Patient Safety Incidents and Product Complaints - Frequently Asked Questions

Reporting & Documentation

Why do I need to submit both an incident report and a product complaint?

Patient Safety incident reports and product complaints serve different purposes.

Patient safety incident reports are required processes to document and meet accreditation standards. Reports are reviewed for risk reduction and process improvements. As well, certain equipment or supply-related incidents need to be reported to Health Canada as Medical Device Incidents within 30 days.

Product complaints are documents used by supply chain to identify and share concerns with the vendor for further investigation. Without this documentation, vendors have no obligation to investigate.

The Patient Safety team acknowledges the burden of documentation that having these two reports separate is creating. Solutions are being explored to include product complaint information in our Provincial Safety Incident reporting system (RL), so that only one report is needed for both processes.

Why is the product complaint form changing?

The form was changed after hearing feedback from staff about how different product complaint forms are used across the province.

The new form simplifies and standardizes documentation of details required by Health Canada. Improvements to the form include impact to patients, actions taken, pump and equipment details.

What do I do if I don't have time?

Speak with your manager or supervisor if you don't have time to complete required patient documentation and reporting.

What happens after I complete a product complaint form and provide evidence?
The product complaint document and the evidence are submitted to the vendor for investigation. When investigation is complete, a report is sent back to Supply Chain and Health Canada (if they are involved).

Through this process, vendors identify and address concerns and issue recalls or alerts.

What should be documented when we have a blood tubing issue?

Documenting the following information is important help all stakeholders, including the vendor, Health Canada, Canadian Blood Services and our experts in blood management to monitor and assess the issues we are experiencing:

- Time from receiving blood to the unit until a successful bag spike
- If the blood product wasted
- Did the tubing spike go through the bag (leading to wastage)?
- Was it an emergency transfusion?

Follow the product complaint process to send the blood bag and tubing to material management.

Consumables & Equipment

Why do I have to keep the IV tubing products and packaging involved in incidents/product complaints?

Supplies or products that are, or may have been a factor in, a patient safety incident need to be kept as evidence for investigation by our Clinical Engineering team and by the vendor.

When Health Canada is aware of the concerns or safety incident, they may ask the vendor to do additional testing. This can only be done if the vendor has access to the supplies/equipment that were involved. If the supplies and packaging aren't kept, the risk is that the complaint is closed without investigation.

How can I know the lot number for IV tubing? We throw out the packaging upon priming the IV tubing set.

A key piece of information required to trend data or confirm product issues is the Lot Number from vendor packaging. One strategy does not work in all clinical environments. Brainstorm as a team on how to keep packaging or have the packaging available to access lot numbers for documentation.

What do I do if equipment, such as a pump, is involved in the patient safety incident?

Equipment involved in an incident/event should be secured or isolated as soon as possible. It needs to be taken out of service to prevent it from being used again until we can confirm that it is working properly. Review your site's process for securing

equipment, tagging it for identification as a “Do Not Use” and sending to right department/location for assessment by Clinical Engineering and/or the vendor.

Both the patient safety incident report and product complaint form should be filled out to allow the incident to be investigated.

Documenting the Asset Tag Number or Equipment Serial Number in the safety incident and product complaint report is important. It allows tracking of the manufacturing date, repeat concerns with the same piece of equipment, and validates the maintenance of the equipment.

What are the criteria for reporting a Medical Device Incident (MDI)?

Individuals reporting and reviewing safety incident involving a medical device should consider the following:

- Equipment failure (based on what’s available)
- Any deterioration of the equipment’s effectiveness
- Unclear, inadequate labelling or directions that led to patient death or serious harm or could led to death or serious harm if an incident were to reoccur.
- Complaint trends
- Potential to lead to death or serious deterioration in health of a patient, user or other person

Tip – include the patient safety incident number on the "Do Not Use" tag so Clinical Engineering can follow up with any missing details.

What should I document in a patient safety incident involving an MDI?

In the section provided to document the description of the incident, please include the following:

- Effect of the medical device incident on the patient’s health outcome
- Anything that you think made the incident more likely happen, such as patient medical conditions, access to equipment/supplies, etc.

Why do we need pump details when this is a tubing issue?

When typical actions (such as checking patency of IV, flushing, ensuring clamp is open and bag height to pump is correct) do not resolve upstream or downstream alarms, it's important that the pump be assessed.

The issue may be with the pump, the tubing or both. Including pump details such as Serial Number or Asset Tag Number allows us track manufacturing date, repeat concerns with the same piece of equipment, and validates the maintenance of the equipment.