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

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Abstract

Canada's healthcare systems continue to experience multiple and lengthy supply chain disruptions, compounded by limited digital infrastructure and a lack of real-time visibility into risks of supply disruptions. Despite growing awareness of health supply vulnerabilities, there is no standardized tool currently to assess the risks of supply shortages for patients or the health workforce. This study introduces a healthcare supply risk assessment tool, co-designed through a national Community of Practice representing over 60 organizations across healthcare, industry and government. Using a participatory, evidence-informed co-design process, the risk assessment tool was developed to quantify both the probability of disruption and its impact on patient care, to enable proactive decision-making to mitigate risks to patients and the health system workforce. Pilot testing with eleven organizations demonstrated that the risk assessment tool enables prioritization of high-risk products, strengthens cross-sector collaboration and embeds risk intelligence into procurement decisions and supply management. The tool offers a scalable solution to enhance supply chain resilience, bridge gaps in data visibility and support health system modernization in Canada.

Introduction

Healthcare systems worldwide face increasingly fragile and complex supply chains for health products required to deliver patient care. In Canada, supply chain vulnerability has reached critical levels, as Canada's healthcare systems continue to experience persistent and lengthy supply chain disruptions that directly compromise the delivery of safe, timely and equitable care.

Supply shortages have significant and measurable consequences for patients. When supply disruptions exceed available inventory, patient care procedures or therapies are not available. In 2017, and again in 2023, shortages of sodium bicarbonate, an essential anesthetic

and resuscitation agent, forced hospitals to cancel surgeries and ration remaining supply to only the most critical cases (Di Trapani 2019). During the 2022 surge in pediatric respiratory infections, widespread shortages of children's acetaminophen and ibuprofen resulted in emergency department overcrowding, parental distress and federal intervention to import children's Tylenol from international sources (Health Canada 2022). Limited digital infrastructure, fragmented and competitive procurement across provinces, territories and health systems and insufficient clinical engagement have left healthcare leaders and clinician teams to respond to supply shortages once harm is already underway (Snowdon and Wright 2022).

To address this gap, the Supply Chain Advancement Network in Health (SCANH), a Social Sciences and Humanities Research Council of Canada (SSHRC) funded initiative, started a national Community of Practice (CoP) of over 60 health sector organizations. A workgroup was established to strengthen national supply chain security by addressing the lack of standardized risk identification and response infrastructure. The group determined that while data could signal supply disruption, the absence of a standardized framework to interpret and act on those signals undermined system readiness. This study introduces a healthcare supply chain risk assessment tool that enables organizations to quantify both the probability of a supply disruption and its impact on system capacity to deliver care.

Literature Review

Healthcare supply chains differ fundamentally from industrial or consumer supply chains because every supply disruption in healthcare directly affects patient care, delays treatment or cancels procedures altogether (Aldrighetti et al. 2019). In 2023, Canada experienced 3,098 drug shortages, contributing to treatment delays, care modifications and increased clinical workload as providers adapted care to manage product shortages (Health Canada 2024; Snowdon et al. 2024).

Healthcare supply chain resilience has become a central concern in Canada, particularly following the COVID-19 pandemic, which exposed major vulnerabilities in procurement systems, designed for efficiency rather than adaptability. The "just-in-time" model prioritizes cost containment over preparedness and collapsed under pandemic pressures, including border closures, demand surges and export restrictions (Snowdon et al. 2021, 2022). These failures have

accelerated advances in supply resilience, defined as the ability to absorb shocks, adapt and maintain service continuity (WHO 2022).

The absence of standardized tools for assessing preparedness or coordinating response (Cheng and Lu 2017; Fleming et al. 2022; Nartey 2023) results in struggles to detect early signals or align system-wide risk mitigation strategies across health systems (Lau et al. 2022; Sawyerr and Harrison 2023; Singh and Parida 2022). Causative factors influencing supply disruptions point to multiple root causes, including economic volatility, manufacturing delays, climate events, limited production incentives and global supply concentration (Sandoz 2024). In Canada, manufacturing and quality-related issues are among the leading causes of disruption (Health Canada 2024).

Digital infrastructure, visibility and evidence-based decision-making

Digital infrastructure is a foundational enabler of healthcare supply chain resilience, yet it remains underdeveloped in Canada. The absence of real-time data on product inventory across the supply network impairs both forecasting risk and risk mitigation planning. Limited transparency in upstream supplier data, geographic dependencies and insufficient tracking of active pharmaceutical ingredients are key barriers to anticipatory action (Health Canada 2023; OECD 2024). Without access to reliable data, procurement and clinical leaders are forced to react to supply disruptions, often responding only after care is compromised (Wright et al. 2023). Clinicians only learn of a supply shortage when a patient is denied access to therapies in shortage (Fox and Wynia 2024). This lack of upstream visibility severely constrains clinical preparedness and patient safety during supply disruptions.

Although governments have proposed national dashboards, shared inventory platforms and digital risk registries, implementation remains inconsistent and highly variable (Everstream Analytics 2023). Healthcare organizations in Canada are unable to identify high-risk products, evaluate disruption signals in real-time or coordinate risk mitigation strategies across jurisdictions due to a lack of digital infrastructure to integrate and share supply chain data across jurisdictions. In addition, there is no capacity to link healthcare supply chain disruption*s* to patient outcomes, leaving decision-makers unable to assess how shortages affect care quality, safety or equity (Snowdon et al. 2021).

Risk assessment tools and matrices

In public health, risk assessment tools provide structured approaches to evaluating the probability and impact of risk due to specific types of threats (e.g., WHO's rapid risk assessment [WHO 2012], the Jeddah Tool Framework for mass gathering health risks [Bieh et al. 2021], the risk-based decision-making framework for blood safety [Sivakaanthan et al. 2021]). These tools are valuable for disease outbreak response and population health planning, but they are scenario-specific and not designed to guide supply chain preparedness or cross-functional decision-making to manage supply disruptions in health systems. The emphasis is on "what might happen" rather than "what we should do to prevent it."

Industrial supply chain evidence has developed risk assessment tools which focus on manufacturing and logistics to assess risks based on disruption type, probability and operational impact (Chopra and Sodhi 2004; Thun and Hoenig 2011). There is no existing assessment tool that fully integrates supply chain risk scoring with system-level impact on patient care in a way that supports proactive decisions to mitigate risks. This study addresses this gap by linking the probability of supply disruption with its downstream impact on patients and the capacity to deliver patient care.

Method

Study design

This participatory qualitative study, grounded in applied health systems research (Bradshaw et al. 2017; Neergaard et al. 2009), examined the development and utility of a healthcare supply chain risk assessment tool. The project was part of a national CoP that engaged partners across government, healthcare, industry and academia. A workgroup was tasked with strengthening supply chain security across health systems and determined that a risk assessment solution could provide an early warning surveillance tool to support proactive management of supply disruptions. The co-design strategy created a risk assessment tool to quantify risk for patients, the health workforce and system capacity to deliver care. The tool was grounded in both published evidence and operational expertise and refined through structured co-design sessions over a two-year period.

Tool development and co-design process

A structured, participatory approach was used to develop the risk assessment tool, grounded in principles of modified Delphi, which supports quality and impactful research (Redman et al. 2021). Partner organizations served as co-designers, ensuring that the tool was relevant, actionable and aligned with the realities of Canadian healthcare supply chain ecosystems. The initial framework was informed by a comprehensive review of literature on healthcare supply chain risk, health system resilience and public health risk assessment models (e.g., Chopra and Sodhi 2004; Kruk et al. 2015; Sivakaanthan et al. 2021; WHO 2012, 2022). This provided the theoretical foundation for developing a tool that could assess both the likelihood of supply disruption and its downstream impact on healthcare delivery. A red-yellow-green surveillance strategy differentiated the operational urgency of supply disruptions.

The workgroup tested early versions of the assessment tool using real-world examples of supply disruptions, refining category definitions, scoring scales and usability features through each round of stakeholder feedback (Appendix). Consensus emerged to further refine the definition of the impact of supply chain disruptions, beyond supply logistics, as the second key dimension of the risk assessment tool. A risk score is assigned to each factor within each of the two dimensions of probability and severity of impact, to arrive at a final score (Table 1) that quantifies the level of risk related to a supply disruption. The tool enables users to identify the highest-risk factors to prioritize risk mitigation approaches to supply disruptions for patients, the health workforce and the capacity of health systems to deliver care.

TABLE 1. Risk assessment tool

Factors That Impact Risk (11 Categories)	Probability Score (Score 0-5)	Severity of Impact for Patients and Populations (Score 0-5)	Risk Score (Probability x Impact)
Supply Resilience and Diversity (3 Categories)			

Production and Inventory Capacity (3 Categories)			
Distribution and Regulatory Infrastructure (2 Categories)			
External Threat Environment (3 Categories)			

Pilot testing

The tool was pilot tested by eleven healthcare supply chain organizations, including provincial procurement teams, federal agencies, group purchasing organizations, retail pharmacies, pharmaceutical and medical device companies and health system procurement teams. Organizations were selected using purposive sampling to ensure representation across organizational size, geographic region and supply chain function. Each organization was provided with guidance materials for completing a risk assessment using historical supply disruption scenarios (e.g., shortages of personal protective equipment, vaccines). Once teams completed their assessments, semi-structured interviews were conducted to gain further insights into the effectiveness of the tool in identifying risks of supply disruptions and applications of the tool for their organization. Interviews were conducted virtually, on Microsoft Teams, and audio-recorded. The transcripts were de-identified, and the data were stored on a secure server. Interviews were completed with teams until saturation was reached. Participant responses were transcribed and used to identify further refinements to the assessment tool's structure, definitions and facilitation needs. The Research Ethics Board (REB) at the University of Windsor provided ethics approval for the study (REB# 24-237).

Data analysis

Data collected from the co-design sessions, pilot test interviews and feedback sessions were analyzed using reflexive thematic analysis (Braun and Clarke 2021). Two researchers

independently coded transcripts and discussion notes, using an inductive approach to identify themes related to usability, functionality, system constraints and opportunities for application of the risk management tool. Codes were iteratively reviewed and themes refined through team discussions. Thematic saturation was achieved when no new themes emerged across multiple transcripts. The generated insights informed further refinements to ensure that the tool remains both scientifically robust and practically useful to support managing the risks associated with real-world healthcare supply disruptions.

Results

Pilot testing of the risk assessment tool across eleven organizations revealed five major themes across participants. The themes include: (1) building consensus on how risk is defined and prioritized, (2) exposing gaps in critical supply chain intelligence to manage supply disruptions, (3) reframing risk around patient impact, (4) risk assessment to inform system readiness and (5) team collaboration and coordination of supply management.

Theme 1: Building consensus on how supply chain risk is defined and prioritized

Participants across pilot sites demonstrated significant variation in how risk is defined and interpreted, depending on professional roles, organizational context and previous experiences. The analysis revealed multiple and varied perspectives on risk that revealed narrow and incomplete views of how supply chain risk is defined. The risk assessment tool served as a catalyst to reveal stakeholder differences in how they define risk, which stimulated discussions among teams to align on shared definitions of supply chain risk among health organizations, as described in the following:

> <BQ> We all act in a certain way based on the information we have to get to the outcomes that we expect ... one of the stakeholders was talking about risk and we were talking about needs ... and then it was like: risk to what? Risk to whom? – Supply chain leader, Retail Pharmacy

The risk assessment tool helped participants uncover these assumptions and stimulated discussions among team members to achieve alignment on risks of supply chain disruptions for health systems.

> <BQ> Everybody's idea of what risk was, was very different. Some people were focused on cost. Some people were thinking about risk to patient care. Others were thinking organizational [risk]. I think that was a big learning – we were not always on the same page at first. – Procurement leader, Provincial Health System

Teams described many differences in how risk was perceived (e.g., financial, clinical or operational) based on their experiences with day-to-day work responsibilities and organizational processes. Procurement teams naturally focused on costs and contracting requirements, while clinical staff prioritized risks related to patient safety.

> <BQ> It was interesting because a few of our people thought, "Oh yeah, that is a five," and someone else said, "No way, that is a two." So, the conversation then became about where our information is coming from. – Procurement leader, Provincial Health System

Differences in scoring often reflected the information sources, knowledge, experience and assumptions of different participants.

Theme 2: Exposing gaps in critical intelligence to manage supply disruptions, "The Black Box" of supply risk

Results revealed a lack of knowledge or insights into critical parts of the health supply chain, particularly for upstream elements such as availability of raw materials, manufacturing sources and geographic concentration of supply. These gaps were not always recognized until participants attempted to assign scores, which highlighted the limitations of their insights or organizational knowledge. The assessment tool exposed what many participants described as "the black box" of healthcare supply chains, such as critical dependencies and vulnerabilities that only become visible once disruption is already underway.

> <BQ> We just do not know ahead of time where products are made. You only learn that when the shortage hits. It is a black box. – Pharmaceutical leader, Federal Health Logistics Agency

Participants commonly described a reactive approach to assessing risk, which revealed the many gaps in critical intelligence that supply chain stakeholders experience.

> <BQ> I did not know where methotrexate was made. I had to Google it. It is not something we track unless there is already a problem. – Pharmaceutical expert, Provincial Health System

Similarly, the use of the risk assessment tool served as a diagnostic prompt, encouraging participants to further examine their own supply chain information to gain greater insights.

> <BQ> It helped us define what was missing. There were processes we assumed we had, but the tool showed us where we actually needed more insight. – Procurement expert, Crown Agency

Participants described how the risk assessment tool helped them identify blind spots in data access and operational assumptions, highlighting the need for greater supply chain intelligence. Some users cautioned that without improved access to information on product supply, particularly for supplier capacity and raw materials, certain dimensions of the assessment tool may be limited to assumptions, rather than verified data. However, participants noted that even imperfect information was better than the current status quo of operating with no systematic risk assessment at all.

Theme 3: Reframing risk from supply disruption to patient impact

A key theme emerging from participants was the use of the risk assessment tool in shifting the conversation from one of traditional supply availability to what supply shortages actually mean for patients. The pilot testing created greater focus on the impact of supply disruptions on patient outcomes rather than the more common focus on logistics, which proved particularly powerful as it aligned different stakeholders around a shared priority, the health and safety of patients.

> <BQ> It is not really a business risk; it is a patient risk. That is what the tool made clear. It helped focus on what matters. – Supply chain expert, National Pharmaceutical Distributor

<BQ> We were working hard on a shortage, but sometimes it is like – wait, what is the patient risk? We needed to ask that question more often. – Supply chain expert, National Pharmaceutical Distributor

Participants described how the assessment tool helped incorporate clinical expertise into risk assessment, prompting teams to distinguish between logistical challenges and high-impact threats to patient care.

<BQ> It was helpful because we usually look at product risk, like what is on backorder or not. But this tool made us look at: What does that actually mean for [patient] care? – Procurement leader, Provincial Health System

Some participants noted that accurate scoring of clinical impact was difficult without the expertise of clinicians, leaving uncertainty about how to assess patient risk.

<BQ> It is hard to quantify patient impact sometimes – we know it is serious, but unless we have data or clinical input, it is just our perception. – Logistics manager, Provincial Health System

The broader organizational issue is that many supply chain teams operate without engagement with clinicians which makes it very challenging for supply chain teams to fully understand or assess risks of supply disruptions for patient care.

Theme 4: Risk assessment to inform readiness

Participants described a wide range of applications for the risk assessment tool including supply prioritization, escalation protocols, vendor engagement strategies and as an internal training tool. These applications had the common purpose of proactive and actionable risk management and preparedness planning.

<BQ> We liked where it seemed to be going … once you have all the ideas flowing – then it is: How do we address it? How do we bring the score down to low? – Supply chain expert, Provincial Agency

Use of the risk assessment tool also offered a structure to communicate the impact of disruptions to senior decision-makers.

> <BQ> We used it to explain to leadership why certain disruptions had to be escalated. The assessment tool helped make the risk visible in a way that was not just gut feel. – Supply chain executive, Shared Services Organization

The use of the risk assessment tool for communication proved particularly valuable for supply chain professionals who often struggled to convey the complexity of supply chain risks to executives to garner their support for supply management strategies.

> <BQ> We were able to tie our rating back to our readiness and say: here is the gap, here is the score and here is what we are doing to fix it. – Procurement expert, Federal Agency

The risk assessment tool was also described as supporting internal readiness reviews by identifying capability gaps and informing response planning. Some participants suggested integrating the tool into their routine vendor discussions to guide and inform early warning conversations.

> <BQ> We have regular cadence meetings with our top suppliers ... Sometimes they give us insight, like, "Hey, it has been harder to get steel." That is the perfect time – the moment you get the hint. The assessment tool helps support that conversation. – Supply chain lead, Provincial Health Services

Structured dialogue with suppliers using the risk assessment tool offered a shared reference point for risk signals.

> <BQ> We have people even using it as training tools with their teams – being like, these are the critical aspects of healthcare supply disruption that we are trying to look at ... Let us walk it through. – Procurement expert, Provincial Health Services

The risk assessment tool was viewed by some as a training tool to educate new team members on the risks associated with supply disruptions. Overall, a key finding across participants revealed multiple use cases and applications of the risk assessment tool to inform leadership decisions on supply management, advance training of supply chain teams and serve as an objective reference point to inform preparedness planning for managing supply disruptions. These reported use cases reflect the assessment tool's practical value in supporting real-world decision-making to advance proactive preparedness for supply disruptions.

Theme 5: Advancing team collaboration and coordination of supply management

While the risk assessment tool was praised for its clarity and structure, pilot participants repeatedly emphasized that it cannot be completed in isolation. Completion required collaborative input from clinical, procurement, logistics and planning stakeholders to ensure accurate scoring. Participants noted that this reliance on team-based input reflected broader system conditions, namely, the absence of shared infrastructure, supply data access and integrated risk governance. In essence, the risk assessment tool revealed that effective risk management requires the very collaboration and coordination that are not well developed in many healthcare organizations.

> <BQ> There is a lot in it, and you kind of feel like, am I even the right person to fill this out alone? It is more of a team tool than a one-person job. – Supply chain lead, Provincial Health Services

Even teams with prior collaboration experience reported misalignment in how sub-dimensions were interpreted, highlighting the need for clear definitions and shared scoring frameworks.

> <BQ>You grow into the tool. It made more sense as we talked through it, not something to do quickly or alone. – Supply chain lead, Provincial Health Services

Participants described a learning curve in not only using the assessment tool, but also in establishing the collaboration required to apply it meaningfully. Several teams reported that the assessment tool prompted new conversations and uncovered roles or gaps in knowledge that

were previously unknown. While the tool stimulated new dialogue, participants identified the need for accurate, upstream information to support accurate scoring.

> <BQ> It is a great tool, but if you do not have the right information or team, the score might be misleading. It is only as good as what goes into it. – Clinical operations lead, Health Services Organization

Participants further identified that gaps in data or knowledge are a fundamental limitation in accurately identifying risk. The risk assessment tool surfaced the gaps in knowledge or data that teams need to ensure that risk assessment scoring is accurate, which may require overcoming gaps in information at both the health system and vendor levels.

> <BQ> I have talked to vendors and said, "Where does the product come from?" They do not know. Then you ask about raw materials, and they do not know either. – Supply chain executive, Shared Services Organization

Findings reveal and validate the limitations in access to data and insights along the full healthcare supply chain that are not organization-specific, but are gaps in visibility of supply risks ranging from manufacturer to health organization and patient outcomes.

Discussion

The results of this study are consistent with the limitations of digital infrastructure in providing visibility across the supply chain (Snowdon et al. 2021). Canadian health systems lack digital infrastructure to track demand utilization and assess risks in real time. Digital infrastructure creates visibility of supply across supply networks that limit data-driven decisions and coordination of supply management responses (Health Canada 2023; Snowdon and Forest 2021). The pilot testing confirmed these gaps, as participants described having to "Google" basic product information, such as manufacturing locations and production capacities, because they were unknown until a disruption occurred**.** Unlike industrial supply chain infrastructures, the healthcare supply chain operates without the basic digital infrastructure to anticipate disruptions (OECD 2024) and accurately assess risks (Fox and Wynia 2024).

Study findings also revealed a disconnect between teams focused on supply management and clinical teams responsible for patient care delivery. This structural disconnect in data systems means that procurement teams rely on operational metrics, such as cost and availability of products, with little or no access to clinical expertise to understand patient safety and care quality risks due to supply disruptions. This finding is consistent with the findings of Vatanpour et al. (2015), whereby risk assessments have the potential to be highly subjective to specific subject areas. Results suggest that the risk assessment tool enabled vertical supply chain integration that connected supply chain nodes with patient impact and outcomes. A procurement leader reflected, "We usually look at product risk, like what is on backorder or not. But this tool made us look at: What does that actually mean for [patient] care?" The risk assessment tool supported teams to bridge this conceptual gap that created vertical integration, with one team noting how the exercise revealed their revelation that "it is not a business risk, it is a patient risk."

The risk assessment tool underscored the current limitations of risk information, which is distributed across vendors, manufacturers, clinicians and procurement teams, which preclude opportunities for coordination across these stakeholder groups. Participants repeatedly emphasized that the risk assessment tool "cannot be completed in isolation" and functions best as "a team tool." Gaps in digital infrastructure make it difficult for organizations to share critical supply chain information, coordinate risk assessments or develop collective risk mitigation strategies, even when they recognize the need for such collaboration. While the risk assessment tool does not eliminate these barriers, these results suggest that it may serve as a structured way to work across them. By aligning stakeholders around shared risk signals, the risk assessment tool may offer health organizations a systematic approach to reducing risk associated with supply disruptions and events, and building consensus on what supply risk is and who is at greatest risk, to inform proactive and "system-level" risk mitigation strategies.

Ultimately, the risk assessment tool may bridge key gaps between clinical and operational teams by mobilizing expertise to advance a "whole system" approach to resilience**.** The risk assessment tool may also serve as a practical tool to advance shared situational awareness to inform proactive, coordinated decisions, echoing the call for structured tools to help teams navigate supply chain complexity (Revilla et al. 2024; Scala and Lindsay 2021). Accurate

and comprehensive risk assessments may enable healthcare systems to move one step closer to proactive, data-driven management of supply disruptions to support health system capacity to deliver safe, high-quality care**.**

While this study demonstrates the practical value of the risk assessment tool, there are several limitations of this study. First, the scoring relies on data that is often unavailable, particularly for upstream supplier sourcing and clinical impact, which reflects digital infrastructure deficits that limit transparency and prevent real-time intelligence gathering. Second, the tool depends on cross-functional collaboration between procurement and clinical leaders, yet many healthcare organizations lack the integrated systems and governance structures to support such collaboration. Third, the assessment tool revealed that effective risk assessment requires information sharing across organizations and sectors, yet cross-sector coordination in the health industry is limited, which is consistent with current evidence documenting the lack of sensitivity of risk matrices to context and data inputs (Pascarella et al. 2021). Finally, the tool was validated through retrospective case studies, where its predictive performance in real-time disruption scenarios remains untested.

Conclusion

This study introduces a co-designed, risk assessment tool that offers a structured and actionable framework to inform risk mitigation and preparedness strategies across healthcare systems. The tool helped reframe supply shortages from logistical challenges to clinical risks, anchoring conversations around patient impact to support preparedness planning. As geopolitical and supply chain volatility persist, Canada's health systems will increasingly depend on system-level strategies that protect patient care, provider well-being and operational capacity to deliver care. Embedding risk management in routine practice and investing in the infrastructure needed to support it is essential to achieving resilient, high-performing healthcare systems.

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Appendix

APPENDIX TABLE 1. Pilot test case study descriptions and outcomes

*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

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 they 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.
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	• Complex interplay between multiple factors including: ○ Seasonal demand surge	This case study illustrated the tool's ability to capture multiple concurrent factors affecting supply chain resilience

	chains were still recovering from pandemic-related disruptions and raw material shortages contributed to production limitations.	○ Raw material constraints ○ Manufacturing capacity limitations	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.

APPENDIX 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, ensure operational efficiency and manage 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.
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.

APPENDIX 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.

APPENDIX 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.