PILOT STUDY ABOUT HOSPITAL PHARMACY RESIDENTS' PERCEPTION OF PHARMACOVIGILANCE IN BELGIUM, FRANCE, CANADA AND SWITZERLAND

Léna Cerruti[1], Denis Lebel[2], Thierry Van Hees[3], Olivier Bourdon[4], Pascal Bonnabry[5], Anne Spinewine[6], Jean-Daniel Hecq[6], Jean-François Bussières[2,7]

[1]Pharmacy Practice Research Unit, CHU Sainte-Justine, Montreal, Quebec, Canada; [2]CHU Sainte-Justine, Montreal, Quebec, Canada; [3]Liège University Hospital and University of Liège, Liège, Belgium; [4]Hôpital Robert Debré, Assistance Publique des Hôpitaux de Paris and Faculté de Pharmacie, Université Paris Descartes, Paris, France; [5]Geneva University Hospitals and University of Geneva, University of Lausanne, Lausanne, Switzerland; [6]CHU Dinant-Godinne and Université catholique de Louvain, Louvain, Belgium; [7]Faculté de pharmacie, Université de Montréal, Montreal, Quebec, Canada

Corresponding Author: Jf.bussieres@ssss.gouv.qc.ca

ABSTRACT

Background
Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions (ADRs). Although pharmacovigilance is a responsibility for all healthcare professionals, this activity is an important part of a pharmacist's practice. Hospital pharmacy residents are expected to have the necessary skills to monitor, manage, report and prevent ADRs as a part of their academic curriculum. Assessing and comparing perceptions of pharmacovigilance of hospital pharmacy residents from four different countries can contribute to a reflection about their education and their role in pharmacovigilance.

Objectives
To assess and compare the perception of pharmacovigilance of hospital pharmacy residents from Belgium, France, Canada and Switzerland.

Methods
A cross-sectional study was conducted in March 2014 using an online-questionnaire administrated to 229 hospital pharmacy residents. Nineteen questions were organized into five sections: demographic data, pharmacovigilance education and practice, attitudes toward reporting adverse drug reactions, obstacles to reporting ADRs and measures to improve ADRs reporting rate.

Results
Unlike the French residents, most of the other respondents believed that they had received an adequate pharmacovigilance education. The main obstacles to ADR reporting were similar: lack of experience and concern about overwork. The same measures concerning the development of pharmacovigilance were identified. Hospital residents expected local measures for a closer pharmacovigilance.

Conclusions
These observations lead us to think that standardizing and changing hospital pharmacy residents' education and good practices in clinical pharmacovigilance are required to optimize patient care.

Key Words: *Adverse drug reactions; adverse drug reaction reporting; pharmacovigilance; hospital pharmacy resident; perception*

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions (ADRs).[1] Although not exclusive to a health-care profession in particular, this activity is an important part of a pharmacist's practice, as defined by the applicable laws of each country. While there are some differences about pharmacists' scope of practice between countries (e.g. relative weight given to pharmaceutical activities, right to prescribe, decentralization of pharmacists at the bedside, collaborative practices), all pharmacists are involved in the drug-use process and it does include pharmacovigilance activities.[2] Hospital pharmacy residents are expected to have the necessary skills to monitor, manage, report and prevent ADRs as a part of their academic curriculum. Few studies have been conducted to evaluate pharmacy students' knowledge of and attitudes toward reporting ADRs.[3-8] However, to our knowledge, no study has investigated hospital pharmacy residents' perception of pharmacovigilance from different countries. The aim of this pilot study was to assess and compare hospital pharmacy residents' perception of pharmacovigilance from four French-speaking countries: Belgium, France, Canada and Switzerland.

METHODS

This was a cross-sectional descriptive study.

Questionnaire Design

A total of 25 variables were identified through a review of the literature,[3-8] 16 of which were selected after a consensus from the investigators. A questionnaire with 17 closed questions and two open questions, organized into five sections, was developed including demographic data (2 questions), pharmacovigilance education and practice (7 questions), attitudes toward reporting ADRs (7 questions), obstacles to reporting ADRs (one question) and measures to improve ADRs reporting rate (2 questions).

As regards to the respondents' satisfaction with their pharmacovigilance education, we used a four-level Likert scale (strongly agree, partially agree, partially disagree and totally disagree). To assess the hospital pharmacy residents' practice of pharmacovigilance, we questioned them about internships. Internships directly linked to pharmacovigilance were defined by the responsibility of reporting ADRs within a care unit or by an internship with a regulatory authority (e.g., pharmacovigilance center or authority responsible for pharmacovigilance nationally). To assess the hospital pharmacy residents' exposure to patients, we used a multiple-choice question with a single answer: fewer than 10 patients, from 10 to 50 patients, 51 to 100 patients, 101 to 500 patients and more than 500 patients. To assess the hospital pharmacy residents' exposure to ADRs and ADR reporting to the regulatory authorities, we used two multiple-choice questions with a single answer: 0 ADR, 1 ADR, 2 to 4 ADRs, 5 to 8 ADRs, 9 to 16 ADRs, 17 to 32 ADRs, and more than 32 ADRs. As regards the factors that can influence the hospital pharmacy residents' reporting of ADRs, we proposed 10 factors concerning ADRs and we used a two-level scale: encouraging factors vs. discouraging factors. To identify the parties that received ADR reports from the hospital pharmacy residents, we used a multiple-choice question with multiple answers: a more experienced colleague, a pharmacovigilance team/coordinator, a regulatory authority, and a pharmaceutical company. As regards to the information access about ADRs, we proposed eight sources of information and we used a five-level frequency scale: often, sometimes, seldom, never and unknown. To identify obstacles to reporting ADRs according to the hospital pharmacy residents, we proposed 12 possible obstacles and we used a four-level importance scale: very high importance, high importance, low importance and none. To identify the measures that could increase the number of ADR reports, we proposed 14 measures and used a four-level scale of importance: very high importance, high importance, low importance and none.

The study was conducted using an online questionnaire published on SurveyMonkey® (https://www.surveymonkey.com/, SurveyMonkey®, Portland, Oregon). In order to validate the questionnaire, five hospital pharmacy residents pre-tested it manually and at least one hospital pharmacist from each country was asked

to evaluate the relevance, clarity, and conciseness of the items included in the questionnaire. The observations and comments were taken into account when developing the final version of the questionnaire. The participants were clearly informed of the aim of the study and of the authors' intention to publish the aggregate results per country by means of an explanatory email (a copy of the email and the survey instrument is available from the author upon request). Participation in the study constituted each respondent's informed consent.

Sample

A convenience sample was established by asking each country's hospital pharmacist to contact the cohorts of hospital pharmacy residents of their university. A link to the online questionnaire and an explanatory letter were emailed in March 2014 to 229 hospital pharmacy residents from four French-speaking countries: French-speaking Belgium (n = 55), France (n = 96), French-speaking Canada/Quebec (n = 67) and French-speaking Switzerland (n = 11). We emailed a reminder to potential respondents a few weeks later. We closed the survey in April 2014.

Analysis of the Answers to the Questionnaire

The questionnaire and processing of the responses remained strictly anonymous. We only analysed complete answers. The results were presented in the form of descriptive data with frequencies and percentages. Data analysis was performed using PASW Statistics 17 (IBM, Armonk, New York). The proportion of respondents for each dimension was compared using a Chi-square test. An alpha level of 5% was use for significance ($p \leq 0.05$).

RESULTS

Of the 229 hospital pharmacy residents, 123 completed the questionnaire for a 54% response rate: 41 out of 55 Belgian residents (1^{st} to3^{rd} year of residency), 39 out of 96 French residents (1^{st} to 4^{th} year of residency), 34 out of 67 Quebec residents (1^{st} year of residency) and 9 out of 11 Swiss residents (1^{st} to 3^{rd} year of residency). The duration of the hospital pharmacy residency program varied according to country. A total of 95 out of 123 (77%) respondents were female, without any significant difference among the different countries ($p = 0.270$).

Only 11 out of 122 (9%) respondents received complementary pharmacovigilance education (e.g., Master's, university degree, congress): 5 Belgian residents, 4 French residents, one Quebec resident and one Swiss resident. The Swiss (6 out of 9, 67%) and French residents (8 out of 39, 21%) did significantly ($p < 0.001$) more internships directly linked to pharmacovigilance than did the Belgian (3 out of 41, 7%) and Quebec residents (1 out of 34, 3%).

Unlike the French residents, most of the other respondents believed that they had received an adequate education in order to analyze ADR events, assess causal relationship between a drug and an adverse reaction, manage ADR and ensure the prevention of ADRs in patients. During their curriculum, 24 out out of 34 (71%) Quebec, 5 out of 9 (56%) Swiss, 21 out of 41 (51%) Belgian and 11 out of 39 (28%) French residents considered that the topic of pharmacovigilance was well-covered. Table 1 shows the profile of hospital pharmacy residents' satisfaction with their pharmacovigilance education.

TABLE 1 Profile of hospital pharmacy residents' satisfaction with their pharmacovigilance education

	Proportion of respondents either strongly agreed or partially agreed with the statement (%)					
I have received an adequate education to	**Belgium (n=41)**	**France (n=39)**	**Quebec (n=34)**	**Switzerland (n=9)**	**p-value**	**All countries (n=123)**
Identify and assess the seriousness of a possible drug-induced adverse reaction.	78%	61%*	85%	89%	0.061	75%**
Analyze the occurrence of a possible drug-induced adverse reaction.	71%	51%	82%	78%	0.032	68%
Assess the potential causal relationship between an adverse reaction and a drug.	78%	56%	85%	78%	0.033	73%
Adopt a position on whether to continue or discontinue a drug.	46%	26%	71%	78%	<0.001	49%
Report an adverse drug reaction to regulatory authority.	83%	72%	79%	89%	0.547	79%
Ensure the prevention of adverse drug reactions in patients.	76%	62%	91%	67%	0.032	75%

*n=38, **n=122

TABLE 2 Comparison of hospital pharmacy residents' exposure to patients, pharmacovigilance internship and adverse drug reactions reporting to the regulatory authorities

	0 report	**1 to 4 reports**	**5 or more reports**	**p-value**
Exposure to ≤ 10 patients	3 (23%)	8 (62%)	2 (15%)	0.716
Exposure to 11 to 100 patients	12 (35%)	17 (50%)	5 (15%)	
Exposure to > 100 patients	22 (29%)	36 (47%)	18 (24%)	
Did not do a pharmacovigilance internship	34 (32%)	53 (51%)	18 (17%)	0.084
Did a pharmacovigilance internship	3 (17%)	8 (44%)	7 (39%)	

Since the beginning of their pharmacy education, 76 out of 123 (62%) respondents were exposed to 101 or more patients (respectively, 30 out of 34 Quebec, 23 out of 39 French, 21 out of 41 Belgian and 2 out of 9 Swiss respondents, $p < 0.001$) versus 34 out of 123 (28%) respondents were exposed to 11 to 100 patients and 13 out of 123 (11%) respondents were exposed to 10 patients or less. Since the beginning of their pharmacy education, 86 out of 123 (70%) respondents faced 5 or more ADRs (respectively, 32 out of 34 Quebec, 27 out of 39 French, 5 out of 9 Swiss and 22 out of 41 Belgian respondents, $p = 0.001$) versus 31 out of 123 (25%) respondents faced 1 to 4 ADRs and 6 out of 123 (5%) respondents didn't face any ADRs. Since the beginning of their pharmacy education, 25 out of 123 (20%) respondents reported 5 or more ADRs to regulatory authority (respectively, 4 out of 9 Swiss, 11 out of 34 Quebec, 8 out of 39 French and 2 out of 41 Belgian respondents, $p = 0.006$) versus 61 out of 123 (50%) respondents reported 1 to 4 ADRs to regulatory authority and 37 out of 123 (30%) respondents did not report any ADRs, 6 of whom didn't face any ADRs. Table 2 shows the comparison of hospital pharmacy residents' exposure to patients, pharmacovigilance internship and ADR reporting to the regulatory authorities. All the respondents considered that ADR reporting was part of their work.

One hundred and seventeen out of 123 (95%) respondents considered that ADR reporting contributed to the development of scientific knowledge. One hundred and seventeen out of 122 (96%) respondents considered that ADR reporting contributed to the improvement of the care quality given to the patients. Table 3 shows the profile of the factors that could influence ADR reporting by the hospital pharmacy residents.

TABLE 3 Profile of the factors that could influence adverse drug reaction reporting by the hospital pharmacy residents

	Proportion of respondents (%)					
Encouraging factors	**Belgium (n=41)**	**France (n=39)**	**Quebec (n=34)**	**Switzerland (n=9)**	**p-value**	**All countries (n=123)**
Severe adverse drug reaction	100%	100%	100%	100%		100%
Adverse drug reaction that appears quickly after drug-exposure	98%	97%	97%	100%	0.967	98%
Visible adverse drug reaction (e.g., skin reaction)	98%	95%	94%**	89%	0.712	95%***
Unexpected adverse drug reaction	85%	87%	85%	78%	0.915	85%
Known adverse drug reaction	24%	29%*	9%	11%	0.146	20%***
Adverse drug reaction due to an old drug	27%	34%*	32%	22%	0.836	30%***
Adverse drug reaction due to a new drug	100%	100%*	100%	100%		100%***
Adverse drug reaction causality is not certain	10%	8%	6%	11%	0.921	8%
Difficulty to exclude other non-drug related causes	15%	13%*	6%	11%	0.669	11%***

*n=38, **n=33, ***n=122

Table 4 shows the profile of who received ADR reports from the hospital pharmacy residents. The procedures for reporting ADRs differed according to country. Respondents who reported at least one ADR did so to one or more parties.

To obtain information on ADRs, the sources often or sometimes consulted by the respondents were: the drug monograph (120 out of 123 respondents, 98%), a more experienced colleague (105 out of 123 respondents, 85%), and biomedical literature search engines like Pubmed® (101 out of 122 respondents, 83%). A more significant proportion of the French (29 out of 39, 74%) and Belgian (28 out of 41, 68%) respondents, contrary to the Quebec (16 out of 34, 47%) and Swiss (3 out of 9, 33%) respondents, considered the drug monograph to be a reliable source of information ($p = 0.023$). The pharmaceutical companies were often or sometimes consulted by only 43 out of 123 (35%) respondents. The pharmacovigilance centers were significantly more consulted by the Swiss (4 out of 9, 44%) and French (12 out of 38, 32%) respondents than by the Quebec (5 out of 34, 15%) and Belgian (4 out of 40, 10%) respondents. The non-specific databanks (e.g., Micromedex®) were significantly more consulted by the Quebec (34 out of 34, 100%), Belgian (34 out of 41, 83%) and Swiss (7 out of 9, 78%) respondents than by the French (12 out of 38, 32%) respondents ($p < 0.001$). The specific databanks (e.g., Livertox®,

Toxnet®, Pneumotox®) were significantly more consulted by the Swiss (6 out of 9, 67%) respondents than by the Quebec (9 out of 34, 27%), French (5 out of 38, 13%) and Belgian (4 out of 41, 10%) respondents (p = 0.001). The reference works (e.g., Martindale®, Meyler's®) were significantly more consulted by the Swiss (7 out of 9, 78%) and Belgian (26 out of 41, 63%) respondents than by the Quebec (8 out of 34, 24%) and French (7 out of 37, 19%) respondents (p = 0.001). Table 5 shows the profile of the obstacles to ADR reporting according to the hospital pharmacy residents. Lastly, Table 6 shows in decreasing order of importance the measures that could increase the number of ADR reports according to the hospital pharmacy residents.

TABLE 4 Profile of recipients of adverse drug reaction reports from the hospital pharmacy residents

	Proportion of respondents (%)					
Recipient	**Belgium (n=41)**	**France (n=39)**	**Quebec (n=34)**	**Switzerland (n=9)**	**p-value**	**All countries (n=123)**
More experienced colleague	59%	33%	41%	11%	0.025	42%
Pharmacovigilance center/coordinator	7%	36%	6%	11%	0.001	16%
Regulatory authority	27%	54%	97%	55%	<0.001	57%
Pharmaceutical company	12%	13%*	12%	0%	0.737	11%

N=35

TABLE 5 Profile of the obstacles to adverse drug reaction reporting according to the hospital pharmacy residents

	Proportion of respondents n(%)					
Obstacles of very high/high importance	**Belgium (n=41)**	**France (n=39)**	**Quebec (n=34)**	**Switzerland (n=9)**	**p-value**	**All countries (n=123)**
Extra work due to adverse drug reaction reporting	44%	36%	68%	33%	0.035	47%
Insufficient clinical knowledge	56%	68%**	18%	56%	<0.001	49%****
Difficulty to determinate the cause of the observed reaction	85%	72%	65%	78%	0.213	75%
Insufficient experience and wish to observe further similar cases	56%	46%	44%	44%	0.717	49%
Unfamiliarity with adverse drug reaction reporting criteria	30%*	38%	38%	44%	0.782	36%****
Unfamiliarity with aims and usefulness of adverse drug reaction reporting	12%	26%	36%***	44%	0.055	25%****
Limited interest in pharmacovigilance	20%	10%	41%	44%	0.008	24%

*N=40, **n=38, ***n=33, ****n=122

TABLE 6 Measures that could increase the number of adverse drug reaction reports according to the hospital pharmacy residents

Measure of very high/high importance	Proportion of respondents All countries (n=123) n(%)
Presence of a clinical pharmacist in the care unit	117 (95%)
Support of a pharmacovigilance coordinator within the hospital (e.g., reporting to the regulatory authority, publishing report cases)	115 (93%)
Regular rounds by a pharmacovigilance team member to gather adverse drug reaction within care units	107 (87%)
Feedback after adverse drug reaction reporting	107 (87%)
Improvement of academic pharmacovigilance education	106 (86%)
Periodical multidisciplinary meetings to discuss about observed adverse drug reactions	105 (85%)
Adoption of adverse drug reactions targets to be reported per care unit	101 (82%)
Improved awareness of adverse drug reaction reporting	99 (80%)
Means of communication with a pharmacovigilance team	97 (79%)
Dissemination of pharmacovigilance alerts from national and international authorities	97 (79%)
Support for a multidisciplinary regional center of pharmacovigilance (e.g., reporting to the regulatory authority, publishing report cases)	94 (76%)
Analysis by a pharmacovigilance team of adverse reaction signals	93 (76%)
Periodic summary of adverse drug reactions reported to the regulatory authority	89 (72%)
Financial compensation to professionals involved in adverse drug reactions reporting	53 (43%)

DISCUSSION

Pharmacovigilance systems

The pharmacovigilance systems in Belgium, France, Canada/Quebec and Switzerland are based on spontaneous reporting of ADRs by healthcare professionals and patients to regional or national pharmacovigilance centers.[9-12] In Belgium, France and Switzerland, these regional or national centers assess ADR reports and sometimes send a brief comment to ADR reporters.[9-11] In Canada/Quebec, a pharmacovigilance coordinator can be assigned locally to each hospital center's pharmacy department in Quebec to assess ADR reports before sending them to Health Canada regional pharmacovigilance centers.[13] In all of the countries, ADR reports are entered into a national database to detect risks and feed the international database of the World Health Organization.[14] These regional or national centers sometimes send a brief comment to ADR reporters.[9-11] While the pharmacovigilance systems of the four countries differ in terms of organization, ADR reporting criteria and objectives remain the same.

Similarities and differences in pharmacovigilance perception

To our knowledge, this is the first study to compare perceptions of pharmacovigilance by hospital pharmacy residents in Belgium, France, Canada/Quebec and Switzerland. Our literature review allowed us to identify only four other studies that were similar, one on undergraduate pharmacy students in Malaysia[5], one on undergraduate pharmacy students in India[8] and two others on American pharmacy students.[6,7]

Our study highlighted three points of similarity and three points of difference among the respondents from each country. As regards to the similarities, the hospital pharmacy residents in Belgium, France, Canada/Quebec and Switzerland undertook the same searching steps to get information about ADRs. The factors that encouraged hospital pharmacy residents to report ADRs were similar and the respondents wrongly thought that a causal link had to be established for ADR reporting. The main obstacles to ADR reporting were similar: lack of experience (difficulty in determining whether the observed reaction was disease or drug related, insufficient experience and a wish to observe more similar cases) and concern about overwork. Ambiguities existed regarding the reporting process in the mind of a certain number of hospital pharmacy residents: unfamiliarity with reporting criteria was an obstacle to reporting and the uncertain relation between the drug and the adverse reaction was a factor that discouraged their reporting ADRs. The same expectation and measures concerning the development of pharmacovigilance were identified by the respondents from the four countries. The expressed wish for closer pharmacovigilance entails local measures: the presence of clinical pharmacists in care units and a pharmacovigilance team or coordinator within the institution as well as the necessity for discussion and communication. The differences concern pharmacovigilance education and practice, attitudes facing ADRs and certain obstacles to reporting ADRs.

The curriculum of Belgian, French, Canada/Quebec and Swiss hospital pharmacy residents is different. In fact, the Belgians deal with theoretical concepts of pharmacovigilance during their Master's in pharmacy. Then they receive specific pharmacovigilance education during their Master's in Hospital Pharmacy. Their hospital pharmacy residency is 3-year long. There is no practical education specifically devoted to pharmacovigilance, but candidates must often have the opportunity to report during their clinical pharmacy internship. The French deal with theoretical pharmacovigilance concepts during their 6 years of university without any specifically dedicated courses. Internships in pharmacovigilance centers and specific courses on pharmacovigilance during complementary education are proposed as part of 4 years of hospital pharmacy residency. Quebecers deal with theoretical pharmacovigilance concepts as part of their Bachelor's/new Doctorate's program in Pharmacy or Master's in Pharmaceutical Practice without any specifically dedicated courses. Reporting ADRs must be done as part of their education in the fourth year internship. Subsequently, reporting is done during a yearlong residency in clinical pharmacy when needed. The Swiss deal with theoretical pharmacovigilance concepts in their pre-graduate curriculum. Then the majority of residents do an internship in a pharmacovigilance center during their 3-year long residency in hospital pharmacy. The hospital pharmacy residents' levels of satisfaction differ according to country. In spite of the opportunity of pharmacovigilance internship, the French seem less satisfied with their pharmacovigilance education. In addition, only the French consider for the most part that the importance given to pharmacovigilance education is insufficient. Opinions on the development of pharmacovigilance education within the academic curriculum remain divided for the Belgians and Swiss. In the study by Gavaza et al., a majority of pharmacy students considered to have inadequate knowledge about reporting serious ADRs.[6] In the study by Elkalmi et al., students were asked whether they believed that, with their current knowledge, they were well-prepared to report any ADR in their future practice. Slightly more than one-third (37%) of the students either strongly agreed or agreed with this statement.[5] Only one-third of the respondents either strongly agreed or agreed that the topic of pharmacovigilance was well-covered in their pharmacy school curriculum.[5]

During their residency, direct exposure to patients was more important for Canada/Quebec, French and Belgian respondents than it was for Swiss respondents. It follows that confronting ADRs is more important in the three countries than it is in Switzerland. Paradoxically, the Swiss were the ones who reported proportionally more ADRs to regulatory authority than did the others.

They were probably more aware of the

need to report ADR to regulatory authorities through their quasi-systematic internship in pharmacovigilance centers. Exposure to patients was not influencing reporting rates but doing a pharmacovigilance internship during residency seemed to encourage residents to report an ADR (the difference between the two groups in table 2 was important even if it wasn't statistically significant). The Belgians were the ones who reported proportionally fewer ADRs to regulatory authority than did the others. However, they tended to declare them to more experienced colleagues. To obtain information on ADRs, the French were few in number when it came to consulting non-specific databases (e.g., Micromedex®). It is possible that the answer to this question was influenced by the lack of appropriate examples used in each country. The Swiss and French were the ones who consulted pharmacovigilance teams the most, likely due to their pharmacovigilance internship, the regional presence of pharmacovigilance centers, feedback after ADRs reporting as well as the hospital procedures that reinforced reporting by all the actors. The Swiss were the ones who consulted the most specific sources of information such as specific databases and reference works, probably due to their pharmacovigilance internship and the ease with which they could access reference works.

Among the obstacles to ADR reporting, insufficient clinical data did not constitute a large or very large obstacle for Quebecers. This can be explained by the more significant presence of hospital pharmacy residents in departments in Quebec. Their interest in pharmacovigilance is significantly different: the Quebecers and Swiss considered this point to be a large or very large obstacle to ADR reporting unlike the Belgians and French.

Our study led us to identify certain possible changes in the education of hospital pharmacy residents. First of all, an initial introduction to the common concept of pharmacovigilance and specific courses should be systematically proposed early in their curriculum. In fact, an English study showed that little time is devoted to teaching pharmacovigilance.[15] In the study by Elkalmi et al., half of students either agreed or strongly agreed that the pharmacovigilance concept should be included as a core topic in pharmacy education.[5] Introducing and incorporating adverse event reporting early in the curriculum would ensure that pharmacy students become aware and benefit from an understanding of the basics of adverse event reporting.[7] In addition, the French Academy of Medicine is now asking that specific pharmacovigilance education be set up according to pharmacological classes for all future healthcare professionals (e.g., students in medicine, pharmacy and dental surgery).[16] More significant exposure to ADRs and field experience through clinical internships could help raise hospital pharmacy residents' awareness of pharmacovigilance. During clinical internships, residents are closest to patients and work with department staff (nurses and physicians). They are then more easily aware of patients' ADRs and have access to all the information they need to report ADRs. An American study and an Iranian study showed that the involvement of pharmacy students in the ADR reporting system had a positive impact on the number of documented ADRs.[17,18] The development of specific pharmacovigilance skills could comprise specific courses and especially an internship on a pharmacovigilance team.

As for the organization of pharmacovigilance, implementing actions aimed at bringing pharmacovigilance closer to healthcare professionals seems to be the wish of the hospital pharmacists surveyed. In fact, communication and the concept of discussing with healthcare professionals seem to be of the utmost importance. Therefore, dedicating appropriate resources is at the same time a challenge and an opportunity for pharmacy departments to ensure drug use safety.

Limits

Our study has limitations. The convenience samples from each country were of different sizes. It is possible that only individuals more interested in pharmacovigilance answered the questionnaire. This is a pilot study and the findings cannot be generalized to all hospital pharmacy residents in each country.

Acknowledgments

The authors thank the hospital pharmacy residents for their participation. Authors declare no funding or conflict of interest for the realization of this work.

REFERENCES

1. World Health Organization. The safety of medicines in public health programmes: Pharmacovigilance an essential tool. http://www.who.int/medicines/areas/quality_safety/safety_efficacy/Pharmacovigilance_B.pdf (October 21, 2014).
2. Van Grootheest K, Olsson Sten, Couper M, et al. Pharmacist's role in reporting adverse drug reaction in international perspective. Pharmacoepidemiol Drug Saf 2004;13:457-64.
3. Vallano A, Cereza G, Pedros C, et al. Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital. Br J Clin Pharmacol 2005;60(6):653.
4. Nichols V, Thériault-Dubé I, Touzin J, et al. Risk Perception and Reasons for Noncompliance in Pharmacovigilance: a Qualitative Study Conducted in Canada. Drug Saf 2009;32(7):579-90.
5. Elkalmi RM, Hassali MA, Ibrahim MI, Widodo RT, Efan QM, Hadi MA. Pharmacy Students' Knowledge and Perceptions About Pharmacovigilance in Malaysian Public Universities. Am J Pharm Educ 2011 Jun 10;75(5):96.
6. Gavaza P, Bihn B. Pharmacy Students' Attitudes Toward Reporting Serious Adverse Drug Events. Am J Pharm Educ 2012;76(10):194.
7. Kalari S, Dormarunno M, Zvenigorodsky O, Mohan A. Pharmacy Student Perceptions of Adverse Event Reporting. Am J Pharm Educ 2011;75(7):131.
8. Sharma S, Sharma J, Aggarwal T. A survey on knowledge and perception of pharmacy students towards adverse drug reaction (ADR) reporting. Asian Journal of Pharmaceutical and Clinical Research 2012;5(3):129-31.
9. Federal agency for medicines and health products. Belgian Centre for Pharmacovigilance. http://www.fagg-afmps.be/en/human_use/medicines/medicines/pharmacovigilance/bcph/ (September 10, 2014).
10. Agence nationale de sécurité du médicament et des produits de santé. Organisation de la pharmacovigilance nationale. http://ansm.sante.fr/Declarer-un-effet-indesirable/Pharmacovigilance/Organisation-de-la-pharmacovigilance-nationale/(offset)/0 (September 10, 2014).
11. Swiss Agency for Therapeutic Products. Pharmacovigilance. https://www.swissmedic.ch/marktueberwachung/00135/00160/index.html?lang=en (September 10, 2014).
12. Health Canada. Canada Vigilance Program.http://www.hc-sc.gc.ca/dhp-mps/medeff/vigilance-eng.php (September 10, 2014).
13. Bussières JF, Blond M, Lebel D. Intégration de la pharmacovigilance à la pratique clinique. Journal de Pharmacie Clinique 2006;25(2):1-8.
14. The Uppsala monitoring centre, World Health Organization. Vigibase. http://www.who-umc.org/DynPage.aspx?id=98082&mn1=7347&mn2=7252&mn3=7322&mn4=7326 (October 15, 2014).
15. Smith MP, Webley SD. Pharmacovigilance teaching in UK undergraduate pharmacy programmes. Pharmacoepidemiol Drug Saf 2013;22(3):223-8.
16. Académie nationale de médecine française. Montastruc JL, Tillement JP. Pharmacovigilance: actualités et perspectives. (November 20, 2012). http://www.academie-medecine.fr/wp-content/uploads/2013/07/pharmacovigilanceVERSION-11.pdf (September 18, 2014).
17. Sullivan KM, Spooner LM. Adverse-drug-reaction reporting by pharmacy students in a teaching hospital. Am J Health-Syst Pharm 2008;65(12):1177-9.
18. 18. Baniasadi S, Habibi M, Haghgoo R, et al. Increasing the Number of Adverse Drug Reactions Reporting: the Role of Clinical Pharmacy Residents. Iran J Pharm Res 2014;13(1):291-7.