A

dverse drug reactions (ADRs) and medical device incidents (MDIs) occur in hospitals, including emergency departments, and in people’s homes – but such events are significantly underreported.

The Protecting Canadians from Unsafe Drugs Act, also known as Vanessa’s Law, honours the memory of Vanessa Young, who died at the age of 15 due to a heart problem after being prescribed cisapride.

Vanessa’s Law is intended to increase medication and device safety in Canada by strengthening Health Canada’s ability to collect information and take quick and appropriate action when a serious health risk is identified. The Law includes a mandatory requirement for hospitals to report serious ADRs and MDIs. This provision of the law comes into effect later this year.

By Ellen Gardner and Valentina Jelincic

The Joint Venture partnership leverages the strengths of our organizations, in collaboration with Health Canada, to support provinces and territories, hospitals and healthcare providers in preparing for implementation of the Vanessa’s Law mandatory reporting requirements,” says ISMP Canada CEO Carolyn Hoffman.

“We are extremely proud to be working with Health Canada in partnership with ISMP and CPSI to address serious gaps in safety reporting in hospitals,” says Leslee Thompson, CEO of HSO.

Making the Content Relevant and Useful

One of the principles guiding the Joint Venture is that the best people to communicate information about mandatory serious ADR and MDI reporting are those closest to their audience.

“The educational modules are designed to be ‘building blocks’ for healthcare providers to integrate into their own learning or to incorporate into orientation, continuing education, and other education activities,” says Sylvia Hyland, Vice President and Chief Operating Officer at ISMP Canada.

The Joint Venture partners suggest the materials be used in the following ways to raise awareness of Vanessa’s Law and to support reporting and learning:

• Hospitals can include some, or all, of the educational slides in their orientation programs.
• Educators can use the content in presentations or as part of a curriculum.
• Professional associations, colleges, and societies can use the content to create accredited courses or certification programs for continuing education.
• Patient and consumer organizations can use the materials to increase awareness and knowledge among their members.

**Education Modules – A Helpful Approach?**

<table>
<thead>
<tr>
<th>Response</th>
<th># of Pilot Respondents</th>
<th>Proportion of Respondents</th>
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<tr>
<td>No</td>
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<tr>
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<td>2.0%</td>
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<tr>
<td>Total</td>
<td>255</td>
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Figure 1: 94% of respondents to the Pilot questionnaire indicated that the approach to education about Vanessa’s Law mandatory requirements is helpful.

Three organizations – the Institute for Safe Medication Practices Canada (ISMP Canada), the Health Standards Organization (HSO), and the Canadian Patient Safety Institute (CPSI) – are working in a joint venture to assist Health Canada with outreach, education, and feedback to encourage serious ADR and MDI reporting.

Therefore, hospitals, educational organizations, and accrediting bodies are encouraged to use the educational material in a way that is most useful and relevant to their stakeholders.

The educational content is contained in five PowerPoint modules, which include one concise overview module.

Module 1

“Vanessa’s Law is essential to Canada’s healthcare system,” says Chris Power, CEO of the Canadian Patient Safety Institute. “We can’t improve what we don’t measure. These new reporting requirements will help contribute to improving the safety of drugs and medical devices. Everyone in Canada deserves safe healthcare.”

Learn more about Vanessa’s Law on the Health Canada website.

**Results from the pilot include:**

• Over 89% of respondents reported they had a good or strong understanding of Vanessa’s Law after reviewing the educational modules.
• 94% of respondents indicated that they will be using the slides/modules in communication about Vanessa’s Law.
• Many respondents provided helpful suggestions for additional information to be included in the final PowerPoint slides.
• Respondents also provided suggestions for additional educational formats that could be considered in future for additional knowledge dissemination/translation.

“The joint venture is that the best people to communicate information about mandatory serious ADR and MDI reporting are those closest to their audience.”