Canadian Psychiatric Association
Association des psychiatres du Canada

Enhancing Patient Safety: New Reporting Requirements for all Hospital-Based Physicians

Abstract

Background

Vanessa's Law requires all hospitals in Canada to report all serious Adverse Drug Reactions and Medical Device Incidents to Health Canada within 30 days of the initial discovery. Psychiatrists working in hospital settings need to be aware of their reporting requirements. This new legislation is expected to make care safer for Canadians regarding licensed medical devices and prescribed medications.[1]

Catalyst for Better Reporting

Vanessa Young was 15 years old when she passed away in 2000. She suffered a cardiac arrhythmia and arrest after taking cisapride (Prepulsid®) as prescribed for upper gastrointestinal symptoms complicated by bulimia.

At the time, Health Canada had some knowledge of side effects linked to cisapride and had written letters to inform physicians across Canada.[2] A World Health Organization study raised concerns regarding cisapride as early as 1992. Moreover, in July 1996, a quarterly Health Canada publication reported that "serious ventricular arrhythmias" had been observed in some patients taking cisparide who had pre-existing heart problems or risk factors for arrhythmia.[3] Despite this, the drug remained available for use and continued to be prescribed by physicians.

Prepulsid® was withdrawn from the U.S. market on March 23, 2000, and from the Canadian market on May 31, 2000. Since August 7, 2000, Prepulsid® has not been available in Canada. At the time of withdrawal, Health Canada had received 44 reports of potential heart rhythm abnormalities, including 10 deaths associated with the drug. In the United States, Prepulsid® had been associated with 341 serious adverse reactions and at least 80 deaths.[4]

Vanessa's death led to a coroner's inquest. Vanessa's father investigated similar situations involving licensed drugs and began advocating for increased regulation of therapeutic products. This propelled Health Canada's requests that hospitals and industry suppliers submit safety data about drugs and medical devices. The federal government passed the ***Protecting Canadians from Unsafe Drugs Act*** (*'Vanessa's Law'*) in June 2014, following consultation with professionals, organizations, and agencies.

Vanessa's Law represents a major change in Canadian drug regulation. Currently, only manufacturers are required to submit ADRs to Health Canada, but studies show that this reporting comprises only a fraction of actual ADRs occurring across Canada.[5] Health Canada anticipates that

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[1] *Ibid* at p. 5.
[2] Risk: Making Medicine Safer for All of Us, *Sudden Cardiac Death: Vanessa's Story* (April 11, 2013) [cited 29 Nov 2019]. Available at https://rxisk.org/sudden-cardiac-death-vanessas-story/.
[3] *Ibid*.
[4] *Ibid*.
[5] Thomas J. Moore et al, *Time to Act on Drug Safety*, Journal of the American Medical Association (1998), Vol. 279 No. 19, pp. 1571-1573.

the new legislation will result in more timely and comprehensive reporting. Health Canada in turn will be better positioned to recall drugs from the market where evidence suggests unacceptable patient safety risks.[6]

Literature Regarding Drug Safety and Respective Reporting

While rare or serious ADRs may take time to discover, such discoveries depend on adequate reporting processes. Monitoring drug safety is increasingly important as major risks associated with drugs, including death, augment. Vioxx and, most recently, Zantac are among some of the most high-profile drug safety withdrawals. A systematic review published in 2006 by Hazell and Shakir confirmed widespread and significant underreporting of ADRs across hospitals and general practices.[7] Underreporting ranged from 82% to as high as 98%. A 2012 Lexchin review analysing drug related safety issues over a 16-year period found that, in 1 out of 5 drugs, safety issues were not detected or understood at the approval stage. The study further found that just under 25% of drugs introduced between 1995 and 2010 had any serious safety issues.

What are Hospitals Doing to Prepare?

In early 2019, Health Canada notified hospitals of the new legislation and the anticipated timeframe for implementation. Health Canada has partnered with the Canadian Patient Safety Institute and Accreditation Canada to develop education modules for hospitals. Throughout 2019, hospitals across Canada have been establishing processes for internal identification, reporting, and routing of ADRs and MDIs to Health Canada. Given the variation across institutions in patient information and safety reporting systems, each hospital will have unique procedures and support for reporting. Accordingly, psychiatrists working in hospitals must ensure they are aware of the reporting process for each hospital in which they work. Indeed, timely and comprehensive reporting depends on physicians identifying and reporting ADRs and MDIs within their respective institutions.

What is an Adverse Drug Reaction (ADR)?

Vanessa's Law defines an ADR as a harmful and unintended response to a drug that occurs at any dose and:

- Requires in-patient hospitalization or prolonged pre-existing hospital stay;
- Causes congenital malformation;
- Results in persistent or significant disability or incapacity;
- Is life-threatening; or
- Results in death.[8]

Examples of incidents in psychiatric medicine that likely should be reported would include:

- Antipsychotic medication induced constipation resulting in small bowel obstruction
- Antidepressant induced hyponatremia resulting in fall and hospitalization
- Major bleed with a patient on SSRI

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[6] Government of Canada, Protecting Canadians from Unsafe Drugs Act (Vanessa's Law): questions/answers. Ottawa (ON): 2014 Oct 31 [cited 2019 Nov 29]. Available at https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/questions-answers-regarding-law-protecting-canadians-unsafe-drugs-act-vanessa-law.html.

[7] Lorna Hazell and Saad A.W. Shakir, *Under-Reporting of Adverse Drug Reactions: A Systematic Review*, Drug Safety (May 2006) Vol. 29, Issue 5, pp. 385–396.

[8] Health Canada *supra* note 3 at p. 3.

Examples of situations in psychiatric medicine that would likely not require reporting include:

- Mood stabilizer / antipsychotic medication induced neutropenia without medical compromise
- Antipsychotic induced acute dystonic reaction that resolves with outpatient treatment
- Clozapine induced constipation which is minor and managed successfully with laxative
- Rash with lamotrigine that resolves with no consequences after drug withdrawal as outpatient

What is a Medical Device Incident (MDI)?

An MDI is any incident related to a failure or reduced effectiveness of a medical device, or any insufficiency in labeling or directions for use that has or could, if it happened again, lead to the death or a serious deterioration in the health of a patient, user, or other person.[9]

Examples of incidents in psychiatric medicine that should likely be reported include:

- Electroconvulsive therapy (ECT) resulting in asystole and transfer to medicine
- ECT treatment resulting in prolonged seizure and prolonged admission

Examples of situations in psychiatric medicine that likely do not require reporting include:

- rTMS treatment resulting in minor pain at application site
- Arrhythmia during ECT which spontaneously resolves
- An infusion pump stopped due to a malfunction but failed to give an alarm. The patient received an under-infusion of antibiotics, septic shock occurred and prolonged the patient's stay in the hospital's intensive care unit.

Hospital physicians must also report additional details such as concurrent medications which may have contributed to the event.[10] While not mandatory, less serious adverse events can be voluntarily reported to Health Canada as usual.[11] It is anticipated that implementation of the requirements of *Vanessa's Law* will prompt a learning curve. Over time, enhanced reporting of serious and/or life-threatening adverse events will improve the healthcare industry's understanding of treatment risk profiles.

Conclusion

Improving reporting of ADRs and MDIs will contribute to enhancing patient safety. Hospital-based physicians will be subject to mandatory reporting of serious adverse drug reactions and medical device incidents beginning December 16, 2019. While the legislation applies solely to hospitals in Canada at present, accurate and timely reporting will rely on hospital-based physicians engaging with their institution's reporting process. Accordingly, psychiatrists have an important role to play in reducing patient safety risks associated with ADRs and MDIs.

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[9] *Ibid*.

[10] Health Canada *supra* note 3 at pp. 18-19.

[11] Health Canada, Report a Side Effect, 26 Nov 2019 [cited 29 Nov 2019]. Accessible at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html.

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