RISK PROFILE



CARE - Supply Shortages

This risk relates to supply shortages (drug shortages) resulting from increased demand, discontinuation, product manufacturing issues or supplier/delivery delays. Supply shortages can lead to negative outcomes such as potential patient harm, delay or cancellation of treatment, decreased confidence of public in healthcare supply chain, increased cost for replacements/back-up inventory. It was also noted that critical drug shortages are increasing in frequency, and extensive resources are required to properly plan for and safely manage drug shortages. This document contains information entered by HIROC subscriber healthcare organizations (acute and non-acute) in the Risk Register application to help you in your assessment of this risk.



Ranking / Ratings¹

- Likelihood average score 3.55
- Impact average score 3.14

The Risk Register allows for risks to be assessed on a five-point likelihood and impact scale, with five being the highest.

Key Controls / Mitigation Strategies

- Medication Shortages, Backorders and Recalls
 - ✓ Strategic approach / system to accurately track and manage recalls (e.g. documentation of recall activities; traceability and notification system; identification, removal, storage, and disposition of recalled medications)
 - ✓ Drug shortages policy (e.g. step down policy when drug supply is limited or restricted (e.g. use oral vs. IV))
 - Adoption of the Ministry of Health and Long Term Care (MOHLTC) drug shortage ethical framework
 - ✓ Inventory management:
 - · Upgrade inventory tracking systems to enable real-time communication with the supply chain
 - · Electronic pharmacy system for tracking drug utilization and inventory
 - Integrated medication inventory management
 - · Inventory monitored routinely through the electronic health record (EHR)
 - · Computerized order system alerting the outages
 - ✓ Pharmacy centralized management and response to drug shortages:
 - · Develop strategic approach to minimize the impact on patient care
 - Define roles and responsibilities of key stakeholders / teams
 - Drug procurement designated staff
 - Manage existing supplies in order to:
 - reduce wastage
 - ensure appropriate allocation of medications
 - determine prescribing restrictions to conserve existing supplies
 - Plan for drug availability challenges
 - Provide therapeutic substitution recommendations to ensure appropriate drug usage
 - · Provide alternative formulations in consultation with compounding pharmacists
 - Ensure special access program available for procurement of medications outside of Canada
 - Process for special access authorization through Health Canada if required to import from another country
 - Monthly updates at Drugs and Therapeutics Committee
 - Process to petition for an increase in allotment (e.g. if manufacturers have limited supply) or to obtain an emergency supply









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- Communication and Collaboration
 - ✓ Fan-out list for inventory status at all sites
 - ✓ Reliable and timely communication structure to prescribers about drug supply issues
 - ✓ Regular drug shortage updates from suppliers to enable timely implementation of plans
 - ✓ Ensure communication regarding pending and current drug shortages, including management strategies, with clinical teams and key stakeholders (e.g. Provincial/Territorial ministry or agency, vendors)
 - ✓ Notification system / structure of drug shortages disseminated by manufacturers to key stakeholders (Directors of Pharmacy, suppliers, acute/non-acute organizations responsible for medication administration) to ensure they have the information they need to make informed decisions
 - ✓ Partner with national/provincial/territorial working groups engaged in management of drug shortages and recalls (e.g. Canadian Association of Provincial Cancer Agencies (CAPCA) drug shortages committee specific for oncology drugs)
 - ✓ Collaborate / liaise with other hospitals, coordinate with community pharmacies in the area, or Group Purchasing Organizations (GPOs) to support sharing inventory levels
 - ✓ Collaborate with Regional Health Authorities (RHAs) to cover immediate shortage concern and address larger issues with problem suppliers



- Supply Chain Management
 - ✓ E-procurement processes
 - ✓ Work together with JIT and external suppliers regarding frequency of backorders
 - ✓ Work with suppliers to reduce impact, provide alternates, and ensure timely communication with end-users and program leadership
 - ✓ Optimize total replenishment process
 - ✓ Maintain a list of alternative vendors
 - √ Robust, detailed contract / agreement (e.g. language to recover costs of generic equivalent from backordered manufacturer)

Monitoring / Indicators

- Regular equipment inventory (e.g. quarterly inventory counts)
- Reports on equipment repairs for analysis
- Staff feedback
- Review of occurrence reports
- Regular supply monitoring (e.g. weekly)
- Monitor pandemic inventory for expired medication and stock level
- Regular review of periodic automatic replenishment (PAR) minimum maximum levels to maintain inventory of supplies for a certain number of days
 - Analyze usage reports to determine PAR levels and operating plans for leadership
- Daily monitoring through barcoding, scanning; review of electronic data
- Regular review of backorder reports; consider using substitution if backordered for an extended amount of time

