Saskatchewan Health Authority

MEMO

DATE: December 18, 2019

TO: Provincial Transfusion Medicine Discipline Committee;
Saskatchewan Transfusion Medicine Laboratory Physicians, Directors and Managers

CC: Dr. F. Magee and L. Howey, Executive Leadership, Pathology and Lab Medicine
P. Robertson, Executive Director, Provincial Programs – Pharmacy Services
N. Cox, Director Clinical Quality Safety Logistics – Pathology and Laboratory Services

FROM: Dr. O. Prokopchuk-Gauk, Transfusion Medicine Consultant, Northern Saskatchewan
Dr. E. Alport, Transfusion Medicine Consultant, Southern Saskatchewan

RE: Vanessa's Law – Impact on Severe Adverse Event Reporting in Transfusion Medicine

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As of December 16, 2019, regulations supporting the ***Protecting Canadians from Unsafe Drugs Act*** (Vanessa's Law) are in effect, requiring hospitals to report information about any serious adverse drug reactions (serious ADRs) and medical device incidents (MDIs) to the Canada Vigilance Program of Health Canada.

Relevant to Transfusion Medicine, this law includes reporting of serious ADRs to biologic drugs, including fractionated blood/plasma protein products and coagulation factors (on and off label use). The definition of a serious ADR is: *a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening, or results in death.*

The communication that was distributed by the Saskatchewan Health Authority Quality, Safety and Strategy portfolio about the reporting of serious adverse drug reactions did not provide specific direction provided regarding transfusion medicine products.

At this time, there is no change to current processes of blood or blood product related adverse event reporting to transfusion medicine laboratories using the SK Transfusion Adverse Event Report (TAER) Form. Any laboratories receiving report of a *severe adverse event* should immediately contact the Transfusion Medicine Physician on-call for discussion.

Forms required for adverse event reporting to the Canada Vigilance Program by transfusion medicine laboratories have been updated. Severe ADRs to fractionated blood/plasma protein products and

coagulation factors must be reported using the Serious Adverse Drug Reaction Reporting Form for Hospitals. If there is any concern of clustered mild ADRs from these blood products, the voluntary Side Effect Reporting Form should be used. Copies of these forms are attached to this memorandum.

Reporting serious adverse reactions to blood components (not related to safety or quality of the blood) are *not* included in Vanessa's Law. However, mandatory reporting of adverse reactions related to the safety or quality of the blood is required by the blood establishment responsible for the activity that was the root cause leading to the adverse reaction, in accordance with Blood Regulations. Voluntary reporting of severe adverse reactions to blood components (considered 'health products') to the Canada Vigilance Program and to the Transfusion Transmitted Injury Surveillance System (TTISS) of the Public Health Agency of Canada are strongly encouraged.

The following SK Transfusion Manual documents have been updated to reflect changes to adverse event reporting, now that Vanessa's Law has come into effect, and are attached to this memorandum:

- Guideline SK 17 Transfusion Associated Adverse Reaction Investigation and Reporting
- Appendix # 12 Reporting Adverse Reactions to Appropriate Authorities – Job Aid for Transfusion Service/Laboratory

A summary of mandatory hospital reporting requirements can be found at this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting.html

Questions may be directed to the on-call Transfusion Medicine consultant or provincial Transfusion Safety Managers:

- **Saskatoon and Northern Saskatchewan:**
    - Transfusion Medicine on-call: Royal University Hospital Switchboard - 306-655-1000
    - Elaine Blais, Transfusion Safety Manager – 306-446-6596

- **Regina and Southern Saskatchewan:**
    - Transfusion Medicine on-call: Regina General Hospital Switchboard - 306-766-4444
    - Paula Van Vliet, Transfusion Safety Manager – 306-766-3109

Please disseminate this communication within your area, as appropriate. Thank you for your ongoing partnership in transfusion safety.