

Introduction

- The success of drug safety surveillance relies on an efficient pharmacovigilance system.
- The Canada Vigilance Program was established in 1965 and is based on spontaneous adverse drug reaction reporting by health professionals and consumers. Reports are collected by the regional offices before being forwarded to the Canada Vigilance National Office for further analysis. Reports are entered into a national database to detect risks and feed the international database of the World Health Organization.
- Drug safety surveillance is a responsibility for all healthcare professionals. Hospital pharmacists and hospital pharmacy residents should play an important role.

Purpose

To evaluate perceptions and practices towards adverse drug reaction reporting among hospital pharmacists and hospital pharmacy residents.

Methods

- Cross-sectional study conducted in April 2014 using a questionnaire.
- Initial draft was developed from a literature review then pilot-tested by five students and reviewed by pharmacists. Observations and comments were taken into account when developing the final version of the questionnaire.
- 16 questions organized in 5 sections: demographics, pharmacovigilance training and practices, obstacles to adverse drug reaction reporting, measures to improve adverse drug reporting.
- The web self-administered questionnaire was sent by email to 67 hospital pharmacy residents and 63 pharmacy directors of hospital with at least 50 acute care beds in Quebec. Pharmacy directors were invited to respond and relay the email to at least three pharmacists per hospital (n=252).
- The questionnaire and processing of the responses remained strictly anonymous.

Results

- 213 respondents (response rate 67%): 179/252 hospital pharmacists and 34/67 hospital pharmacy residents.
- 166/212 (78%) of female pharmacists and 98/213 (46%) of respondents having 11 years or more of practice experience.
- 118/213 (55%) of the respondents considered that the topic of pharmacovigilance was well-covered during their undergrad pharmacy curriculum nevertheless 45/213 (21 %) of respondents had completed some pharmacovigilance additional training.

Table I: Ability of respondents to practice pharmacovigilance

Statements	Proportion of respondents either strongly agreed or partially agreed n/N (%)
I am able to analyze the occurrence of a possible adverse drug reaction.	199/213 (93%)
I am able to assess the potential causal relationship between an adverse reaction and a drug.	195/213 (92%)
I am able to identify and assess the seriousness of a possible adverse drug reaction.	194/213 (91%)
I am able to ensure the prevention of adverse drug reactions in patients.	193/213 (91%)
I am able to adopt a position on whether to continue or discontinue a drug.	192/213 (90%)
I am able to report an adverse drug reaction to Health Canada.	189/213 (89%)

Most of the respondents considered that adverse drug reaction reporting:

- was part of their work (203/212, 96%),
- contributed to the development of scientific knowledge (208/212, 98%),
- contributed to the improvement of the care quality given to the patients (203/212, 96%).

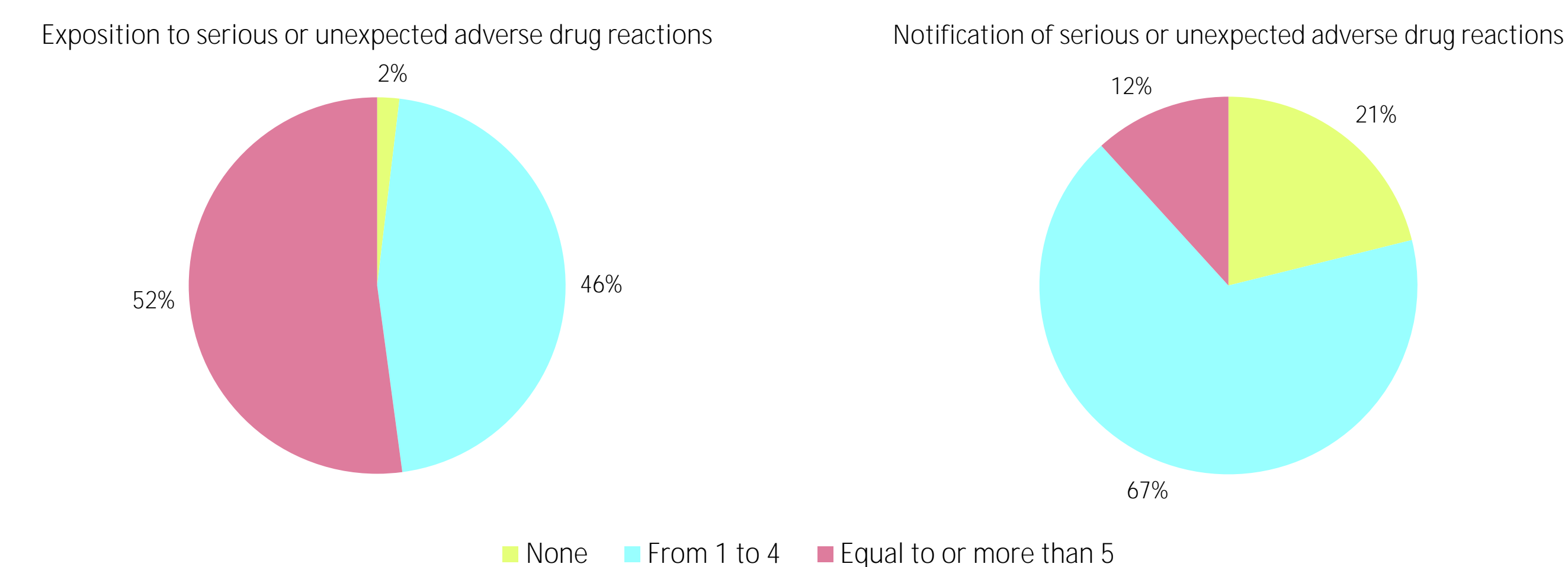


Figure 1: Respondents' exposition to and notification of serious or unexpected adverse drug reactions per year

Respondents, who notified at least one adverse drug reaction, did it to one or more recipient(s):

- 134/168 (80%) to Health Canada,
- 53/168 (32%) to a more experienced colleague,
- 53/168 (32%) to a pharmaceutical company,
- and 28/168 (16%) to a pharmacovigilance team or drug therapy committee responsible of the notification to Health Canada.

Table II: Sources of information about adverse drug reactions often consulted by the respondents

Sources of information about adverse drug reactions	n/N (%)
Evidence-based databases (e.g. Micromedex®)	187/213 (88%)
Bibliographic databases (e.g. Pubmed®)	159/212 (75%)
Drug monographs	133/211 (63%)
More experienced colleagues	81/211 (38%)
References (e.g. Martindale®, Meyler's®)	29/211 (14%)
Pharmaceutical companies	22/210 (10%)
Specific databases (e.g. Livertox®, Toxnet®, Pneumotox®)	16/211 (8%)
Pharmacovigilance team	12/207 (6%)

Only 90/212 (42%) of the respondents considered the drug monograph as being a reliable source of information.

Table III: Top 5 reasons for reporting or not reporting adverse drug reactions

Reasons for reporting	n/N (%)
Serious reaction	213/213 (100%)
Quick apparition of the reaction after drug exposure	206/211 (98%)
Reaction due to a recent drug	206/213 (97%)
Visible reaction (cutaneous > renal)	187/202 (93%)
Unexpected reaction	189/213 (89%)
Reasons for not reporting	n/N (%)
Concern that an adverse drug reaction report will generate extra work	146/213 (69%)
Difficulty in determining whether the observed adverse reaction was disease or drug related	86/213 (40%)
Insufficient experience and wish to observe further similar cases	82/211 (39%)
Unfamiliarity with adverse drug reaction reporting criteria	57/213 (27%)
Limited interest in pharmacovigilance	46/212 (22%)

Table IV: Measures that could improve adverse drug reaction reporting

Measures	Number of favorable respondents n/N(%)
Support of a pharmacovigilance coordinator within the hospital (e.g. documentation, reporting to the Health Canada, and help in publishing report cases)	188/212 (89%)
Presence of a clinical pharmacist in the care unit	180/212 (85%)
Regular rounds by a pharmacovigilance team member to gather adverse drug reaction within care units	174/212 (82%)
Feedback after adverse drug reaction reporting	174/212 (82%)
Periodical multidisciplinary meetings to discuss the cases of adverse drug reactions	170/212 (80%)
Improvement of academic pharmacovigilance education	170/212 (80%)
Adoption of adverse drug reactions targets to be reported per care unit	167/212 (79%)
Support for a multidisciplinary regional center of pharmacovigilance	166/212 (78%)
Analysis by the pharmacovigilance team of adverse reaction signals	160/212 (75%)
Dissemination of pharmacovigilance alerts from national and international authorities	157/212 (74%)
Means of communicating that facilitate contact with the pharmacovigilance team	156/212 (74%)
Periodical summary of adverse drug reactions reported to Health Canada	151/212 (71%)
Improved awareness of adverse drug reaction reporting (e.g. posters/notices, periodical reminders)	126/212 (59%)
Financial compensation to professionals involved in adverse drug reaction reporting	87/212 (41%)

Conclusions

- This study reveals a lack of training in pharmacovigilance but a willingness of hospital pharmacists and pharmacy residents to contribute to drug safety surveillance activities.
- Even though hospital pharmacists and pharmacy residents are exposed to a large number of serious or unexpected adverse drug reactions, underreporting remains a critical issue to resolve.
- A better understanding of perceptions and practices towards adverse drug reaction reporting can help identify measures to improve drug safety surveillance. According to respondents, interaction of a pharmacovigilance team 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.