

PPE RISK MITIGATION STUDY

2021



Bioscience
Association
Manitoba

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Executive Summary

Bioscience Association Manitoba commissioned a study to understand and mitigate the risks to the supply chain for Personal Protective Equipment (PPE) in Manitoba. The study collected information from health authorities, academia, and manufacturers and was limited to the procurement and production of level 1 and 3 procedural masks.

It was noted that Shared Health and the Regional Health Authorities' reliance on a group purchasing contract with HealthPro decreased the agility of their response to the pandemic. This group purchasing contract required 80% of purchases to be from the supplier PRIMED, which operates manufacturing facilities in China (but is currently building a facility in Ontario). When demand for PPE increased due to the pandemic, Manitoba made ad hoc purchases from other suppliers, but these required clinical validation before procurement decisions could be made, which created a roadblock.

The governments of British Columbia and Alberta also used group purchasing contracts for PPE before the pandemic. Due to the pandemic, Alberta added an emergency and disaster team and centralized their purchasing processes. BC's group purchasing contract used a mix of both domestic and overseas suppliers and four new domestic manufacturers started up as a result of the pandemic, alleviating procurement difficulties. Manitoba garment manufacturers who were interviewed for this study were asked about barriers to their pivoting to PPE production. They indicated that acquiring the necessary capital was their largest barrier; they also lack of technical expertise.



Methodology

In order to gain a better insight into supply chain management risk mitigation for PPE masks in Manitoba, data was collected from relevant respondents in two interview phases. The first phase focused on health care and academia while the second phase focused on business and manufacturing.

In the first phase of the project, local health authorities and health authorities in other provinces, namely British Columbia, Alberta and Saskatchewan, were interviewed. Academics in Manitoba and Ontario were also interviewed for the project. Interviewees were sent a list of short-answer questions and phone interviews were scheduled to clarify responses and to ask follow-up questions as required.

In the second phase of the project, following a similar methodology to phase one, interviewees were sent a list of short-answer questions and phone interviews were scheduled to clarify responses and to ask follow-up questions as required. Respondents included businesses and manufacturers in Manitoba and British Columbia.

Data collected from these interviews were categorized to find recurring themes and to uncover gaps and risk points in Manitoba's processes. The selected respondents were chosen based on their fit with the research objectives, their ability to provide timely responses, and the pool was limited to the 10-week timeline of the project. Although data from interviews tend to produce results that are difficult to be generalized beyond the sample group, they provided a more in-depth understanding of the respondent's risk points, barriers, and opportunities going forward.

The scope of the project was refined to only include level 1 and 3 procedural masks. The decision to tighten the scope allowed for more in depth interviews with our respondents and an overall better quality of information was gathered.

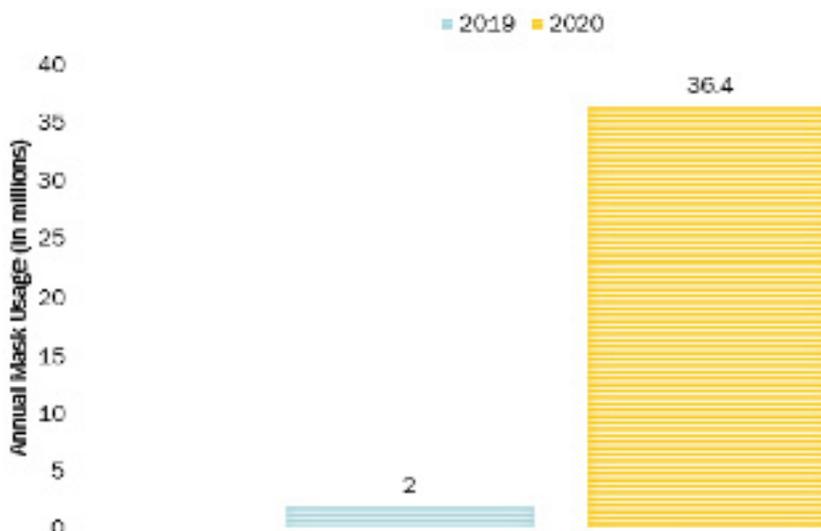


Findings- Healthcare

Manitoba – Shared Health

In Manitoba, Level 1 and 3 Procedural Disposable Masks (disposable masks) were procured through a group purchasing contract organized by HealthPro. Shared Health (SH) and the Regional Health Authorities (RHA) are participants in the group purchasing contract for procedural masks with PRIMED as the selected supplier, where 80% of SH and RHA call-ups under this contract must be from PRIMED. This group purchasing contract was put into place prior to the COVID-19 pandemic.

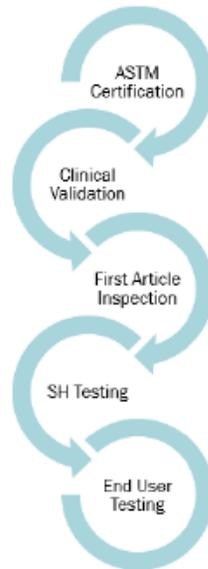
Since the start of COVID-19, SH estimated demand for masks in Manitoba has increased by approximately 1,800%. Although daily average usage of disposable masks fluctuates and the usage data is blended with overall provincial government use outside of healthcare, SH estimates 85,000 - 100,000 disposable masks were consumed per day based on current PPE guidelines. See figure below.



Issues

The existing group purchasing contract could not meet the increased volume requirements at the start of the pandemic and because demand increased in all regions, participants of the group purchasing contract were put on a percentage allocation. As a result, Manitoba began spot-buying from domestic and overseas suppliers outside of the group purchasing contract to secure more supply. Ad-hoc purchases required clinical validation before procurement decisions could be made and changing PPE requirements both created challenges and further delayed the supply of masks in Manitoba.

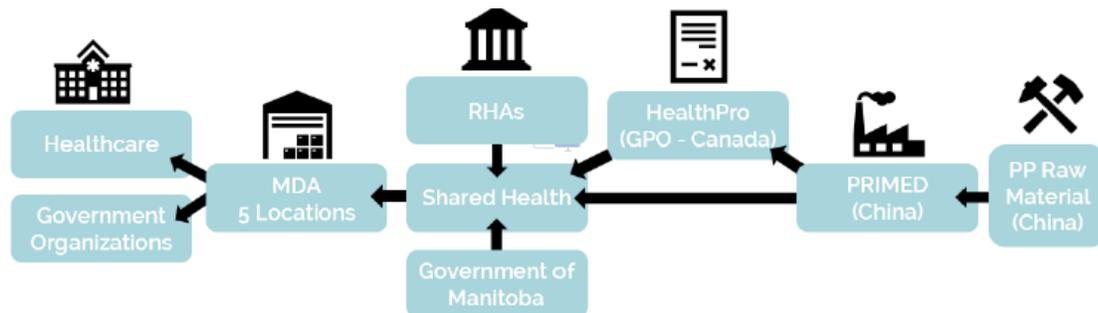
Validation Process



The validation process for SH approve a new PPE supplier follows the process described in the figure above. Suppliers must have their ASTM certification completed and pass their clinical validation requirements, first article inspection, as well as SH and end-user testing and acceptance. SH cited there may be opportunities to complete these validation process steps concurrently to reduce validation time. The validation process was a critical backlog to the approval and onboarding of new PPE suppliers for SH.



Presently, additional sources of supply are in place and current lead times for disposable masks vary from two days to three months, depending on volumes and which supplier is called on to supply procedural masks.



See figure above, Supply Chain Map for Procedural Masks. PrimeMed owns and operates manufacturing facilities in China with a new manufacturing facility being built in Cambridge, ON, estimated completion date is unknown at this time. The primary raw material used in producing disposable masks is polypropylene. China is the leading producer of polypropylene and there are currently no domestic sources of polypropylene. Under the group purchasing contract with HealthPro, SH is required to source 80% of the call ups under this contract from PrimeMed.

BC Health

In British Columbia, usage in disposable masks doubled to approximately 200,000 disposable masks daily since the start of COVID-19. Previous to the pandemic, masks were procured through both RFX processes run by the BC government and through participation in group purchasing contracts. The selected suppliers were a mix of domestic and overseas suppliers. In BC, there was an influx of new mask suppliers in the market shortly after the start of the pandemic and BC Health notes at least four new manufacturers started as a result of the pandemic. Because of this, procurement from domestic suppliers increased at the start of the pandemic. BC Health cites at least four new procedural mask suppliers since March 2020.

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Alberta Health Services

Alberta's procurement process for disposable masks, similar to Manitoba processes, includes long term contracts with overseas suppliers. Purchasing processes for PPE have since centralized at Alberta Health Services since the start of the pandemic with the addition of an emergency and disaster team.

Saskatchewan Health

Saskatchewan Health declined to respond.



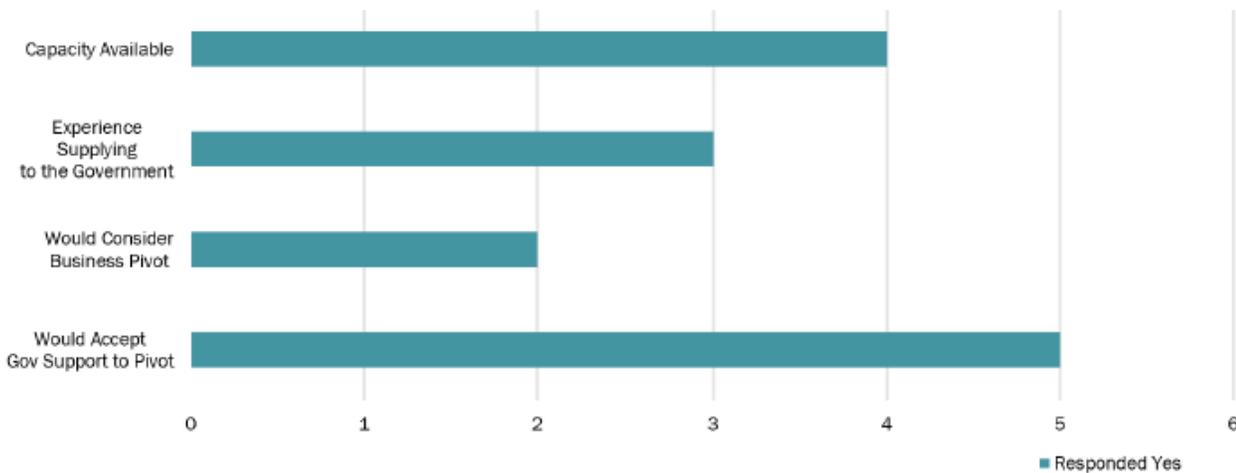
Findings- Manufacturing

Manitoba

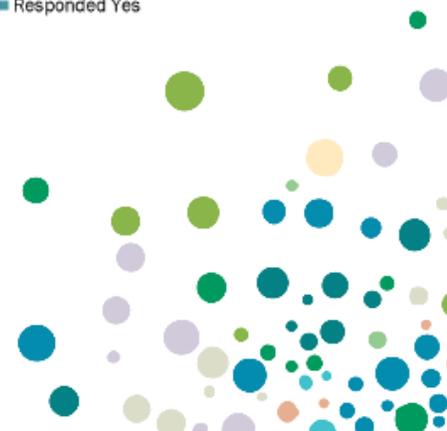
Ten manufacturers were interviewed; seven of the businesses are located in Manitoba and three outside of Manitoba. The respondents either currently manufacture PPE or garments.

We asked:

- Does your company have the capacity to expand or support new business?
- Does your company have experience with supplying to the government?
- Has your company considered retooling or pivoting the business to support increased PPE demand in Manitoba?
- If given government support, would your company pivot the business to support increased PPE demand in Manitoba?



■ Responded Yes



See figure above – Responses from Manitoba Manufacturing. When asked, most respondents in Manitoba had capacity to expand their business and would accept government funding to expand their business to support growing demands for PPE. The respondents in Manitoba had varying responses when asked what barriers exist for their company to produce PPE. Three of the manufacturers interviewed indicated acquiring capital equipment as their biggest barrier. Other respondents noted a lack of technical expertise as another barrier to pivoting their business to support PPE manufacturing.

BC/SK Manufacturers

Similar to the manufacturing interviews conducted in Manitoba, respondents were selected because they either currently manufacture PPE or garments. Of the seven companies approached, four responded to the standardized questionnaire. The same set of questions used in the Manitoba interviews were used in the interviews for manufacturers outside of Manitoba. The standardized questions did not provide any particularly useful insights into the industry outside of Manitoba; however, practices at a supplier, Vitacore lead to follow up questions for future benchmarking opportunities. Details on the findings at Vitacore are covered in the Issues and Risks portion of this report.



Findings- Academia

Academia in Manitoba and Ontario were interviewed as part of our Phase Two interviews.

A representative from the Center of Advanced Manufacturing and Design Technology (CAMDT) at Sheridan College in Ontario was interviewed. CAMDT engages with companies to develop products and support innovation in manufacturing. The college engages students to solve industry problems by allowing students to help industry partners develop products requiring technical expertise, all while creating a unique learning opportunity for students and sparking innovation in the manufacturing sector. Through government funding and industry support, CAMDT facilitates this program for its students. At the start of the COVID-19 pandemic, CAMDT supported Ontario manufacturers in pivoting their businesses to better support the spike in demand for PPE, namely masks and face shields. The college found that those manufacturers that were agile in their supply chains and operations succeeded at supporting new projects. CAMDT also cited clinical validation and end-user acceptance as the biggest challenges to getting products to the market quickly.

In Manitoba, we have observed some innovations in PPE manufacturing, namely in the textile industry. Unlike Ontario, we did not observe strong support from academia to further manufacturing innovations to support the surge in PPE demand in Manitoba.



Issues & Risks Identified- Themes

Based on the findings from Phase One and Two interviews, the following risks have been identified.

- Slow manufacturing innovation
- Poor demand surge planning
- Reliance on off-shore supply
- Lengthy clinical validation process
- Impact to the environment

Slow manufacturing innovation

Slow manufacturing innovation to support new production of procedural masks was observed in Manitoba. This is identified as a missed opportunity for Manitoba's manufacturing industry as the information gathered in our interviews indicated a willingness of Manitoba manufacturing to pivot their business to support increased demand for PPE but barriers in securing clinical validation and capital made potential pivots not feasible.

Poor surge demand planning in Manitoba

Because Manitoba relied on a majority of its procedural mask supply coming from a single supplier through its participation in the group purchasing contract, the province had difficulty in securing supply at the start of the COVID-19 pandemic. While the purpose of this project is not necessarily to correct Manitoba PPE procurement processes, it is important to note this finding as a risk point in the overall supply chain for procedural masks in Manitoba and capturing this risk point better equips the province in the event of another similar spike in demand.

BC Health is identified as a potential partner to benchmark best practices against. Their supply chain risk mitigation strategy involved a mix of both domestic and overseas suppliers.



Supplier diversification allowed BC Health to secure alternate domestic sources of supply when the COVID-19 pandemic started. BC Health also noted that quick local innovation and ramp up of PPE production locally helped the organization to spot buy supplies when demand surged above their regular suppliers' capacity.

Reliance on off-shore supply

Further to the risk of poor demand surge planning, most respondents, both in the healthcare sectors and in manufacturing, cited a common risk in their supply chains as their reliance on off-shore raw materials. Polypropylene is the main raw material used in manufacturing of procedural masks and is primarily produced in China and there are currently no domestic sources of polypropylene.

Lengthy clinical validation process

Lengthy clinical validation process was a common risk point identified from a number of respondents in both the healthcare and manufacturing interviews. Respondents stated at all levels of the clinical validation process, backlogs are present making it difficult to complete clinical validations required to sell PPE.

An example provided by one of our respondents noted the National Institute for Occupational Safety and Health (NIOSH) certification at the time had a three-year back log for validations. The validations are completed in the US and manufacturers in the US are prioritized in certification completion, making it difficult for a Canadian supplier to complete the NIOSH clinical validation. A second example from a different respondent stated the Medical Device Establishment License (MDEL) certification having a one-year back log to complete.

While both of these clinical validations are not the required validation for manufacturers to produce procedural masks, it is important to note backlogs in clinical validation was listed as a pain point for a majority of our respondents and the examples provided from other PPE clinical validation



processes gives insight into the backlogs experienced by the PPE manufacturing industry at a higher level.

Impact to the environment

The increased used of disposable masks has a had a serious environmental impact globally and the increased usage in Manitoba contributes to this growing environmental issue. We have not observed strong initiative in Manitoba, both in health care or manufacturing, to reduce disposable PPE waste and its potential negative impact to the environment.

Vitacore is identified as a potential manufacturing partner to benchmark best practices against. The company had launched the first single-use mask end-to-end recycling program which was done in partnership with McMaster University and the University of British Columbia. Though a circular economy model, used masks are broken down and re-pelletized so that the re-pelletized materials can be used as a reinforcement in concrete that is then used in construction. Vitacore would be an excellent manufacturing partner to benchmark because of their innovation in circular economy and how the company has successfully leveraged academic support to bring sustainability innovation to PPE manufacturing.



Recommendations



1

Remove Barriers To Clinical Validation

The lengthy validation process for new PPE creates a bottleneck for potential PPE manufacturers and also in the procurement process for government departments. Additional funding to regulators that would allow increased staffing could help alleviate this bottleneck and expedite the innovation process.



2

Create Partnerships With Academia To Support Manufacturing Innovation

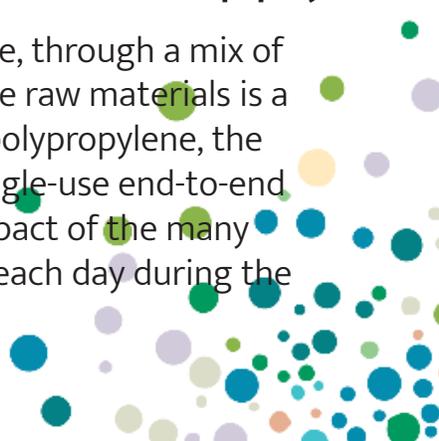
A lack of technical expertise was identified as a reason that manufacturers could not pivot to produce PPE, yet many researchers would have been interested in assisting had they been aware of the opportunity. In the future, greater partnerships between academics and manufacturers could overcome this barrier. An excellent example of this is the Centre for Advanced Manufacturing and Design Technology (CAMDT) at Sheridan College in Ontario, which engages with companies to develop products and support innovation in manufacturing with the assistance of their students. At the start of the pandemic, CAMDT supported ON manufacturers in pivoting to manufacture PPE.



3

Innovate And Mitigate Risk In The Supply

Supply chain risks should be mitigated, where possible, through a mix of domestic and overseas suppliers. Reliance on off-shore raw materials is a greater weakness; there are no domestic sources of polypropylene, the raw material for masks. Other innovations such as single-use end-to-end recycling programs can reduce the environmental impact of the many thousands of masks used and discarded in Manitoba each day during the pandemic.



Appendix A - Respondents

Healthcare

- Shared Health – Manitoba
- WRHA
- BC Health

Academia

- Sheridan College, CAMDT
- University of Manitoba, engineering

Manufacturing

- Canada Goose
- Continental Enterprise
- Deasil Custom Sewing
- EQ3
- GarmaTech
- IBDigital
- Peerless Garments
- Precision ADM
- Western Glove Works
- Winnipeg Stitch Factory
- PriMED
- Cardinal
- Bionuclear Diagnostics
- Stevens
- Vitacore
- Sleepworks Medical
- Schaan Health
- Winner Garment

