An "Early Warning" Risk Assessment Strategy to Enable Proactive Management of Supply Shortages in Canada

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Appendix 1

TABLE 1.

Pilot test case study descriptions and outcomes

Case study	Description	Factors affecting risk	Case study outcomes
Personal protective equipment shortage (2020–2021)	The COVID-19 pandemic caused a sudden and massive global shortage of personal protective equipment, including masks, gloves, face shields and gowns. Overseas manufacturing disruptions, supply transportation restrictions, demand spikes and panic buying and hoarding worsened the shortage.	• Limited alternative product supply options • High dependency on overseas manufacturing • Significant transportation and distribution challenges • Multiple concurrent geopolitical and economic factors affecting supply	The case study illustrated the tool's ability to identify risks during a global health crisis and how these risks impacted populations across Canada.
Heparin shortage (2007–2008)	Heparin is a critical blood-thinning medication, with the active ingredient sourced primarily from pig intestines in China. Contamination in the heparin supply chain led to a global shortage of heparin.	• Access to raw materials • Supplier diversity (concentrated in one geographical region) • Quality and regulatory concerns	The case study validated the tool's ability to capture risks associated with single-source raw materials and the impact of quality control issues in the supply chain.
Ozempic (semaglutide) shortage (2022–2023)	Ozempic, a treatment for type 2 diabetes, gained popularity as an off-label weight loss treatment. The unexpected surge in demand due to its off-label use as a weight loss treatment made it challenging for manufacturing capacity to keep up with demand.	• High impact scores due to the critical nature of the medication for diabetes management • Manufacturing capacity constraints • Limited alternative product options for the affected patient population	The case study demonstrated how the tool can identify risks associated with limited production capacity and unexpected market dynamics.

Case study	Description	Factors affecting risk	Case study outcomes
Children's Tylenol shortage (2022–2023)	A "tripledemic"* of the COVID-19 pandemic, flu and respiratory syncytial virus among children led to a surge in demand. Health supply chains were still recovering from pandemic-related disruptions and raw material shortages contributed to production limitations.	▪ Complex interplay between multiple factors including: › Seasonal demand surge › Raw material constraints › Manufacturing capacity limitations	This case study illustrated the tool's ability to capture multiple concurrent factors affecting supply chain resilience and their high impact on vulnerable populations.
Vincristine shortage (2019)	Vincristine is a crucial chemotherapy drug for treating childhood cancers. Teva Pharmaceutical, one of two U.S. manufacturers, discontinued production of the drug, leaving Pfizer as the sole supplier, making it challenging to immediately meet the full market demand.	▪ Significant vulnerability in the supplier diversity dimension ▪ Manufacturing capacity constraints following single-supplier exit	The case study demonstrated the tool's effectiveness in assessing risks associated with limited manufacturer diversity and critical medications, leading to a lack of therapeutic alternatives.

*Fiedler M. 2022. Canada Passes 50,000 Registered COVID-19 Deaths as "Tripledemic" Wreaks Havoc on Health Care Systems Nationwide. World Socialist Web Site. Retrieved April 21, 2026. https://www.wsws.org/en/articles/2022/12/22/zobm-d22.html.

TABLE 2.
Risk assessment tool impact and probability factors

Impact	Definition
Capacity to deliver patient care	The capacity to deliver patient care refers to the ability of healthcare systems to provide timely and effective healthcare to patients, especially during disruptions. It includes the availability of critical resources, such as vaccines, essential healthcare supplies and a well-supported workforce, to ensure patient safety and the continuity of vital services. It encompasses the impact on the healthcare workforce's health and ability to deliver care, which directly affects patient outcomes. This capacity involves maintaining the ability to conduct critical procedures, ensuring operational efficiency and managing surges in demand, while also considering the equitable distribution of care to ensure all populations, including vulnerable groups, receive the necessary attention during challenges.
Probability (factors that impact risk)	**Definition**
Alternative product supply	There is limited availability of viable alternative or substitute products to mitigate the risk of a disruption for populations. "Very likely" means there are few, or no substitute products, which places populations at great risk due to the disruption.
Supplier diversity	There is a limited number of suppliers who can provide the product in a disruption. "Very likely" means the product is sourced from a specific supplier with limited or no alternative suppliers available to meet supply demand.
Domestic supplier capacity (shortened supply chain)	There is a limited number of domestic manufacturers who could manufacture the product in shortage. "Very likely" means there is limited or no known domestic manufacturers able to supply the product.
Access to raw materials	The raw materials for product manufacturing are in shortage which results in disruption to the supply of a product from the manufacturer (e.g., the active pharmaceutical ingredient or the micro-chip for a device is in shortage resulting in disruption to product supply). "Very likely" means there is no access to raw materials to manufacture a product, especially when 80% of raw materials come from outside of the country.
Supply inventory, stockpiles or "buffer stock"	Reserve stock available in either stockpiles or warehouse inventories (e.g., managed by health systems or government agencies), which can be accessed to manage or mitigate a supply disruption, including knowledge of stockpile inventory and transparency of inventory content. "Very likely" means there are limited or no reserved stock available to ensure that patient care is maintained.

Impact	Definition
Distribution logistics	Transportation disruptions that prevent or limit the distribution of supplies to maintain effective care delivery are assessed for risk. Disruptions include environmental disasters (e.g., earthquakes), labour disruptions (e.g., railroad strike) and specialized capacity to distribute, such as cold chain. "Very likely" means the distribution logistics for product supply are limited or severely reduced due to transportation challenges.
Product manufacturing capacity	The capacity and time required for manufacturers to increase production capacity to meet the demand for the product. "Very likely" means manufacturers require a lengthy lead time to increase production to meet the product demand.
Regulatory	Regulation in the healthcare supply chain refers to the laws, guidelines and standards governing the production, labeling, distribution and use of medical products to ensure safety, efficacy and compliance. "Very likely" indicates that past regulatory changes have disrupted healthcare supply chains and there is a high probability that future changes will similarly affect supply chain operations and product availability.
Disruptive "historical" event	Historical events and natural disasters that impact healthcare supply chains by disrupting transportation networks, damaging infrastructure and creating resource shortages by interrupting manufacturing or distribution. Very likely indicates that similar disruptions have occurred in the past due to severe weather events or labour disruptions, and there is a high probability that future incidents will continue to impact critical healthcare supply chains.
Economic and geopolitical factors	The stability and reliability of the global supply chain due to geopolitical factors (e.g., border closure, war) or economic conditions in key supplier regions (e.g., China, Taiwan, India). Examples include conflict, weather events, border policy changes and distribution logistics to ensure access to the product. "Very likely" means there is instability in the global supply chain.
Duration of shortage	The estimated duration (in days, weeks, months) of the supply disruption, with the longer the duration, the greater the impact of the disruption on the capacity to deliver safe care. "Very likely" means the disruption is prolonged to weeks or months, or is unknown.

TABLE 3.
Risk assessment tool impact level definitions

Score	Impact level	Definition
1	Very low impact	Very few people are impacted in one or two regions or jurisdictions (<2% of the population).
2	Low impact	A small number of people will be impacted (<10% of the population) in one or two regions or jurisdictions.
3	Moderate impact	11–25% of the population could be impacted by the disruption in multiple regions or jurisdictions.
4	High impact	A large segment of the population will be impacted in many regions or jurisdictions, or multiple and unique populations are significantly impacted (e.g., children, seniors).
5	Very high impact	The majority of a population (e.g., >50% of the population) is impacted in all or most regions or jurisdictions, or entire populations that are vulnerable are significantly impacted, such as seniors or children.
0	Not applicable	The supply disruption is expected to have little to no impact on the health or well-being of the population.

TABLE 4.
Risk assessment tool probability level definitions

Score	Probability level	Definition
1	Very unlikely	The disruption is highly unlikely to occur, and historically, there has been little or no disruption. Very unlikely also means the risk posed by the disruption is viewed as having very minimal risk.
2	Unlikely	The disruption is considered possible, but not likely to occur. Unlikely may also mean the disruption carries very few risks to populations, or risks are minor for very small populations.
3	Possible	The disruption is anticipated to occur and will impact a limited population.
4	Likely	The disruption is likely to occur, and disruptions have occurred historically. The disruption will impact the majority of regions or jurisdictions.
5	Very likely	The disruption is almost certain to occur, with clear evidence of alerts of disruption. The widespread disruption is anticipated to affect all jurisdictions and populations.
0	Not applicable	The supply disruption is not relevant or does not impact healthcare or populations.