

Important Bulletin for all Healthcare Professionals

What is changing?

On December 8, 2014, Fraser Health (FH) became the first Health Authority to launch the new **Adverse Drug Reaction (ADR) Report Form** in BC Patient Safety & Learning System (BC PSLs).

On May 4, 2015, a new question will be added to the ADR Report Form to improve data collection about serious ADRs associated with **clozapine**. This change will allow clinicians to learn more about the incidence, predisposing factors, management and prevention of these types of ADRs.



*New question!

Note: Reporters may be contacted by the clozapine project team for more information. This **does not replace** standard follow-up processes already in place at FH for reported ADRs.

*** Was this a serious ADR involving clozapine?**

Yes Choose "Yes" to report an ADR involving clozapine

No

*** Reaction to clozapine**

Select all that apply.

If you choose "yes" a drop down box will open with a list of serious clozapine-related ADRs.

- Agranulocytosis
- Cardiac arrest
- Cardiotoxicity: myocarditis
- Cardiotoxicity: pericardial effusion
- Cardiotoxicity: pericarditis
- Granulocytopenia
- Hyperglycemia (severe), ketoacidosis, hyperosmolar coma
- Liver failure
- Paralytic ileus
- Respiratory arrest
- Seizure
- Venous thromboembolism
- Other

Why is this change happening?

Clozapine is a complex antipsychotic agent that remains the gold standard for treatment of patients with **treatment resistant psychosis**. The complex actions of clozapine effectively manage psychiatric symptoms, but these actions can also result in unexpected serious side effects for patients, such as **agranulocytosis**. To date, other serious ADRs related to clozapine are not routinely tracked or reported, although best practice recommends monitoring for associated conditions such as serious GI adverse effects, myocarditis or hyperglycemia.

Data collected about clozapine-related ADRs will be monitored by the **Clozapine Serious ADR BC Surveillance Monitoring Project**, a multi-health authority group of mental health clinicians, to support the safe and effective use of clozapine, which may include the development of additional education and/or guidance for staff. Patient-specific data will also be retained to support patient care by avoiding unnecessary clozapine trials or, conversely, to identify patients that could be re-challenged.

Note:

- By linking the Clozapine Serious ADR BC Surveillance Monitoring Project with ADR reporting in BC PSLs, clinicians will avoid unnecessary dual reporting of these types of ADRs. Health Canada and the clozapine project leads will be notified when serious clozapine-related ADRs are reported at FH.

Where can I find more information?

If you have questions, please contact Dr. Debbie Thompson Debbie.thompson@fraserhealth.ca, Dr. David Nelson david.nelson@vch.ca or Tammy Simpson tammy.simpson@fraserhealth.ca