. The report should be available on the pharmacovigilance centre's website for download, and online submission might be facilitated through the website</p> <p>On receipt of the reports, providing an acknowledgement letter to consumers can help engage them by assuring them that the proper action will be taken to investigate the reports and showing them the value of each report</p>	Increasing public awareness is the most important factor for the successful and sustainable operation of an ADR reporting programme
Sweden	Before you start with a new consumer reporting scheme you have to think of what your goals will be and how are you going to use the system	<p>You should check what other countries are doing, for example in the EU, and what the legal requirements are for the system</p> <p>It is really important to have a good reporting form and to work with a good coding system for the cases</p> <p>Think about the structure of your database and how you are going to do signal detection with the reports</p>	
UK		<p>It makes sense to have a joint system for patients' and healthcare professionals' reports with the same database. It is important to define how you want to analyze patients' reports for signal detection, e.g. together with the healthcare professionals' reports</p> <p>You really have to make sure that your reporting forms are piloted before you make them available for patients to make sure that they are user-friendly</p>	
US	Consumers offer a unique perspective and their reports should be part of any ongoing evaluation of the safety of marketed products. The US FDA feels this is an important policy that allows consumers to have a voice in making sure that products are safe and to minimize risks and injury		

TGA = Therapeutic Goods Administration.

and database adaptations, such as automatically importing reporting forms, having automated checks for duplicate reports, having automated

signal detection systems/data mining, etc. Obviously not all countries have the same resources for development of these systems.

Making the information/reporting forms user-friendly and comprehensible can be challenging but a number of organizations have tried to improve this, for instance by field-testing reporting forms.^[48] Patients who reported ADRs in the UK found this (fairly) easy to do.^[42] However, usability testing of the reporting methods revealed some issues with the online reporting form.^[48]

A number of pharmacovigilance centres give information aimed at patients on their website. Importantly, the active involvement of patients and their organizations throughout the process when setting up patient reporting systems is vital in order to create a well functioning and easy-to-use patient reporting system.

No major pitfalls with patient reporting were mentioned by the participating pharmacovigilance centres.

Evaluation of Patient Reporting Schemes

Although over the past few years more organizations have shared their experiences with patient reporting of ADRs through publications/abstracts, for example the Netherlands,^[9,15,23,31,49-51] the UK,^[10,11,32-34,42,43,48,52-54] Denmark,^[8] Sweden,^[55] the US^[56] and the AME Line in Australia,^[38,57] only a limited number of countries have been actively evaluating their patient reporting scheme. Sharing information between organizations is still important to optimize the current systems. In light of the recent European Parliament legislative resolution of 22 September 2010 on pharmacovigilance of medicinal products for human use (Regulation [EC] No 1235/2010)^[12] the need for information about, and evaluation of, patient reporting schemes seems evident.

Strengths and Limitations

The countries participating in the study were mainly identified in the published literature. A limitation of this study is that other countries where patient reporting is permitted remain unidentified. Also, a purposive selection was made of the countries who allow patients to report adverse reactions. As a result, a limited number of countries and organizations were interviewed, which affects the generalizability of the findings,

especially for lower income countries who permit patients to report.^[58]

Conclusions

This article provides a comprehensive review on the methods used in patient reporting of ADRs. Although there are some differences in the way various countries handle patient reports of ADRs, the importance of giving the public the possibility of reporting and the additional scientific value of the collected data is widely recognized by the countries who participated in this review.

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