Evaluation of the rate of compliance with good pharmacovigilance reporting practices 12 months after their adoption

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Background

- In response to the legislative changes introduced by Vanessa's law regarding the reporting of adverse drug reactions (ADRs) in Canada, Quebec pharmacy department heads have adopted by a Delphi method good pharmacovigilance reporting practices[1] (GPRPs).

Purpose

To evaluate the rate of compliance with GPRPs 12 months after their adoption.

Methods

- Descriptive transversal study.
- GPRPs have 37 statements.
- GRPRs compliance of each pharmacy department was evaluated from a measurement scale (compliant, partially compliant, and non-compliant).
- An online survey was conducted in October 2019 with a member of the pharmacovigilance community of practice from each of the 30 hospital pharmacy departments of Quebec.
- Compliance was reported in proportion of respondents by compliance threshold and by criterion.

Results

30 respondents responded to the survey (100% response rate)

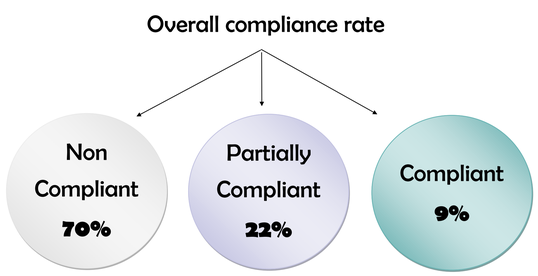

Table 1. Rate of compliance with GPRPs 12 months after their adoption

Good practices	n/N (%)		
	Non-compliant	Partially compliant	Compliant
1.1 All ADRs must be documented in the patient's file by at least one healthcare professional responsible for the patient.	8/30 (27)	21/30 (70)	1/30 (3)
1.2 Any serious ADR resulting from regular care or an incident/accident must be reported to Health Canada.	10/30 (33)	19/30 (63)	1/30 (3)
1.3 An ADR identified after the patient's discharge from hospital should be documented in the patient's file.	19/30 (63)	11/30 (37)	0/30 (0)
1.4 Serious ADR must be documented on the summary sheet within the patient record at the end of the hospital stay.	8/30 (27)	20/30 (67)	2/30 (7)
1.5 All ADR reports to Health Canada must be documented in the patient's file.	13/30 (43)	13/30 (43)	4/30 (13)
1.6 Each patient with a suspected ADR must be informed of the ADR.	7/30 (23)	19/30 (63)	4/30 (13)
1.7 Each pharmacy department must appoint a pharmacovigilance coordinator.	20/30 (67)	2/30 (7)	8/30 (27)
1.8 The pharmacovigilance coordinator must hold a university degree in the field of health sciences.	21/30 (70)	1/30 (3)	8/30 (27)
1.9 The pharmacovigilance coordinator should be informed of any ADR reported to Health Canada by a healthcare professional.	22/29* (76)	5/29* (17)	2/29* (7)
1.10 A ratio of 1 FTE/1000 beds should be allocated to the pharmacovigilance coordinator.	25/30 (83)	3/30 (10)	2/30 (7)
1.11 On each patient care unit, a healthcare professional (e.g., pharmacist, physician, or nurse) trained in pharmacovigilance should be designated as a resource person, for liaison with the pharmacovigilance coordinator.	25/30 (83)	3/30 (10)	2/30 (7)
1.12 The pharmacovigilance coordinator should conduct periodic rounds in all care units and should meet at least one healthcare professional on each floor to discuss ADRs.	28/30 (93)	2/30 (7)	0/30 (0)
2.1 The pharmacovigilance committee must report to the pharmacology and therapeutics committee of the hospital.	19/30 (63)	8/30 (27)	3/30 (10)
2.2 The pharmacovigilance committee should be composed of at least one pharmacovigilance coordinator, a designed pharmacist, and one representative from each key sector of the hospital, as defined in the hospital's mission statement.	22/30 (73)	6/30 (20)	2/30 (7)
2.3 The pharmacovigilance committee should meet at least four times per year to review any ADRs that have been reported, determine whether there is a need to disseminate information, change practices, and promote ADR reporting.	26/30 (87)	4/30 (13)	0/30 (0)
2.4 Information about pharmacovigilance and ADRs should be disseminated at least 4 times per year to all healthcare professionals in the facility.	24/30 (80)	5/30 (17)	1/30 (3)
3.1 All ADRs managed by the pharmacovigilance coordinator must be recorded in a local database maintained by the pharmacy department, for management and statistical purposes.	23/30 (77)	4/30 (13)	3/30 (10)
3.2 The local database must be able of compiling activity and reports by period.	20/30 (67)	4/30 (13)	6/30 (20)
3.3 The local database must generate reports that can be sent to Health Canada.	23/30 (77)	2/30 (7)	5/30 (17)
3.4 An national ADR database supported by the pharmacovigilance coordinator should be shared between the pharmacy departments.	26/30 (87)	2/30 (7)	2/30 (7)
3.5 ADRs that do not result from an incident/accident (medication error) may be reported on the Incident Reporting Form.	15/29* (52)	10/29* (34)	4/29* (14)
4.1 The pharmacovigilance coordinator must complete sufficient and standardized	22/29* (76)	4/29* (14)	3/29* (10)
4.2 Basic pharmacovigilance training must be offered to pharmacists and healthcare professionals at the time of hiring.	27/30 (90)	2/30 (7)	1/30 (3)
4.3 The Order of Pharmacists of Quebec should require that, of the 20 mandatory hours of professional development per year, at least 1 hour be devoted specifically to pharmacovigilance.	0/30 (0)	0/30 (0)	0/30 (0)
4.4 Basic pharmacovigilance training should be available in online self-learning formats.	25/28** (90)	3/28** (11)	0/28** (0)
4.5 To encourage ADR reporting by hospital pharmacists, hospitals may set up a regular fun activity or event.	24/30 (80)	4/30 (13)	2/30 (7)
5.1 A procedure and a checklist must be available, detailing the ADR characteristics to be reported and explaining the best way to complete the report form.	18/30 (60)	8/30 (27)	4/30 (13)
5.2 The hospital's website must include a pharmacovigilance page containing: contact information of the pharmacovigilance coordinator, a link to the ADR reporting form, a link to the reporting procedure, monthly pharmacovigilance reports, published case reports, and links to relevant databases.	23/30 (77)	6/30 (20)	1/30 (3)
5.3 All pharmacists in the department must be registered to receive Health Canada Advisories, Warnings, and Recalls and Health Canada's Health Product Info Watch Newsletter.	6/30 (20)	20/30 (67)	4/30 (13)
6.1 The pharmacovigilance coordinator should review, at least monthly, ADR records compiled by the medical records department from patients' files and summary sheets.	28/30 (93)	1/30 (3)	1/30 (3)
6.2 An analysis of discrepancies between ADRs reported to Health Canada and those coded by medical records personnel should be conducted periodically.	27/29* (93)	1/29* (3)	1/29* (3)
6.3 A list of drugs and drug combinations with a known risk of ADRs must be established and updated by the pharmacovigilance committee.	27/30 (90)	0/30 (0)	3/30 (10)
6.4 Tools for detecting the prescription of drugs at high risk for ADRs must be in place.	27/30 (90)	3/30 (10)	0/30 (0)
6.5 Each ADR reported to Health Canada may be assessed using the Naranjo or Koh and Li probability scale.	20/30 (67)	4/30 (13)	6/30 (20)
6.6 To encourage best practice, a target ADR reporting rate (per 100 beds) should be identified.	27/30 (90)	1/30 (3)	2/30 (7)
6.7 The pharmacovigilance program must be reassessed every year.	24/30 (80)	5/30 (17)	1/30 (3)
6.8 The pharmacovigilance coordinator must provide feedback to the professionals involved in identifying and managing ADRs.	24/29* (83)	3/29* (10)	2/29* (7)
6.9 A dedicated section of the pharmacy record must include suspected ADRs for each patient.	25/30 (83)	2/30 (7)	3/30 (10)
6.10 Any serious or unexpected ADR may be published as a case report by hospital professionals involved in managing the ADR.	17/29* (59)	8/29* (28)	4/29* (14)
6.11 Healthcare professionals must be aware of the their hospital's obligation to report to Health Canada any serious ADR occurring in any inpatient or outpatient.	7/30 (23)	18/30 (60)	5/30 (17)
6.12 The pharmacovigilance coordinator for each facility should be present at local meetings of the regional pharmacy services committee, to relay relevant pharmacovigilance data between the community and hospital settings.	28/30 (93)	2/30 (7)	0/30 (0)

* Although all members responded (n = 30), one respondent only provided qualitative responses without answering the questions related to the score so N = 29; ** N = 28

Conclusion

- Twelve months after adoption, the compliance rate for GPRPs is still low, but a majority of respondents are in action to implement these good practices and to comply with Health Canada's new reporting requirements.

1. Rault P, Mégrourèche É, Labarre JS, Pettersen-Coulombe F, Lebel D, Bussières JF. Determination of good pharmacovigilance reporting practices in Quebec hospital pharmacies using a modified Delphi method. Pharmacoepidemiol Drug Saf. 2019;28(7):985-992. doi:10.1002/pds.4840

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