

STANDARDS RESEARCH

Realizing A Made-in Canada Pandemic Response Products Ecosystem

Action and Impact

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Executive Summary

Introduction

When the COVID-19 pandemic was declared in March 2020, Canada faced significant challenges in ensuring adequate supplies of products needed to respond to this emergency. This experience revealed important gaps in the Canadian pandemic response products ecosystem. The product ecosystem includes actors across manufacturing and procurement, and end users. It is critical that these gaps be filled to improve preparedness for future emergencies and to create a self-sufficient and sustainable products ecosystem.

In a previous report published in May 2021, we developed 12 recommendations (shown in the Action Items section below) across three domains (quality infrastructure, supply chain, and sustainability) to move towards a self-sufficient and sustainable pandemic response products ecosystem in Canada. A deeper analysis of the recommendations is needed to help facilitate future action.

The objectives of the current report are to understand the feasibility of the 12 recommendations and explore in greater detail what specific actions are needed. Action items, potential impacts and lead actors will be identified when possible. These findings will be aimed broadly at stakeholders across health care, public health, manufacturing, standards development, and government.

Methods

This work was informed by the following main activities:

1. Development of a feasibility assessment framework;
2. A survey of the project advisory panel to prioritize recommendations;
3. Stakeholder interviews;
4. Targeted literature searches aligned to each of the 12 recommendations; and
5. Development of case studies to illustrate key differences between the current ecosystem and a desired future state.

Findings

The survey of the project advisory panel showed that their top three priorities, as scored by urgency and importance, were to support Canadian manufacturers, design products that are recyclable, compostable, or biodegradable, and improve mask design, standards, and guidance. Overall, differences in prioritization scores given to the recommendations were small.

Stakeholder interviews were conducted with 24 individuals with expertise across the three ecosystem domains. Most interviewed stakeholders worked in organizations with a federal perspective. During the interviews, the feasibility assessment framework was used as a guide to address questions of the operational, technical, economic, and scheduling feasibility of the proposed recommendations. These interviews guided the development of action items for each recommendation, shown below.

Action Items

Improve mask design, standards, and guidance:

- Adopt global standards for consumer masks that will facilitate exports for Canadian manufacturers.
- Design masks that address issues including breathability, material transparency, filtration efficiency, and fit.
- Explore new designs and feasibility of alternatives, including elastomeric respirators.
- Develop guidance on mask use that addresses aerosol transmission and/or uncertainty about droplet versus aerosol transmission as evidence emerges (i.e., better understanding of who needs to wear what mask under what conditions).
  - Without concerns of scarce supply, essential workers and health workers may transition to higher-quality masks.

Invest in product testing infrastructure:

- Ensure ongoing federal funding support for new public testing laboratories.
- Expand existing centralized databases describing Canadian lab capacity. The database hosted by the Standards Council of Canada (SCC) lists labs accredited and/or recognized by the SCC. More details could be added to this existing database.
  - An additional centralized database of Canadian labs and institutions with accreditation from other accreditation bodies, and those that are non-accredited, could also be developed to describe their testing capacity and resources.
- Enhance collaborations with university and college labs with product testing capacity and explore the need for support to obtain and maintain accreditation.
- Explore avenues of support for private labs to ensure sustainability and competition for price and services.

Invest in traceability infrastructure:

- Federal leadership is needed on the adoption of global standards and actions on non-compliance.
- Health care leadership is needed to bring health stakeholders together and ensure there is an understanding of the impact of traceability systems on patient safety and quality.
- Draw on experiences of mature sectors such as the grocery industry and on health care examples such as pharmaceutical products and Alberta Health Services (AHS) for medical devices.
  - AHS integration of products into electronic health records (EHRs) such as EPIC are likely of particular interest.
- Encourage adoption of enterprise resource planning (ERP) software.
- Determine costs of implementation and responsibility for these costs, balanced against potential return on investment (ROI).
- Embed evaluation planning into traceability implementation.
  - Draw on scorecards used in other sectors, e.g., pharmaceuticals.

Align regulations and standards internationally:

- Support international harmonization of standards by providing enhanced international leadership in standards development.
  - To ensure Canadian input on international standards, the Standards Council of Canada could support Canadian stakeholders in the personal protective equipment (PPE) field attend international meetings when possible.
- Collaborate with regulatory authorities in jurisdictions outside Canada to reduce barriers to accepting Canadian products and standards.
- Create pre-designed emergency interim orders to be enacted by Health Canada based on pre-defined triggers (e.g., declaration of a pandemic).
- Explore adoption of performance or objectives-based standards.

Redesign the National Emergency Strategic Stockpile (NESS):

- Ensure federal agencies implement changes as recommended by the Auditor General's May 2021 report.
- Conduct a review of the NESS that considers the function of the stockpile (i.e., pandemics versus other emergencies) and develops a short list of critical products.
- For critical products, analyze quantities needed for stockpiling based on supply chain and manufacturing lead times.
- Develop methods for rotating stock held in the NESS, along with data sharing agreements and efficient communications with health stakeholders needing access to the NESS.
- Explore use of virtual stockpiles and/or agreements that would reduce the need for warehousing of physical items but ensure rapid responsiveness by domestic manufacturers in an emergency.
- Use the NESS as a tool to support domestic production by pursuing agreements for the stockpile with Canadian manufacturers.

Update procurement practices:

- Explore movement to centralized procurement offices for provincial health authorities, similar to practices at Alberta Health Services.
- Outside of public procurement, facilitate centralized open procurement marketplaces that connect buyers and sellers of pandemic products, with an oversight body to ensure safety and quality of goods in the marketplace.

Inform demand planning:

- Devote research funding and public sector groups to dedicated modelling of pandemic response product demand under a variety of potential disease profiles.
- Model use of pandemic products to inform purchasing and stockpiling, potentially using traceability data as it becomes increasingly available and shared.
- Encourage regular data collection and surveillance of emerging disease threats (e.g., by use of All Hazards Risk Assessment tools) to identify needed pandemic products.

Develop and maintain diagnostic capacity:

- Address health human resource challenges in the lab sector by investing in training programs for laboratory technicians and technologists.
- Create centralized database hosting information on organizations with diagnostic capacity, including tests available.
- Build on collaborations and relationships developed between hospitals and public health labs during the COVID-19 pandemic, potentially creating new, recurring forums for communication.
- Create framework to evaluate capacity of organizations to pivot to help produce diagnostic equipment or host testing initiatives.

Increase reprocessing of PPE and medical devices:

- Increase adoption of existing reprocessing standards in Canada through voluntary measures in the short term, and in the longer term address federal regulatory enforcement of reprocessing standards.
- Analyze existing capacity for reprocessing in hospitals and through third parties and examine need for further capacity and roles of third-party reprocessing companies.
- Consider expansion of accredited reprocessing training programs and require that reprocessing staff be certified.

Develop pandemic response products that are recyclable, compostable, or biodegradable:

- Provide ongoing support of Canadian small and medium-sized enterprises (SMEs) for the designing and manufacturing of environmentally friendly products through existing innovation/economic development funding bodies.
  - Explore alignment with federal initiatives to eliminate single-use plastic.
- Support can also be given to Canadian SMEs through contracts.
  - More widespread use and acceptance of new mask types may need to be supported by communication and education efforts.
- Explore the opportunity to focus on masks for the public given their significant waste impact.

Support Canadian manufacturers:

- Explore the sustainability needs of companies to continue in this space as demand shifts and ensure that minimum levels of domestic production are maintained.
- Explore adoption of Buy Canadian public procurement policies, in line with trade agreements.
  - Aim to prioritize Canadian manufacturers in agreements for virtual product stockpiles/production lines.
  - Pursue education and communication efforts to ensure equivalent products are procured widely (i.e., change requirements from N95 to N95 or equivalent, e.g., PFE95).
- Implement social and value-based procurement practices, which may overlap with Buy Canadian policies.
- Support export of Canadian products.
  - International alignment of standards and regulations will facilitate exports.

Support innovation and evidence generation for new technologies:

- Provide ongoing support to create an innovative environment in Canada.
- Examine intellectual property (IP) issues related to open-source design and 3D-printing technologies.
- Evolve evidence generation and health technology assessment methods to capture emerging evidence during pandemics and emergencies.
- Give support to evidence generation for structural changes in built environments needed to improve ventilation, sanitization, and disease screening.

Discussion

This report found that support for Canadian manufacturers will be critical to ensuring a self-sufficient and sustainable domestic pandemic response products ecosystem. There are many ways to achieve this support. Simply, buying their products in large, sustained quantities as might occur through large public procurement contracts and agreements is encouraged. There is an opportunity to both support Canadian manufacturers and achieve environmental goals by designing, producing, and using products that are recyclable, compostable, or biodegradable.

Significant progress has already been made in some areas, including domestic product testing capacity, production capacity, and standards development. Stakeholders also highlighted the benefits of increased collegiality and networking during these challenging times. Stakeholders expressed concerns that this progress and momentum may be lost when the pandemic ends.

There are limitations to note in this report. As in the first report, some relevant geographical perspectives were not represented in our stakeholder interview sample. In particular, rural, remote, and Northern stakeholders were underrepresented. It is also possible that use of snowball recruitment methods led to an echo-chamber of similar-minded individuals being interviewed. It is noted, however, that stakeholders came from a diverse range of disciplines, including government, standards development, academia, and manufacturing.

Conclusion

Support of Canadian manufacturers is critical to ensuring a self-sufficient and sustainable pandemic response products ecosystem. This support can be achieved through multiple mechanisms, including prioritizing these suppliers in purchasing, supporting innovation and development, maintaining affordable product testing capacity, and making it easier to export products by aligning international standards and regulations. The need to maintain domestic production capacity can also be balanced with other important objectives, including reducing environmental impacts.



"When the COVID-19 pandemic was declared in March 2020, Canada faced significant challenges in ensuring adequate supplies of products needed to respond to this emergency."

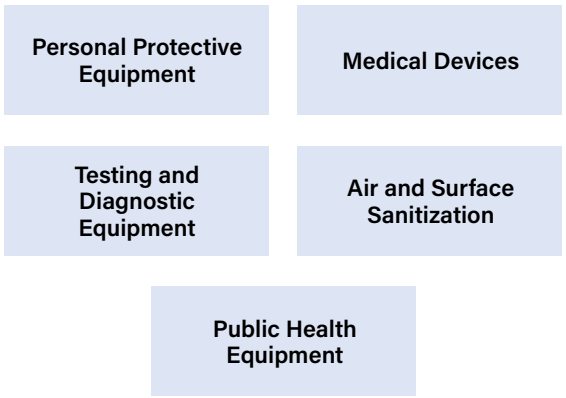
1 Introduction

When the COVID-19 pandemic was declared in March 2020, Canada faced significant challenges in ensuring adequate supplies of products needed to respond to this emergency. This experience revealed important gaps in the Canadian pandemic response products ecosystem. The product ecosystem includes actors across manufacturing and procurement, and end users. It is critical that these gaps be filled to improve preparedness for future emergencies and create a self-sufficient and sustainable products ecosystem [1]. There has been some progress made to address these gaps, and it appears there is fertile ground to build on the lessons learned and on the increased collaboration that emerged between actors across the ecosystem to make meaningful changes.

How can a self-sufficient and sustainable pandemic response products ecosystem be developed in Canada? This question has been broadly posed by many individuals, organizations, and institutions. In June 2020, EKOS conducted a survey of over 1,000 Canadians that was part of a broader syndicated project called Risk Monitor. In the June 2020 survey, the highest priority for expansion of Canada's manufacturing capacity was given to medical equipment, ranking slightly above vaccines and pharmaceuticals and double the scores given to vehicles and communications [2].

In May 2021, we published a research report that characterized the existing pandemic response products ecosystem, identified gaps in that ecosystem, and proposed recommendations to address these gaps [3]. A project framework was developed in collaboration with stakeholders with broad representation across sectors, including health care, public health, manufacturing, standards development, and government. Products included in the ecosystem were classified according to broad categories and included personal protective equipment (PPE), medical devices, testing and diagnostic equipment, air and surface sanitization, and public health equipment (e.g., non-medical masks) (Figure 1).

Figure 1: Functions of products included in the project framework to define the pandemic response products ecosystem



The first report characterized the pandemic response products ecosystem as being comprised of three key domains: quality infrastructure, supply chains, and sustainability (Figure 2). Domains were further defined with relevant subdomains.

Several gaps were identified in the current ecosystem that limit Canada's ability to mobilize a self-sufficient and rapid response to a global pandemic. Identification of gaps was based on a review of published documents and discussions with stakeholders. The first report ultimately proposed 12 recommendations across the three domains to address the identified gaps (Figure 3). While these recommendations were developed based on extensive consultation with stakeholders, a deeper analysis and an assessment of their feasibility, prioritization, and impact is needed to help validate the recommendations in a real-world context and facilitate future action.

The objectives of the current report are to understand and describe the feasibility of the 12 proposed recommendations, and to explore in greater detail what specific actions are needed to move towards a sustainable and self-sufficient pandemic response ecosystem in Canada. Action items and their potential impacts will be identified and discussed, along with lead actors when possible. These findings will be aimed broadly at stakeholders across health care, public health, manufacturing, standards development, and government.

Figure 2: Domains and subdomains included in the project framework to define the pandemic response products ecosystem



Figure 3: Overview of recommendations to move towards a self-sufficient and sustainable ecosystem of pandemic response products in Canada

Providing Quality Infrastructure	**1.** Improve Mask Design, Standards, and Guidance **2.** Invest in Product Testing Infrastructure **3.** Invest in Traceability Infrastructure **4.** Align Regulations and Standards Internationally
Ensuring Adequate Supply	**1.** Redesign the National Emergency Strategic Stockpile **2.** Update Procurement Practices* **3.** Inform Demand Through Enhanced Scenario Planning and Forecasting **4.** Develop and Maintain Diagnostic Capacity
Support Economic and Environmental Sustainability	**1.** Increase Reprocessing of PPE and Medical Devices **2.** Develop Pandemic Response Products that are Recyclable, Compostable, or Biodegradable **3.** Support Canadian Manufacturers **4.** Support Innovation and Evidence Generation for New Technologies

*In the interim between the first and second report, this recommendation evolved from a focus on open procurement marketplaces to procurement practices more generally.

2 Methodology

This work was informed by the following main activities:

1. Development of a feasibility assessment framework;
2. A survey of the project advisory panel to prioritize recommendations;
3. Stakeholder interviews;
4. Targeted literature searches aligned to each of the 12 recommendations;
5. Development of case studies to illustrate key differences between the current ecosystem and a desired future state.

This section provides a brief description of these methods, with further details provided in the Appendices.

2.1 Development of a Feasibility Assessment Framework

A feasibility assessment typically involves a realistic assessment of a new policy, plan, or product, and helps organizations to understand whether to execute the proposed new initiative. A feasibility assessment framework was developed to address questions of the operational, technical, economic, and scheduling feasibility of the proposed recommendations [4], [5]. The potential impact of each recommendation was also considered. Examples of questions asked in the feasibility assessment framework are shown in Table 1. These questions were incorporated into the stakeholder interviews and targeted literature searches. Additional examples of questions are shown in Appendix B.

Table 1: Feasibility assessment framework used to assess recommendations

Feasibility Category	General Question Asked	Specific Questions Asked (Examples)
Operational	Is it allowed?	Are there any legal barriers to adopting made-in-Canada procurement policies?
Technical	Can it be done?	What technical steps are needed to support implementing traceability infrastructure?
Economic	Is it affordable?	What are the up-front costs and potential returns on investment for the recommendations?
Schedule	How long will it take?	What are the short-term and long-term needs for the National Emergency Strategic Stockpile?
Impact	What is the impact?	What are the health and other impacts of implementing this recommendation?

2.2 Survey of the Project Advisory Panel to Prioritize Recommendations

A survey was developed to help inform prioritization of the 12 recommendations. The survey was developed in SurveyMonkey and the link was emailed to the project advisory panel. The 12 recommendations were presented along with a brief description of what they might entail. Respondents were then asked to assign a score for the urgency and importance of each recommendation. A score of 1 indicated lowest urgency/importance and a score of 5 indicated highest urgency/importance. Respondents were instructed that they did not have to distribute their scores (i.e., all the recommendations could be given a score of 5 if desired). The survey was conducted from April to May 2021. It was analyzed with simple descriptive statistics.

2.3 Stakeholder Interviews

Stakeholders with expertise in at least one of the domains and/or recommendations were identified. A "snowball" approach was also used to identify stakeholders, where interviewed stakeholders were asked to identify additional participants. Broad representation in terms of sector, geographic location, and subject matter expertise was desired. A formal interview guide was not used. Stakeholders were shown a short slide deck describing the process of generating the recommendations during the first research phase, the final 12 recommendations and the feasibility assessment framework are summarized in Table 1 and Figure 5 in Appendix B.

Interviews were conducted from February to May 2021. This study received approval from the University of Toronto Ethics Review Office. Participants listed in the acknowledgements section signed a written consent form, and their comments are anonymized.

2.4 Development of Case Studies to Illustrate Key Differences between the Current and Future Ecosystems

Case studies were used to highlight key differences between the current ecosystem and the proposed future ecosystem. Topics for case studies were selected based on products that presented unique challenges during the COVID-19 pandemic, as informed by stakeholder interviews. The content of the case studies was informed primarily by the experience of stakeholders interviewed and supplemented by targeted literature searches.

3 Summary of Results

3.1 Survey of the Project Advisory Panel to Prioritize Recommendations

The survey was completed by 14 members of the project advisory panel. The rank, domain, and mean score for each recommendation is shown in Table 2.

As shown in Table 2, the most urgent and important recommendation was to support Canadian manufacturers, followed by developing products that are recyclable, compostable, or biodegradable. Open text responses indicated that there were synergies

Table 2: Scoring of recommendations, urgency, and importance by members of the Project Advisory Panel

Rank	Domain	Recommendation	Urgency (mean)	Importance (mean)	Combined (Urgency + Importance)
1	S	Support Canadian manufacturers	4.42	4.62	9.03
2	S	Design products that are recyclable/compostable/ biodegradable	4.33	4.38	8.72
3	QI	Improve mask design, standards, and guidance	4.15	4.36	8.51
4	QI	Align standards and regulations internationally	4.00	4.43	8.43
5	SC	Redesign the NESS	3.82	4.31	8.13
6	SC	Update procurement practices	3.83	4.27	8.11
7	SC	Develop and maintain diagnostic testing capacity	3.83	4.15	7.99
8	SC	Forecasting and demand planning	3.75	3.92	7.67
9	QI	Invest in product testing infrastructure	3.62	4.00	7.62
10	QI	Invest in traceability infrastructure	3.38	3.86	7.24
11	S	Support innovation for new technologies and evidence generation	3.33	3.62	6.95
12	S	Increase reprocessing	3.00	3.08	6.08

***Note:** Green = sustainability domain; Orange = supply chain domain; Blue = quality infrastructure domain.

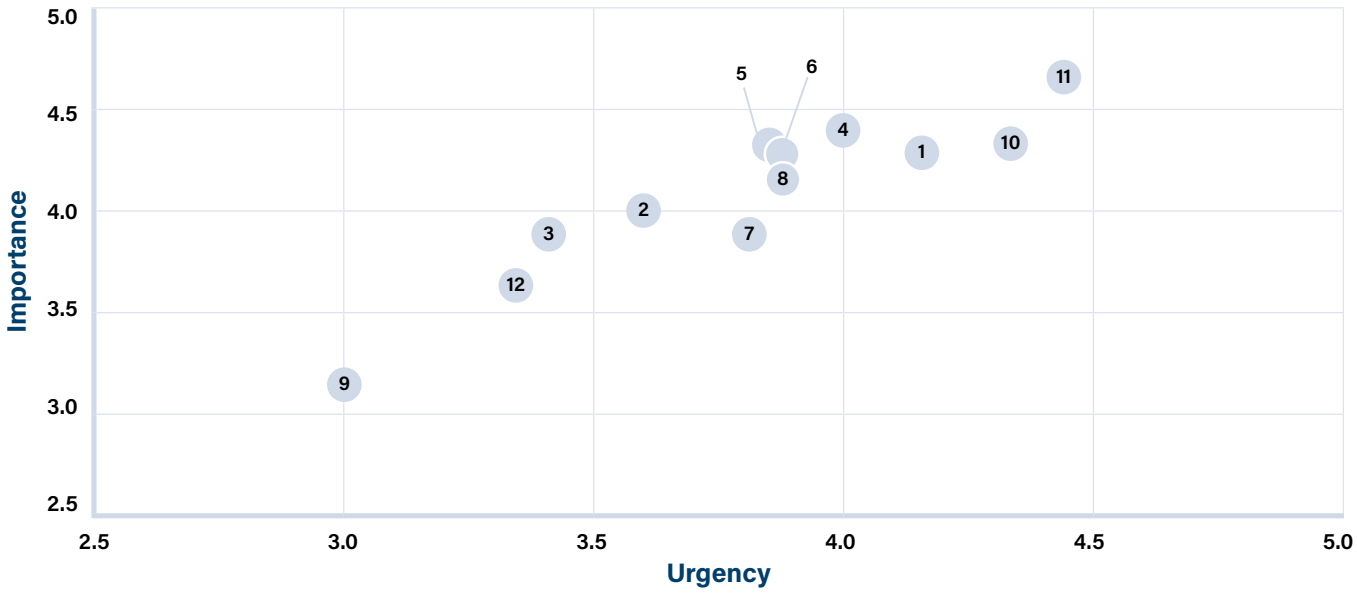
between these two recommendations, as Canadian manufacturers could fill an important market gap by leveraging existing capabilities and expertise to become domestic and global leaders in sustainable product design and manufacturing. The recommendations with the lowest scores were to support innovation for new technologies and evidence generation, and increase reprocessing of PPE and medical devices. Open text responses indicated that since reprocessing of items labelled as single-use introduces several complex challenges, a focus on developing non-single use products and/or recyclable/compostable/biodegradable products may be preferred. It was observed that the top and bottom third of the recommendations (i.e., scores ranked 1–4 and 9–12) were evenly divided between the quality infrastructure and sustainability domains, while the supply chain domains were ranked in the middle third (ranked 5–8).

Visualized graphically, the prioritization of recommendations is shown in Figure 4. The score for importance is on the y-axis, with the score for urgency on the x-axis. The origin was set to 2.5 to enhance visual distinctions between scores; the lowest score was 3.00, indicating that all the recommendations were both urgent and important, and the differences in the rankings were overall small. Importance was always scored higher than urgency, but the differences between the scores were minimal, meaning that recommendations with high importance were also scored as having high urgency.

3.2 Stakeholder Interviews

Twenty-four stakeholders were interviewed. Stakeholders were primarily based in federal organizations (n = 14); five participants worked at organizations based in Ontario, two in Alberta, one in British Columbia, and two were internationally based. Table 3 provides information on participant area(s) of expertise as defined by the three domains included in the project framework (quality infrastructure, supply chain, and sustainability); some interviewees had expertise across multiple domains. Stakeholders who declined to participate, agreed to participate but needed to cancel on short notice and could not be rescheduled, or who did not respond to the invitation were all counted as incomplete (n=12).

Figure 4: Prioritization of recommendations by urgency and importance



Legend:

Domain	Recommendation #	Description
Quality Infrastructure	1	Improve Mask Design, Standards, and Guidance
	2	Invest in Product Testing Infrastructure
	3	Invest in Traceability Infrastructure
	4	Align Regulations and Standards Internationally
Supply Chain	5	Redesign the National Emergency Strategic Stockpile
	6	Update Procurement Practices
	7	Inform Demand Through Enhanced Scenario Planning and Forecasting
	8	Develop and Maintain Diagnostic Capacity
Sustainability	9	Increase Reprocessing of PPE and Medical Devices
	10	Develop Pandemic Response Products that are Recyclable, Compostable, or Biodegradable
	11	Support Canadian Manufacturers
	12	Support Innovation and Evidence Generation for New Technologies

Table 3: Summary of interviews and expertise of stakeholders

	Complete	Incomplete[2]	Total
Total Interviews	24	12	36
Expertise by Domain[1]			
Quality Infrastructure	8	3	11
Supply Chain	14	9	25
Sustainability	7	2	9

1 Counts by domain do not match the total number of interviews, as stakeholders with expertise in more than one domain were counted in multiple categories.

2 Stakeholders who declined to participate, agreed to participate but needed to cancel on short notice and could not be rescheduled, or did not respond to the invitation were all counted as incomplete.

4 Feasibility Assessment of Proposed Recommendations to Move Towards a Self-Sufficient and Sustainable Ecosystem of Pandemic Response Products in Canada

4.1 Providing Quality Infrastructure

4.1.1 Improve Mask Design, Standards, and Guidance

4.1.1.1 Action Items

- Adopt global standards for consumer masks which will facilitate exports for Canadian manufacturers.
- Design masks that address issues including breathability, filtration efficiency, and fit.
- Explore new designs and feasibility of alternatives, including elastomeric respirators.
- Develop guidance on mask use that addresses aerosol transmission and/or uncertainty about droplet versus aerosol transmission as evidence emerges (i.e., better understanding of who needs to wear what mask under what conditions).
  - Without concerns of scarce supply, essential workers and health workers may transition to higher-quality masks.

While all other recommendations are generalizable across product categories, specific concerns with the issues facing masks (including face filtering respirators [FFRs]) necessitated a stand-alone recommendation to improve mask design, standards, and guidance. The issues with masks can also be representative of challenges more generally and will be discussed in additional detail in the case study on FFRs (Section 5.1).

Consumer Masks

Guidance on mask use has evolved significantly since March 2020, with perhaps the most notable changes for the public. As the pandemic progressed, three large jurisdictions moved a motion that required members of the public to wear medical masks [6]. Questions of more effective masks for the public have also been raised in Canada [7], along with calls for updated public health guidance on mask wearing [8].

Unprecedented use of masks by the public has raised several challenges and questions about their efficacy, as well as issues related to comfort that may affect compliance with proper use techniques. Masks that are not surgical grade are called barrier face coverings. As barrier face coverings are not classified as medical devices, historically they have differed widely in terms of material, quality, efficacy, function, and fit, with a lack of prescriptive and comprehensive standards guiding their production. In the first report, standards for consumer masks were called for and, in the interim, ASTM has released the first-ever standard for barrier face coverings and released a white paper on PPE design [9], [10]. It is recommended that Canada align with ASTM (ASTM International F3502-21 Barrier Face Covering Standard) and follow these developments closely. Guidance on consumer masks could be a shorter-term goal with standards as a longer-term goal.

The question of what masks are appropriate in workplaces is also a critical one. In Quebec, a judge ruled that workers in long-term care should wear N95 respirators whether or not they are directly caring for COVID-19 patients, in contradiction of mask guidance from the health authorities [11]. The Bureau de normalisation du Québec (BNQ) released requirements for masks used in workplaces that are unable to meet physical distancing measures [12], [13]. Workplaces might adopt stricter standards for mask wearing than

what is recommended in current guidance as supplies of respirators and medical masks become less strained. It is important that decisions for worker health and safety be made distinct from concerns about mask scarcity [8].

Mask Design

Stakeholders have called for innovations to be made in mask design that would address concerns that have become more apparent with widespread mask use. In addition to common issues of fit, filtration, and efficacy, stakeholders commented that new issues and concerns include the impact of facial hair, transparency of material, smart material, anti-fog properties, and increased distinctions between requirements for masks used in health care settings versus masks used in industrial settings. There is also interest in increased use of elastomeric masks and respirators that do not require fit testing.

Designing masks with transparent material so that mouths can be visualized is important for several reasons. It is important to improve communication for the deaf and hard of hearing population [14]. Wearing opaque masks may create barriers for the deaf and hard of hearing that are incompatible with human rights and accessibility laws [15]. An inability to see people's faces may affect infant and child development. Transparent masks may be critical for people working with these populations to avoid further health consequences [16].

Stakeholders described that work is already being done to produce masks that are recyclable, compostable, or biodegradable, which will be discussed in Section 4.3.2. Recommendations supporting mask design also relate to innovation (Section 4.3.4). It is noteworthy that U.S. President Biden's administration has launched a $500,000 "Mask Innovation Challenge" to eliminate common concerns with consumer masks [17].

4.1.1.2 Potential Impact

It is believed that if higher-quality masks were worn more broadly, disease transmission would be reduced. Use of higher-quality masks by the public and front-line workers may also increase confidence in reopening and returns to work. Masks that are more comfortable may increase compliance with use. A diverse range of mask options also improves supply chain resiliency.

4.1.2 Invest in Product Testing Infrastructure

4.1.2.1 Action Items

- Ensure ongoing federal funding support for new public testing laboratories.
- Expand existing centralized databases describing Canadian lab capacity. The database hosted by the Standards Council of Canada (SCC) lists labs accredited and/or recognized by the SCC. More details could be added to this existing database.
  - An additional centralized database of Canadian labs and institutions with accreditation from other accreditation bodies, and those that are non-accredited, could also be developed to describe their testing capacity and resources.
- Enhance collaborations with university and college labs with product testing capacity and explore need for support to obtain and maintain accreditation.
- Explore avenues of support for private labs to ensure sustainability and competition for price and services.

Significant progress has been made on domestic product testing capacity since the beginning of the COVID-19 pandemic. There is a need to ensure the momentum in this space continues so that domestic testing can be relied upon in the future.

Laboratory Testing and Certification Capacity

In October 2020, CSA Group announced the opening of a new accredited, special-purpose laboratory dedicated to testing and certifying the safety of medical-grade PPE in Toronto [18]. The National Research Council (NRC) has also expanded testing capacity in Ottawa. Stakeholders stated that these recent activities made significant progress in addressing domestic product testing capacity. As noted in the May 2021 Auditor General's report on securing PPE, in addition to federal efforts, private and provincial labs have expanded their testing capacity [19].

Stakeholders stated that more detailed and accessible information about product testing capacity would be beneficial. The SCC currently has online databases hosting information on Canadian product testing facilities accredited and/or recognized by SCC [20], certification bodies [21], and various accreditation programs [22]. The central database offers public-facing testing information that can be used to

identify capacity. Entries for product testing facilities already include details on recognition criteria, date of recognitions, and areas of expertise. More specific information and details could be added to the database to offer third parties essential information on testing approaches, equipment used, and standards implementation.

Stakeholders stated that universities and colleges may have capacity to supplement testing during an emergency. Not all these laboratories, however, are accredited. It is suggested that the SCC database or an alternative database could be designed to also include facilities that are not accredited but could be leveraged during an emergency. This database of non-accredited sites could include similar information as what is available for accredited facilities, but also include information on facility resources such as available equipment and skilled labour that could be shared or accessed during emergencies. Stakeholders also described that university and college labs may have low incentive and funding to pursue accreditation, but that the strategic need for accreditation could be further explored, along with avenues for collaboration and funding support. Stakeholders also had concerns with the ability of such a database to remain up to date.

Product Testing Standards Development

Many stakeholders in the first research phase shared that Canadian firms would benefit from a set of national Canadian testing standards where international standards cannot be adopted and used. This need has been identified by Canadian organizations such as the SCC [23] and could simply be based on adopting some of the international ones (e.g., ASTM) as national standards rather than developing new ones, which could be an added challenge for Canadian manufacturers.

Similar to the progress with laboratory capacity, significant efforts have been made in Canada to create a Canadian standard for FFRs. Canada has developed its own standard for FFRs [24]. New standards can be developed based on existing system principles to reduce technical barriers to trade and acceptance on the international stage. The SCC plays a main role in coordinating conformity assessment activities in Canada and is involved with international organizations developing conformity assessment agreements [25]. New Canadian standards would need to be developed in collaboration with institutions that help assure product reliability and create user confidence.

4.1.2.2 Potential Impact

Product testing and certification are critical activities to assure that quality products are available to Canadians. They are key enablers of domestic production, as well as assuring the safety of imports.

4.1.3 Invest in Traceability Infrastructure

4.1.3.1 Action Items

- Federal leadership is needed on adoption of global standards and actions on non-compliance.
  - Stakeholders suggested that a traceability standard regulation should come from the federal government to avoid barriers to trade between provinces. A national approach is needed and will need to be adopted by the provinces.
  - GS1 standards were suggested as the optimal choice to facilitate global trade.
- Health care leadership is needed to bring health stakeholders together and ensure there is an understanding of the impact of traceability systems on patient safety and quality.
- Draw on experiences of mature sectors such as the grocery industry and on health care examples such as pharmaceutical products and Alberta Health Services (AHS) for medical devices.
  - AHS integration of products into electronic health records (EHRs) such as EPIC are likely of particular interest.
- Encourage adoption of enterprise resource planning (ERP) software.
- Determine costs of implementation and responsibility for these costs, balanced against potential return on investment (ROI).
- Embed evaluation planning into traceability implementation.
  - Draw on scorecards used in other sectors, e.g., pharmaceuticals.



"Stakeholders described a desire from industry for more regulation of traceability standards and a willingness to comply with these international standards."

Prior to the pandemic, clinically integrated digital traceability systems that enable tracing of products from the manufacturer to the patient's bedside were already being called for as a critical tool to improve patient safety, reduce waste, and support inventory management and procurement [26]. In addition to these important benefits, traceability systems are also needed to improve resilience in future emergencies as they provide vital data on product use and quantities.

What is a clinically integrated traceability system, and how is it implemented? A traceability system enables tracking of goods used in health care settings across their entire life cycle [27]. Traceability systems are used in many other sectors such as grocery, retail, and transportation, where adoption of these systems have led to safety improvements [28], [29]. Within the Canadian health care sector, there has been limited progress on the systems-level changes needed to enact traceability systems for medical devices, including PPE, with a notable exception in Alberta.

The required steps to implement traceability systems will be reviewed at a high level in this section, along with lessons learned in Alberta. Key steps to achieving traceability include regulated adoption of global bar code standards, health care system leadership to facilitate adoption and awareness, adoption of ERP software, alignment with electronic health records, and development of evaluation criteria.

Adoption of Global Standards

A foundational element of a traceability system is the use of bar codes that align with international standards. Stakeholders with expertise in traceability recommended that Canadian systems adopt existing technologies, such as GS1 products (other technologies exist, yet stakeholders described GS1 as the one to which industry has predominantly gravitated) [30]. GS1 is a not-for-profit organization that develops and maintains global standards for business communication [31]. Dr. Anne Snowdon, a Canadian expert in supply chain management, previously published a pathway to creating integrated health care supply chains [26]. This pathway also stated that adoption of global standards is the key first step.

Stakeholders described a desire from industry for more regulation of traceability standards and a willingness to comply with these international standards. Decision-makers are also positioned to introduce policy to outline concise routes to compliance [26]. Stakeholders shared that Health Canada is already examining traceability tools and currently looking to conduct consultations on the use of unique device identifiers for medical products. Stakeholders shared that customers sometimes print over labels of received products when performing intake, moving to track the item in a separate internal system. Each stakeholder in the supply chain is not expected to use the exact same traceability system. Instead, systems must be able to use and support standardized data and be built upon a set of standards that allow for interoperability between stakeholders [32].

Leadership and Clinical Integration

End-to-end traceability systems rely on the involvement of several actors, including health care practitioners [26], [30]. Stakeholders identified the essential roles of health care leaders to champion traceability initiatives across the health system. Participants stated that awareness about the importance of traceability standards at the unit level for medical devices and PPE may still be low. Indeed, the prioritization survey of the project advisory panel ranked traceability infrastructure relatively low, although this may have been due to a lack of clarity in the phrasing of the question on traceability in manufacturing versus clinically integrated traceability. While manufacturers appear ready and eager for these systems to be implemented, health providers will likely require additional support with the needed back-end changes.

End-to-end traceability relies on integration with clinical records. The ERP system coordinates resources, information, and activities during business processes in a shared system [33]. These include sales, product development, inventory, and purchasing [35]. By centralizing processes on a single program, institutions enhance coordination and workflow performance and reduce operational costs [35]. The ERP system can be implemented over the short or long term, where the ideal course of action is dependent on the size of the organization, risk tolerance, desired pace of return on investment, and cost [36]. Additional steps are needed in health care to integrate ERP systems with electronic health records. Electronic health records are needed to support a clinically integrated traceability system; however, they do not perform the same functions as the traceability system.

Evaluation

When traceability infrastructure is changed, Canadian firms must actively monitor processes to ensure the system is optimized. Evaluation criteria can be borrowed from sectors that currently have traceability systems in place and actively perform evaluations. Stakeholders highlighted the value of scorecards in the pharmaceutical sector. These evaluations give equal weighting to product price as to supply chain reliability and factors influenced by traceability. Health care experts see comparable value of scorecards for medical products, specifically those that can measure supply chain outcomes [37].

4.1.3.2 Potential Impact

Implementation of a traceability system has implications for patient safety, supply chain integrity, waste, and data gathering [38]. With a traceability system in place, supply chain stakeholders should be able to identify objects and their locations, capture product details, and then share using standardized methods of data formatting [32]. Supply chain stakeholders would also have access to information about the parties involved with manufacturing and distribution, dates and times of processes, and processes undertaken to manufacture or distribute product [32]. Product effectiveness can be shared across stakeholder groups, increasing the odds of identifying adverse events [28]. Some aspects of product recalls can be more easily managed. Data on rates of use for products such as masks can be gathered and used to inform procurement and scenario planning.

The potential impact of a clinically integrated traceability system can be observed in Alberta. Over a decade ago, Alberta Health Services (AHS) centralized procurement and supply chain management under one group. The AHS invested in the necessary software to track use of products, which gave them an early detection signal about use of PPE. This allowed them valuable time to obtain needed products early in the pandemic. As the pandemic progressed, they have been able to rely on actual usage data for critical products to inform procurement and stockpile use. More details on the Alberta Health Services approach to procurement and tracing will be provided in Section 4.2.2.

Improved efficiency stemming from traceability systems is expected to create cost savings. Savings are expected to be distributed along the supply chain, with benefits for manufacturers, distributors, and hospitals. Traceability systems are expected to reduce medical waste, lower supply chain costs, and increase supply chain efficiencies. It has been estimated that 40% of medical products are wasted [39]. Introducing traceability systems also reduces human labour required to perform product recall, inventory costs, and product waste [27]. Other benefits include automated transactions, inventory management improvements, and authentication of medical products [27]. A potential return on investment (ROI) of 4:1–8:1 has been estimated, which is expected to support self-funding of software implementation [40].

Additional case studies of health care systems that have introduced traceability systems reveal substantial cost savings, among other benefits [40]. The National Health System (NHS) in the UK has adopted standards from GS1 and PEPPOL – a set of technical standards intended to improve interoperability [41] – to maintain patient safety. The program is expected to save the NHS £1.5 billion with a 4:1 ROI in inventory savings and £2.4 million for each participating hospital in operational costs, all while improving tracking of medical products [40]. The Mercy Health System (MHS) in the U.S. made changes to its supply chain to improve transparency, relying on GS1 standards that included end-to-end traceability and point-of-care scanning of medical products in hospitals. MHS saw an additional $81 million in revenue growth over four years in two participating hospitals, as well as optimized inventory management and reduced labour costs from point-of-care testing.

Traceability has implications for other recommendations discussed in this report. Stockpiles, including the National Emergency Strategic Stockpile (NESS), would benefit from integrating traceability into inventory management (see Section 4.2.1). Implementing an inventory management system was a recommendation in the Auditor General's report on securing PPE [19]. Traceability also has implications for pandemic preparedness planning (see Section 4.2.3). Data insights gained from traceability systems, such as use patterns and burn rates, can also be used in modelling pandemic scenarios and early signal detection.

4.1.4 Align Regulations and Standards Internationally

4.1.4.1 Action Items

- Support international harmonization of standards by providing enhanced international leadership in standards development.
  - To ensure Canadian input on international standards, the Standards Council of Canada could support Canadian stakeholders in the PPE field attend international meetings when possible.
- Collaborate with regulatory authorities in jurisdictions outside Canada to reduce barriers to accepting Canadian products and standards.
- Create pre-designed emergency interim orders to be enacted by Health Canada based on pre-defined triggers (e.g., declaration of a pandemic).
- Explore adoption of performance or objectives-based standards.

Regulatory frameworks vary between jurisdictions, and this may create barriers to trade. The COVID-19 pandemic has highlighted the need for greater cooperation between regulatory authorities to coordinate standards. International organizations, such as the World Trade Organization, are currently working to align frameworks between regulatory authorities [42]. Aligning regulatory frameworks across countries is difficult and time-consuming, and depends on the goals of those involved. This section highlights cooperative regulatory approaches that can be used to reimagine standards development and ease trade barriers.

International Standards Development and Harmonization

Harmonization with international standards has also been recommended by Canada's Industry Strategy Council [43]. There are several regulatory approaches stakeholders can pursue to ease barriers between jurisdictions. These include harmonized, or shared, standards, equivalence, and accepting results of conformity assessment procedures from a different regulatory body.

There are several key stakeholders involved in coordinating international standard development. Stakeholders shared that Canada has had strong representation in international standards development organizations (SDOs), having held high-level positions at the International Organization for Standardization (ISO) and ASTM International. Moving forward, Canadian representatives are well-positioned to adopt leadership roles in venues for international standards development and advocate for alignment on a global scale. Optimizing standards involves stakeholders who will eventually rely on the standard in their work. Regulatory authorities identify and engage stakeholders that bring technical and political knowledge [44]. The SCC hosts a directory of accredited SDOs with representation in Canada,

including CSA Group and ASTM International [45]. Pre- and post-market researchers assess needs and determine proper approaches to standard design and implementation.

The International Medical Device Regulators Forum (IMDRF) has outlined needs to achieve harmonized standards between jurisdictions [44]. Best practices underscore consensus principles in harmonized standard development. Consensus principles ensure standards receive input from stakeholders across different sectors and that no single party has disproportionate influence on the final standards. New standards should also include key background information (e.g., rationale, risks), measurement criteria, and testing requirements.

Equivalence acts as another significant technical barrier to trade. Rather than aligning standards across countries, equivalence looks to recognize comparable product quality between jurisdictions [42]. The U.S., Canada, and Australia currently have frameworks in place to support regional trade agreements [42]. Agreements can be relied on to accept technical regulations as equivalent, conformity assessment procedures as appropriate, and promote acceptance of international standards. Mutual recognition agreements may also lend themselves to international alignment of conformity standards.

Ensuring quality standards are met while fostering alignment may also be achieved through mutual recognition agreements (MRAs). MRAs are legal or voluntary arrangements between jurisdictions that recognize the legitimacy of conformity assessment processes from one party as meeting regulatory requirements in another [42]. Mutual recognition offers an alternative to harmonization and equivalency [42]. MRAs reduce the number of times a product must be tested for conformity and fast-track availability to the market [46]. MRAs also reduce costs of testing and certification and increase transparency. Canada is party to a number of MRAs for drugs and medicinal products [47].

Coordinating standards across regulatory jurisdictions risks conflicts with existing regulations or regulatory frameworks and difficulties that stem from working towards consensus. A recent OECD regulatory policy paper describes several challenges when working to align international standards [42]. First, depending on the agreement introduced to align standards, there may be additional costs to administer and coordinate regulations. Second, some policymakers may also push back against limitations on their regulatory autonomy and prefer to have complete control over domestic processes. Third, regulatory frameworks are well-established and may create friction between countries.

Performance-Based Standards

Stakeholders suggested that the use of performance-based standards – in place of design standards – as an alternative to traditional standard development. Performance based standards, sometimes termed objectives based standards, specify a desired purpose that must be achieved to permit use and contrast design standards that instead require a product be manufactured according to pre-determined specifications [44]. One interview participant suggested that the use of performance-based standards allows for greater flexibility in product design. In doing so, global manufacturers may find it easier to access different markets.

4.1.4.2 Potential Impact

Reduced barriers to trade increases the ability of Canadian manufacturers to export, which supports their operations and resilience. International harmonization may also allow for more rapid responses to crises. Performance-based standards may also support innovation.

4.2 Ensuring Adequate Supply

4.2.1 Redesign the National Emergency Strategic Stockpile (NESS)

4.2.1.1 Action Items

- Public Health Agency of Canada (PHAC) to implement changes recommended by the Auditor General's report in May 2021 [19].
- Conduct a review of the NESS that considers the function of the stockpile (i.e., pandemics vs. other emergencies) and develop a short list of critical products.



"Virtual stockpiles could involve designing agreements so that production capacity could be held in reserve for emergencies, with agreed upon pivot times, rather than stockpiling physical items."

- For critical products, analyze quantities needed for stockpiling based on supply chain and manufacturing lead times.
- Develop methods for rotating stock held in the NESS, along with data sharing agreements and efficient communications with health stakeholders needing access to the NESS.
- Explore use of virtual stockpiles and/or agreements that would reduce the need for warehousing of physical items but ensure rapid responsiveness by domestic manufacturers in an emergency.
- Use the NESS as a tool to support domestic production by pursuing agreements for the stockpile with Canadian manufacturers.
  - Buy Canadian public procurement policies are explored in further detail in Section 4.3.3.

The COVID-19 pandemic revealed inefficiencies in the NESS, as well as provincial stockpiles. Large portions of products had expired, and responsibilities for product distribution and management were unclear. The shortcomings and recommendations for action have previously been described in detail in the Auditor General's report released in May 2021, and the recommendations presented here are in line with that report [19], [48]. This section outlines main concerns to be considered when making over the NESS, considerations for local stockpiles, and a review of novel approaches that can be adapted from stockpile systems in other countries. These recommendations are aimed at PHAC and Health Canada.

To ensure the NESS fulfills its intended purpose as a bridge to meet demand surges while production is ramped up during emergencies, a top-down analysis of the stockpile is recommended. Bigger picture questions start with what products go into the NESS. Historically, the NESS has had multiple functions, including responding to natural disasters as well as pandemics, and the suitability and quantity of included items for pandemic responses specifically may need to be reconsidered. Consideration should be given to whether stockpiles for natural disasters and other emergencies and stockpiles for pandemics should be separated. For pandemic stockpiles, consideration of multiple infectious disease transmission profiles (e.g., waterborne) is encouraged.

Once critical products have been identified, the quantities needed can be assessed using real world data as well as understandings of times needed for production lines to ramp up. For example, it is understood that moulded plastic products such as face shields can be manufactured readily, with a potential manufacturing pivot time of two weeks. More complicated products would have longer manufacturing pivot/ramp-up times and therefore require additional quantities in the stockpile. Exploring options such as virtual stockpiles has also been advised by stakeholders. Virtual stockpiles could involve designing agreements so that production capacity could be held in reserve for emergencies, with agreed upon pivot times, rather than stockpiling physical items. Dedicated government funding is needed to perform necessary upkeep.

Stock Rotation and Inventory Management

Inventory management practices require updating to enable a rotating stockpile. Modern systems are needed to track quantities of items in the stockpile and expiration dates. The NESS would ideally rotate inventory routinely to ensure items are fresh, up-to-date, and in proper quantities. This may be done by distributing stockpiled items into public and commercial settings before expiry.

The federal and provincial governments could coordinate stockpile rotations with group purchasing organizations (GPOs), or distributors and health care facilities to integrate items from the NESS with local supplies. Rotation systems carry a set of challenges that must be properly evaluated to guarantee stockpile effectiveness. A 2014 Australian National Audit Office report found that only 10 to 15% of P2 respirators (FFRs built to the Australian standard) in the Australian stockpile could be rotated [49]. Marketability of products is one crucial factor in successful stockpile rotations [49]. Domestic health care facilities and local and global markets may be relied on to distribute surplus products. The role of regular disposal of faulty products must also be considered with a rotating stockpile. Identifying products and product quantities that can part of a rotation regimen is outside the scope of this report but will be critical to designing a more efficient stockpile in future. Stakeholders recommended increased research into the shelf life of products and that considerations of shelf life be incorporated into product price considerations.

Stakeholders highlighted the contributions of traceability technology to improve NESS inventory management (see Section 4.1.3 for this discussion of clinically integrated traceability and ERP software). Interview participants reflected on difficulties managing products in the stockpile and knowing which items were available. Traceability infrastructure offers a comprehensive solution to identifying which products are in the stockpile, expiry dates, and lot information. Stakeholders involved with NESS management should be involved in stakeholder discussions to expand traceability technology in Canada. The federal government has already made significant progress with dashboards and data sharing agreements with provinces, and these efforts should be carried forward.

More attention could be given to local stockpiles, including provincial stockpiles and those held by large hospitals. This may be done in collaboration with shared services organizations (SSOs) or GPOs to increase capacity. All stockpiles have the potential to be wasteful in terms of physical space needed, shelf-life concerns, and the logistics of integration into regular use. Increased local stockpiling would need to be balanced against these concerns.

Communication and Best Practices

Interview participants believe that communication is a critical aspect to improving the efficiency of the NESS. The federal government must open communication channels with provinces to actively coordinate resources during a pandemic emergency. Members of federal governmental departments have commented on the lack of clarity of stockpile responsibilities [50]. Similarly, participants involved in the first research phase recalled issues with the NESS that centred on mismanagement. That is, few knew who was responsible for what and which items were in the NESS. An evaluation of the NESS found that stakeholders involved with the stockpile believe that information should be shared across departments and jurisdictions to bolster Canada's emergency preparedness [50]. Data sharing between NESS managers and users will also be needed; stakeholders highlighted that data sharing is a critical element.

Canada can look to emergency stockpile practices in other countries to gain insights on best practices. The stockpile model for PPE in Taiwan demonstrates use of a replacement model and multi-tiered management of stockpile assets. The Taiwan Centers for Disease Control established a three-tier stockpile system following the SARS pandemic. The stockpile system is composed of a central health authority, local health authorities, and medical institutions [51]. Products are moved from a large PPE reserve to small local stockpiles from which they are later distributed [51]. Stocks are replaced with the same product type and quantity as what had been used [51]. Products that are received from suppliers first are also the first distributed. The stockpile model currently used in the U.S. functions similarly. Products in the Strategic National Stockpile in the U.S. are regularly rotated to ensure that stock does not exceed its shelf life.

Stakeholders advised that Canadian manufacturers be prioritized in NESS procurement activities to support domestic manufacturers and suppliers (discussed further in Section 4.3.3).

4.2.1.2 Potential Impact

It is not expected that there would be a significant increase in spending on NESS products following the implementation of rotations. In this model, rotated products are distributed to health care facilities. This assumes that the rotation plan accounts for regular need for the product and the quantity being shuffled out. Other jurisdictions have found that not all items in the stockpile can be efficiently rotated, and it is expected that some degree of waste will occur. Additional costs may arise in the form of logistics such as product distribution, human resources, or routine disposal of faulty items discovered during rotation.

The 2014 ANAO report highlighted two "extreme" risks from rotating inventories. These are contractual failures to send products and deployment delays [49]. In other words, frequent reshuffling of products relies on proper management of stakeholders that manufacture products and distribute along the supply chain. The report identified potential solutions to reducing risk, which include strong contractual agreements, traceability networks, and regular inventory counts.

4.2.2 Update Procurement Practices

4.2.2.1 Action Items

- Explore movement to centralized procurement offices for provincial health authorities, similar to practices at AHS.
- Outside of public procurement, facilitate centralized open procurement marketplaces that connect buyers and sellers of pandemic products, with an oversight body to ensure safety and quality of goods in the marketplace.

There are many opportunities to update and improve procurement practices in Canada. This section will examine the centralization of public procurement, digital technologies, and open procurement marketplaces. Procurement practices are also highly relevant to the recommendation to support Canadian manufacturers; Buy Canadian policies and social and value-based procurement will be discussed in Section 4.3.3.

Procurement Centralization

Centralization of procurement has potential benefits during a pandemic. In 2020, the Ontario government centralized procurement across the Ontario Public Service and the greater public sector to maximize buying power [52]. It is estimated that this could generate total savings of approximately $1 billion annually and improve supply chain efficiency [52]. As previously described, AHS has centralized procurement and this has supported cost savings [40]. The AHS movement to centralized procurement was implemented alongside new data and traceability systems (see Section 4.1.3).

Procurement management practices are shared among other organizations and departments that should be involved in redesigning procurement practices. The Office of the Auditor General, Health Canada's Audit and Accountability Bureau, and the Office of the Procurement Ombudsman are responsible for procurement planning, tendering, acquisition, and closure [53]. In relying on a centralized procurement system, Canadian bodies must ensure that national and international trade agreements are honoured. Domestic and international vendors must be able to access the procurement marketplace, which may require technological infrastructure or labour specializations.

Ideally, public procurement systems should have a central oversight body to review processes and maintain relations between stakeholders [54]. Responsibilities for public procurement system management must be determined by relevant federal bodies such as Health Canada and Public Services Procurement Canada. Health Canada is expected to play a large role in novel procurement activities. Currently, Health Canada collaborates with domestic and international partners when assessing health and safety risks of products [53]. Health Canada has existing infrastructure that can lend itself to a robust procurement system, such as a specialist to review procurement activities and a Contract Review Committee to offer regulatory oversight [53]. These activities align with a recent Health Canada departmental plan to improve post-market surveillance

of medical devices and focus on international inspections of health product licence holders to improve compliance [53]. It is not within the scope of this report to determine which agency should be given authority to manage open procurement marketplaces.

A further discussion of procurement is given in Section 4.3.3, "Support Canadian Manufacturers". Stakeholders described difficulties of new companies, notably domestic ones, in gaining the large public procurement contracts that may provide a solid business foundation. Long contract cycles, inflexible terms, and prioritization of lowest cost may be barriers for the many new PPE and pandemic response product manufacturers in Canada.

Procurement Technologies

In 2017, the Public Spending Forum released the report Public Procurement Technology Landscape reviewing procurement technologies that can be leveraged to improve performance [55]. The Public Spending Forum report highlights several case studies looking at digital procurement technology in California, Virginia, Florida, Portugal, and the country of Georgia. One key takeaway is that employees working in procurement will have to adapt to new processes with support and training. All relevant stakeholders must also be involved in system planning from inception, which may increase support for new systems. Procurement needs and issues should be reviewed on an ongoing basis and involve diverse stakeholders.

Open Procurement Marketplaces

Open procurement marketplaces are important for stakeholders outside of public procurement bodies, and it is important to strengthen these marketplaces in terms of quality oversight and availability. Emergency procurement services, such as COVID PPE Help and the Rapid Response Platform Canada, were introduced during the COVID-19 pandemic to connect vendors selling PPE to buyers in need. Stakeholders in the procurement space believed the emergency buy-and-sell marketplaces had difficulty coordinating a planned response. Multiple procurement markets had been established prior to the COVID-19 pandemic to meet needs of health care institutions. Different marketplaces typically vary in clientele. For example, buyandsell.gc.ca, hosted by Public Services and Procurement Canada, posts opportunities for sellers interested in government contracts [56] whereas HealthPRO Procurement services focuses specifically on connecting stakeholders within health care systems [57]. Stakeholders described that open procurement marketplaces outside of public systems are important but would also require quality oversight and vetting of suppliers to ensure quality.

4.2.2.2 Potential Impact

Centralized procurement systems have shown significant benefits for stakeholders [55]. Improving procurement systems may generate cost savings and improved efficiency, and these benefits would be realized during usual times as well as pandemic emergencies. Centralized systems have been implemented in Virginia (eVA eProcurement) and Florida (MyFloridaMarketPlace) [55]. Benefits include improved data transparency, allowing suppliers to see purchase orders in real time, and reduced need for manual data inputs. Savings varied between states. eVA eProcurement was estimated to have reduced annual administrative costs and increased annual savings on purchased items by $11 million and $30 million, respectively. The MyFloridaMarketPlace saved an estimated $2 million per year from reduced procurement cycles. Online business to business (B2B) marketplaces offer benefits for both buyers and sellers. Buyers are given a wide range of options and sellers gain easy access to buyers [58].

4.2.3 Inform Demand through Enhanced Scenario Planning and Forecasting

4.2.3.1 Action Items

- Devote research funding and public sector groups to dedicated modelling of pandemic response product demand under a variety of potential disease profiles.
- Model use of pandemic products to inform purchasing and stockpiling, potentially using traceability data as it becomes increasingly available and shared.
- Encourage regular data collection and surveillance of emerging disease threats (e.g., by use of All Hazards Risk Assessment tools) to identify needed pandemic products.

Quality data informs decision-makers on best courses of action during a pandemic emergency. Stakeholders stated that epidemiology and modelling expertise in Canada is high, and that challenges with disease modelling and forecasting often relate to data availability [59]. This section considers what embedded research is needed to support ongoing planning and forecasting and improve data inputs.

Building on Existing Modelling Capabilities

Throughout the COVID-19 pandemic, scientists and professionals have convened in groups to create models to inform decision-making. Modelling groups have been active on the federal level (e.g., PHAC modelling group and CanCOVID Network [60], [61]), provincial levels (e.g., BC COVID-19 Modelling Group [62], Ontario COVID-19 Science Advisory Table) [63]), and in non-government institutions (e.g., COVID-19 Modelling Collaborative [64]). COVID-19 models input factors relevant to disease transmission, individual and population factors influencing vulnerability (e.g., age and gender, pre-existing conditions), and strategic policies implemented to reduce virus impact [59]. Multiple scenarios are developed to describe the virus burden given select factors. Ongoing disease surveillance provides more epidemiological knowledge and improves accuracy when advancing models of virus behaviour.

Consideration needs to be given to how resources can be devoted to experts in these areas to continue work through non-emergency times. Stakeholders remarked that it is difficult to sustain pandemic preparedness groups between emergencies and this would require strong leadership from decision-makers in health care to maintain engagement. Stakeholders suggested regular meetings to update approaches to modelling pandemic-relevant information. Regular meetings help with logistical upkeep, ensuring member availability and up-to-date contact information.

Using Modelling to Inform Product Demand

A primary goal of disease modelling is to understand case numbers. It is recommended that modelling efforts also include estimates of health care resource consumption, including products. In two early examples, [65], [66] models were created using disease profile and hospital capacity inputs to determine the impact of public health interventions on health outcomes and the use of pandemic products. The first model links depletion of hospital resources – as an outcome of poor intervention measures – to patient deaths during the COVID-19 pandemic [65], and the second offers a much-needed prediction model for pandemic resource requirements in health care systems [66]. Disease modelling that explicitly addresses resource consumption is needed.

While reasonable estimates of health resource use can be made and used to inform modelling, real world and real time data is important. Stakeholders described that product-use patterns can evolve quickly; for example, PPE requirements may go down when communication technologies (i.e., walkie-talkies, baby monitors, iPads) are distributed to isolated patients to reduce in-person contact with health care workers. Changes such as these demonstrate why it is important to have insight into real-world burn rates for PPE and medical devices, which may be offered through improved tracing and inventory management systems.

Stakeholders described a need for additional ongoing modelling activities. Impacts outside of the health care system, such as in schools and essential workplaces, require explicit consideration in forecasting demand. Consideration of public institutions and essential workplaces in modelling and forecasting is important. Modelling of different disease profiles is also important. Stakeholders stated that there are regular threats that may lead to an outbreak, and it is difficult to track each one. Developing models that address a variety of transmission modes and other factors could help address uncertainty.

Venues must be established for experts to model new significant disease threats when identified. The All Hazards Risk Assessment (AHRA) methodology and the Capability Based Planning (CBP) system can be adapted by researchers to identify and prepare for risks as they emerge. The AHRA methodology has been developed by Public Safety Canada in partnership with Defence Research and Development Canada's Centre for Security Science. The assessment provides tools to identify, analyze, and prioritize potential and emerging



"While reasonable estimates of health resource use can be made and used to inform modelling, real world and real time data is important."

threats [67]. Threats are assessed on an annual basis and findings are made available to decision-makers. CBP is utilized by the Canadian Armed Forces to identify methods of responding to potential threats [34]. Planning initiatives prepare relevant stakeholders for generic threats, identifying gaps in tasks needed to ensure national security. This can be adapted by pandemic planning groups to actively review emerging pathogen threats and coordinate with stakeholder bodies that could engage in pandemic mitigation efforts.

4.2.3.2 Potential Impact

Traceability infrastructure can inform modelling and demand forecasting. As outlined in Section 4.1.3, traceability infrastructure aggregates historical data on product use and can be used as an input in prediction models to determine needs in future pandemics. Health Canada has developed novel dashboards that could inform modelling. Models are more useful when they are based on high-quality data inputs. Key priorities for research and governments are to maintain embedded capacity for modelling activities to understand product demand, and to evaluate the risk of emerging threats, ideally at the federal level.

4.2.4 Develop and Maintain Diagnostic Capacity

4.2.4.1 Action Items

- Address health human resource challenges in the lab sector by investing in training programs for laboratory technicians and technologists.
- Create centralized database hosting information on organizations with diagnostic capacity, including tests available.
- Build on collaborations and relationships developed between hospitals and public health labs during the COVID-19 pandemic, potentially creating new, recurring forums for communication.
- Create a framework to evaluate an organization's capacity to pivot in order to help produce diagnostic equipment or host testing initiatives.

Canadian labs have experienced challenges meeting the demand for diagnostic tests during the COVID-19 pandemic. These include shortages of essential testing items (e.g., swabs) and personnel who could carry out procedures [68], [69], [70]. This section explores options to bolster capacity for diagnostic testing in Canada.

Health Human Resources in the Lab Sector

The COVID-19 pandemic worsened existing staffing constraints at testing facilities [71]. Staff were required to take on additional logistical, training, community outreach, and data analytical responsibilities; work extended hours; and provide support to non-traditional testing sites [71]. Medical laboratory technologists (MLTs) and medical laboratory assistants (MLAs) are two key front-line staff in diagnostic testing. MLTs perform various medical tests on samples, and MLAs perform pre-analytic tasks such as collecting and processing samples and working with testing chemicals [72], [73].

A key issue in the lab sector is health human resources. In 2010, the Canadian Institute for Health Information (CIHI) reported that nearly half of MLTs would be eligible to retire within the next decade [74]. To compensate for lost workers, approximately 400 additional student spots must be added to MLT programs [75]. Stakeholders remarked that MLTs typically require three to four years of training. Changes must be made in the short term to be prepared for the next pandemic.

Training of lab staff may require adjustment in a changing landscape. Clinical placement opportunities for students have decreased over the years due to a lack of financial capital, a lack of training resources, workload expectations, and staffing shortages [75], [76]. Some of these issues have been previously identified by academic institutions and employers [76]. The Canadian Society for Medical Laboratory Science (CSMLS) has suggested that revised curricula and educational models specific to the needs of different institutions can help train students for positions as MLTs and MLAs [76]. These include reductions in clinical placement hours (and/or replacement of front-line hours with simulations) and models that allow more students to participate in clinical environments (e.g., buddy system training) [76].

Products Used in the Diagnostic Process

Supplies of products used in the diagnostic testing process, such as swabs and reagents, were insufficient. An Ontario Health document found 15 items used for diagnostic testing had a medium or high risk of running out [68]. The federal government turned to domestic sources of diagnostic products to supplement supplies and newly signed contracts with plastics and technology companies [68]. Stakeholders in the diagnostics space reported challenges finding companies that could pivot to testing during a pandemic emergency. Companies that pivoted to producing diagnostic products faced challenges in rapidly meeting shifting regulatory requirements. Challenges related to pivoting are further discussed in the section on supporting Canadian manufacturers (Section 4.3.3, while swabs are the focus of a case study in section 5.3).

Coordination and Collaboration

Additional efforts to coordinate responses from the diagnostic sector may also come from non-governmental organizations. The Canadian Public Health Laboratory Network (CPHLN) is a national association in Canada that brings together public health laboratory professionals and represents members' needs [77]. The CPHLN is well-positioned to play a key role in improving diagnostic capacity in Canada. The CPHLN's 2016–2020 strategic plan outlines priorities for the organization [78]. This includes guidance documents for sharing data between laboratories, guidelines for emerging and unknown pathogens, and sharing best practices between laboratories [78]. Some priorities have been advanced through recent CPHLN reports [77]. Remaining priority areas and further advancements should be shared regularly.

The 2018 CPHLN report suggested the creation of a centralized database hosting information on testing services and practices in Canadian laboratories [78]. The CPHLN is an ideal lead actor for this initiative. Provincial testing bodies currently feature public data on testing services (e.g., Public Health Ontario Laboratories and Provincial Laboratory for Public Health Alberta) [79], [80]. The CPHLN and provincial testing bodies can coordinate integration of testing information into a platform that creates easy access to testing service and product details. This information will bolster diagnostic planning efforts.

In developing national testing strategies, the Center for Infectious Disease Research and Policy highlights the need for an expert panel at the federal level to identify key actions [81]. Although not a panel, the CanCOVID Network connected health professionals working in research and policy to collect and share information to improve the response to COVID-19 [61]. The network includes professionals with expertise in diagnostics and vaccines and therapeutics, as well as modelling and clinical trials. The expert panel and/or CanCOVID Network can be maintained according to the recommendations in Section 4.2.3.

4.2.4.2 Potential Impact

The Canadian laboratory sector is thought to have suffered from historical underfunding. Addressing capacity issues in the Canadian lab sector may enable repatriation of some tests that are currently sent internationally in non-emergency times. Seizing on the current momentum in the lab sector could lead to important benefits after the current pandemic.

4.3 Supporting Economic and Environmental Sustainability

4.3.1 Increase Reprocessing of PPE and Medical Devices

4.3.1.1 Action Items

- Increase adoption of existing reprocessing standards in Canada through voluntary measures in the short term, and in the longer term address federal regulatory enforcement of reprocessing standards.
- Analyze existing capacity for reprocessing in hospitals and through third parties, and examine need for further capacity and roles of third-party reprocessing companies.
  - Traceability systems for reprocessed items are a key start-up cost item for hospitals expanding or launching a reprocessing program.
- Consider expansion of accredited reprocessing training programs and require that reprocessing staff be certified.

Reprocessing refers to the "cleaning, sanitization, disinfection, decontamination, and/or sterilization of devices and equipment in health care settings" [82]. It is important to consider the quality, consistency, and efficacy of reprocessing practices, particularly in light of the pressures faced in this sector during the pandemic [83], [84]. There are distinct considerations of the feasibility of reprocessing products intended to be reused and those labelled as single-use. This recommendation primarily focuses on reprocessing of single-use devices.

An increased reliance on single-use medical devices has led to environmental and public health harms, supply chain disruptions, and greater health care expenditures [83]. Reprocessing, therefore, has important implications for the creation of more economically and environmentally sustainable health care systems and circular economies [85], [86]. Reprocessing items labelled as single-use, however, introduces a range of safety, legal, and ethical issues [82].

Regulatory Framework

The regulatory framework for reprocessing single-use medical devices and PPE needs strengthening. Regulatory oversight of single-use reprocessing is needed at the federal level in Canada and has long been advocated for by specialists in the area. Stakeholders described that while Canadian and international standards and guidelines for reprocessing single-use devices exist, they are voluntary and this creates inconsistencies in compliance, efficacy, and quality [87], [88]. In 2013, Medtech Canada (previously MEDEC) asserted that reuse and reprocessing of single-use medical devices by health care facilities or third-party reprocessing companies should be regulated by Health Canada as per Canada's *Food and Drugs Act* and Medical Devices Regulations [89]. An increased understanding of liability issues and risks related to faulty reprocessing will be important as the practice is increased.

Reprocessing Capacity

Expanded reprocessing requires an evaluation of capacity. While hospitals typically have in-house reprocessing sites, these sites may require expansion. In addition to physical capacity, a tracking and tracing system is also needed for reprocessed items. When the item is reprocessed, it becomes the product of the reprocessing facility rather than the manufacturer. New bar codes or labels are needed to indicate reprocessing dates and other information such as number of uses. These tracking and tracing systems would ideally link with other inventory systems as well as patient records (as described in Section 4.1.3 on traceability). Stakeholders relayed that these systems require an up-front investment from hospitals, in the range of CAD$250,000 to $500,000 per hospital.

Consideration needs to be given to what extent third-party reprocessing companies are required to support reprocessing outside of large hospitals. Third-party reprocessing companies have a limited presence in Canada compared to other jurisdictions such as the U.S. [82], although it is believed that their presence in

Canada has increased during the pandemic as new partnerships were made during the crisis. Existing third-party reprocessing companies are all U.S. multinationals, to date there is not one Canadian reprocessing organization. Items to be reprocessed must typically be transported across the U.S. border and back.

Certification and Training

A lack of consistent formal training within Canada's reprocessing sector was identified by stakeholders as an action item. Courses, programs, and certifications are offered by post-secondary institutions and standards organizations (e.g., the Certified Medical Device Reprocessing Technician [CMDRT] Personnel Certification, developed by CSA Group and Canadian medical device reprocessing experts) [90]. Stakeholders noted that due to lack of regulation, facilities may hire staff who do not hold training certificates. This may lead to issues with quality. Strengthening enforcement of training requirements or transforming reprocessing into an accredited profession may help address this challenge [90]. An analysis of training programs in this field may be needed to ensure there is sufficient capacity to meet the growing need in certified reprocessing staff.

4.3.1.2 Potential Impact

While there are regulatory and technical barriers to expanding reprocessing of single-use devices, there is a strong base of expertise and practice in this area in Canada. Stakeholders stated that although one-time capital investments to address capacity may be required, and significant changes may take five to ten years to be realized, a greater reliance on reprocessed medical devices would result in cost savings and environmental benefits [91]. Prior to the pandemic, the Association of Medical Device Reprocessors (AMDR) reported that reprocessing in North America and Europe led to lower hospital solid-waste production by almost 7,100 tons, and greater cost savings of at least US$470 million for device users in 2018; these estimates did not give particular consideration to PPE [83]. Although use of single-use medical devices may appear less costly in the short term, the lifetime cost of reusable devices is often significantly lower over the long term [83], [92], [93]. Expanding reprocessing and moving towards a circular economy could also help achieve some of the United Nations Sustainable Development Goals (SDGs), according to a 2018 World Health Organization (WHO) European Region report [94], [95].

Transforming the medical device industry from a linear economy to a more circular economy where "products are maintained in use at the highest-value application for as long as possible without terminating in disposal" is a worthy objective [83], [96]. Reprocessing is one component of a circular economy, among others. In a circular economy, manufactured products cascade through a regenerative cycle where material value is maximized and waste disposal is minimized [83]. A transition to a circular economy is not simple; to quote MacNeill et al.: "Achieving a circular economy in health care will require systemic transformation with buy-in from device consumers, original equipment manufacturers, regulators, accreditors, and professional standards organizations alike. This will require the introduction of complementary market- and policy-based solutions toward the shared objectives of eliminating waste and maximizing material and societal value" [83]. Canada can learn from other jurisdictions, such as the European Union's Circular Economy Action Plan [83], [97].

4.3.2 Develop Pandemic Response Products that Are Recyclable, Compostable, or Biodegradable

4.3.2.1 Action Items

- Ongoing support of Canadian small and medium-sized enterprises (SMEs) designing and manufacturing environmentally friendly products through existing innovation/economic development funding bodies.
  - Explore alignment with federal initiatives to eliminate single-use plastic.
- Support can also be given to Canadian SMEs through contracts.
  - More widespread use and acceptance of new mask types may need to be supported by communication and education efforts.
- Explore opportunity to focus on masks for the public given significant waste impact.



"Existing efforts in Canada to research and develop biodegradable products should be supported and advanced."

Increased consumption of pandemic response products during the COVID-19 pandemic has led to strained supply chains and higher amounts of plastic and medical waste generated globally [98]-[100]. Greater product use and improper disposal have and will continue to negatively affect natural biota, agriculture, and fisheries as well as human and animal health [101]. To address these challenges, pandemic response products that are recyclable, compostable, or biodegradable should be developed and adopted. In addition, development of responsive and innovative waste management systems should be further explored, however the scope for this analysis of waste management was not available in this report.

Use of biodegradable masks is particularly important for the public. Surges in consumer PPE use has led to increased litter in public settings (e.g., streets, parks, and rivers [100]). Stakeholders stated that biodegradable masks for public use specifically should thus be prioritized. Shelf-life concerns about biodegradable products have also been raised, which may pose challenges if these products were stockpiled. Shelf-life management concerns may be ameliorated by adoption of traceability technologies as described in Section 4.1.3.

An Opportunity for Canada to Lead

Existing efforts in Canada to research and develop biodegradable products should be supported and advanced. The recent development of a single-use biodegradable face mask made from plant fibre [102], [103] is an example of a current initiative underway. Referred to as Canadian-Mask or Can-Mask, the fully compostable and biodegradable mask was developed by Canadian researchers using locally sourced materials [102], [103]. The researchers have stated that the mask materials could also be used to construct other products such as gauze [103].

There have been several federal initiatives in this space. In October 2020, Innovation, Science and Economic Development Canada (ISED) launched two business challenges for Canadian SMEs interested in developing compostable masks and recycling technologies for single-use PPE [100], [104]. In February 2021, Canada's Minister of Natural Resources announced a $3.3-million investment allocated to a Canadian company to further develop their non-medical biodegradable and environmentally friendly single-use mask [105]. Environment and Climate Change Canada is supporting a project run by the Canadian Coalition for Green Health Care on "Reducing Health Care-Related PPE and Medical Single Use Plastic Waste Through Circular Economy Principles" [106].

Stakeholders noted that as environmentally sustainable technologies and domestic capacity already exist in Canada, future efforts should focus on accelerating research related to scaling up technology production and distribution. Scaling up production is also likely to lower market and manufacturing costs. Stakeholders described inflexible procurement practices that make it difficult for new products and smaller batches to gain contracts. They also described brand preferences for certain products that lead to less diversity in product

use, which would need to be addressed with education efforts to ensure users have confidence in product equivalence and efficacy. These issues are discussed in more detail in sections on procurement and mask design but are also relevant for new environmentally friendly products.

4.3.2.2 Potential Impact

Manufacturing recyclable, compostable, and biodegradable pandemic response products has several benefits. Through use of locally sourced materials and facilities, there is a potential for the widespread adoption of a "made-in-Canada" biodegradable mask that supports domestic manufacturing and economic development. There is already significant Canadian expertise in these technologies that could position Canada as a future leader in this product category. There is a synergy between this recommendation and the recommendation to support Canadian manufacturers (Section 4.3.3).

Widespread use of more environmentally friendly masks would also advance UN SDGs such as SDG 3: Good Health and Well-being and SDG 12: Responsible Consumption and Production [103] among others. The UN Environment Programme estimates that the annual financial cost of plastic waste to industries such as tourism and maritime transport is approximately $40 billion globally [107]. Scaling up quality and environmentally friendly masks may lead to cost savings in other sectors and support overall health and wellness in Canada.

4.3.3 Support Canadian Manufacturers

4.3.3.1 Action Items

- Explore the sustainability needs of companies to continue in this space as demand shifts and ensure at least minimum levels of domestic production maintained.
- Explore adoption of Buy Canadian public procurement policies, in line with trade agreements.
  - Aim to prioritize Canadian manufacturers in agreements for virtual product stockpiles/production lines.
  - Pursue education and communication efforts to ensure equivalent products are procured widely (i.e., change requirements from N95 to N95 or equivalent, e.g., PFE95).
- Implement social and value-based procurement practices, which may overlap with Buy Canadian policies.
- Support export of Canadian products.
  - International alignment of standards and regulations will facilitate exports.

Canada must ensure it has adequate domestic production capacity over the long term. Similar to other advanced economies, manufacturing in Canada has markedly declined since the early 2000s [108]. Currently, manufacturing represents approximately 10% of Canada's gross domestic product (GDP) [109]. Research has shown that manufacturing decline has contributed to wage stagnation and loss of quality jobs [110].

A lack of domestic production capacity was notable for critical PPE products early in the pandemic; more recently, a lack of domestic vaccine production capacity has been a topic of national policy action [111], [112]. The associate assistant deputy minister at ISED emphasized the value of domestic production in a National Post article: "If I was taking a lesson away from this, it's really you never want to be a country that can't build things … It's really important to be able to make things in a country" [113].

Many domestic companies have pivoted or massively scaled up their production of pandemic response products, but it is well recognized that peak levels of demand will not continue. Canadian manufacturers face many challenges, such as the need for late-stage growth capital [114], [115]. Embracing policies aimed at increasing opportunities for these firms should be further explored. This recommendation examines how support for Canadian manufacturers can be advanced through changes to procurement policies and other types of agreements.

Shaping Domestic Production through Strategic Procurement

Explicit Buy Canadian public procurement policies have been suggested by stakeholders as one pathway to supporting Canadian manufacturers. In doing so,

procurement officials must ensure procurement-related obligations outlined in existing domestic or international trade agreements are met (e.g., [116]). Additionally, companies that were given government aid as part of the COVID-19 response should be required to move and sustain a minimal (but economically significant) percentage of their sourcing and production back to Canada. A key challenge is defining "Made in Canada"; stakeholders describe that complex supply chains will still rely on foreign inputs and materials, and this is not expected to change in the short term.

Rigid procurement practices may hinder the ability for Canadian SMEs to win contracts vital to their survival. Looking at one product category, in this pandemic we saw that a preference for the N95 mask led to significant challenges in access to FFRs. Stakeholders described that several organizations, even in 2021, still require an N95 mask and are not purchasing equivalent products such as the Canadian-made PFE95. Stakeholders emphasized the need for procurement RFPs to open requirements for FFRs to N95s or equivalent. This may require working with unions and occupational health and labour groups to ensure that workers and their representatives understand that they are protected by N95 equivalents. Diversifying supply chains by working with multiple suppliers of critical products can help build resilience [110].

Stakeholders described social procurement (also termed sustainable procurement) as a promising practice that government and other institutions can undertake to achieve multiple policy objectives, including support of domestic manufacturers. Social procurement can be defined as "leveraging existing procurement spending to create a social value" [117]. These initiatives use government buying power to drive broader value and may enable greater opportunities for domestic companies. During procurement cycles, points may be awarded to contract bidders for domains such as environmental and labour practices. International standards for guiding sustainable procurement were established in 2017 through ISO 20400 [118]. Public and private institutions across several jurisdictions have implemented social procurement policies, including in Scotland [119], Victoria Government, Australia [120], the UK [121], [122], and the City of Toronto [123], to name a few.

There is also a growing body of literature focused on widening considerations of value within health care procurement to support better outcomes – termed value-based procurement (VBP) [124]. Although it differs based on type of purchase, health care procurement has traditionally been driven by narrow price-based sourcing strategies [124]. Stakeholders highlighted the importance of VBP, which focuses on applying a more holistic evaluation during the purchasing of goods and services to enable better long-term outcomes. Considerations around price are not omitted under this paradigm; rather, VBP extends criteria to include other forms of value such as improved quality of life [124]. In Ontario, VBP was recommended by experts in 2014 and 2017 reports, indicating an interest in advancing a more holistic approach to procurement [125]. Moving away from purchasing decisions based solely on price may support Canadian firms to be more competitive, although Canadian firms may also be competitive on price as well.

Barriers to implementation have inhibited advancement of value-based and social procurement across Europe and North America. A 2009 literature review identified limited organizational capacity, lack of knowledge, and complexity in assessing social value as some of the barriers for implementing social procurement [126]. A 2018 Deloitte report identified key barriers to implementing VBP as organizational immaturity, low health care provider capacity, lack of experience among suppliers, and complexities with qualitatively measuring value (e.g., patient comfort) [124]. A 2017 report submitted to the Ontario government describes a lack of clarity within existing procurement guidelines and health care silos as an impediment to VBP implementation [125].

There are a range of best practices for implementing VBP and social procurement that have been described in the literature. The Deloitte report suggests adopting the following best practices to overcome these barriers: a focused approach where purchases are prioritized based on factors such as potential impact, complexity, and readiness for change; a step-by-step methodology that is adapted based on needs; and supporting multidisciplinary collaboration as well as openness to change among internal stakeholders. MedTech Europe has also recommended similar practices to advance VBP in health care settings [124].

4.3.3.2 Potential Impact

There are many benefits to having a stable domestic production base in Canada. Relying solely on imports for several critical products left Canada extremely vulnerable at the beginning of the pandemic, and this must not be repeated. As previously highlighted, manufacturing jobs are typically well paid and support other sustainability goals.

Implementing social procurement and VBP can facilitate long-term positive impacts across economic, environmental, and social lines. A 2017 analysis of procurement reforms within the Ontario health care system, including VBP, estimated that reforms would result in cost savings of at least $500 million annually [125]. The report highlights cost-savings of up to 8% associated with adopting VBP in other jurisdictions. A 2018 McKinsey & Company report estimated that a medium-sized medical technology company in Europe can achieve 2.5 to 5.0% economic growth over a three-year period through proactive investment in VBP [127]. In Spain, Catalonia health authorities used a VBP approach to procure cardiac medical devices, resulting in various benefits including reduced hospital visits and improved patient experience [125].

4.3.4 Support Innovation and Evidence Generation for New Technologies

4.3.4.1 Action Items

- Provide ongoing support to create an innovative environment in Canada.
- Examine intellectual property (IP) issues related to open-source design and 3D-printing technologies.
- Evolve evidence generation and health technology assessment methods to capture emerging evidence during pandemics and emergencies.
- Give support to evidence generation for structural changes in built environments needed to improve ventilation, sanitization, and disease screening.

Innovative technologies offer new approaches to mitigate pandemic impact and improve health outcomes. Innovation support and incubation has been an area of policy focus in recent years [128], [129]. It is important to address ongoing challenges related to creating an innovative environment in Canada, such as supporting scaling and addressing IP issues. Major innovations and structural changes to improve ventilation, cleanliness, and enhanced disease screening in public spaces and workplaces will require additional efforts and evidence to advance.

Creating an Innovative Environment

In 2017, the Government of Canada committed to spending $950 million over five years to support business-led superclusters with the largest potential for growth and innovation [130]. A 2020 report from Canada's Industry Strategy Council outlines recommendations to build innovation and support evidence generation for new technologies at the macro level [43]. To strengthen Canada's R&D and innovation ecosystem, actions such as strengthening Canada's Digital Charter and IP strategy and modernizing government programs to promote short- and long-term investments in innovation and R&D are recommended [43]. For the health/biosciences sector, in particular, activities such as streamlining and measuring regulatory approval processes against international actors to enable more efficient entry of innovative products into the domestic market are recommended [43]. The federal 2021 budget announced billions in new funding to support innovation [131].

Although Canada has strong research and development (R&D) capabilities and ranks relatively high on measures such as early-stage entrepreneurial activity, issues such as the inability of Canadian companies to grow to scale persist [43], [132]. Compared to OECD peers, Canada ranks relatively low on indices of innovation such as enforcement of IP regimes, and adoption of robotics and e-commerce [43, 132, 133]. Emerging technologies face additional burdens between inception and introduction to the market. To address these and related challenges, action is required across sectors and at various levels. National partnerships of health organizations are already emerging to address market access challenges for innovative Canadian products, such as the CAN Health Network [134].

Standardization plays an important role in fostering innovation and evidence generation for nascent technologies. The SCC launched its Innovation Initiative in 2017 to assist Canadian innovators with leveraging the standardization system to amplify their organizations' growth. The initiative outlined a pathway with four key steps (preparation, proposal, development, and adoption) and grouped key actors into three entities (government, industry, and standardization) [132]. These efforts were amplified during COVID-19 [132].

Government funding opportunities could be introduced to help address some of these challenges. Stakeholders noted that evaluation capabilities for smaller and newer companies could be enhanced at all levels of government to better direct investments. The process of developing, testing, and scaling innovation to achieve a sustainable impact requires buy-in and support from actors across the value chain (e.g., research institutions, government, and incubators and accelerators) [135]. Funding opportunities could be introduced for facilities manufacturing and/or distributing nascent technologies to facilitate networking, development, and scaling. Evidence generation and technology assessment bodies, such as the Canadian Agency for Drugs and Technology in Health, will need sustained funding to be able to innovate their methods and ensure responsiveness during emergencies [136].

Specific Technologies Combatting Infectious Disease

Many relevant technologies to detect infectious disease and create cleaner environments are used in other jurisdictions but have not yet been widely adopted in Canada. For example, despite being widely adopted in Asia following the SARS outbreak in 2003, thermal scanning has only been used in some Canadian airports following the pandemic [137], [138]. UV robotic sanitization is also more widely used outside of Canada [139]. While these technologies may not have proved to be effective against detecting and limiting COVID-19, they may be critical for different viruses. There is also a need for improved ventilation and building design; a cleaner indoor has additional benefits beyond limiting infectious disease spread, particularly in schools [140], [141]. The embedded nature of these technologies means they can't easily be put in place in a reactive nature to future pandemics, and sustained attention and investment is needed [142].

Additional evidence generation regarding the effectiveness of embedded technologies against infectious disease, such as ventilation, thermal scanning, UV sanitization, and other robotics in the Canadian setting, may be needed to inform policymaking processes and health technology assessments. Evidence generation would ideally incorporate flexibility for unknown pandemic profiles. Thresholds for adoption and implementation of new technologies during a pandemic may also merit consideration by evaluation and assessment bodies. Improved ventilation, and overall cleaner workplaces and public settings, are needed and will be expected by returning workers [143]. Optimal implementation of these changes will require significant considerations across different government funding silos and the private sector.

4.3.4.2 Potential Impact

Stakeholders described the importance of supporting innovation and evidence generation that has the greatest potential for impact and success in a competitive global marketplace. Canadians firms describe that investment in advanced manufacturing technology is needed for them to make a high-quality product that is competitive among outside bidders [111]. Strengthening the innovation policy ecosystem could increase the number of available medical products. For example, a study from 2021 suggested that public funding increases pharmaceutical R&D in public institutions [144].

5 Case Studies of Key Products Illustrating Differences between Current and Future Ecosystems

Case studies demonstrate differences between the current state of the ecosystem and a desired future state. In the future state, concepts are mapped to the corresponding report recommendation.

5.1 Case Study: Face Filtering Respirators for Health Care Workers

Current State

- N95s are the preferred FFR.
  - N95s are FFRs built to NIOSH (U.S.) standards.
- Some groups will not accept products that are equivalent to N95 FFRs.
  - Awareness of equivalent products is low.
- FFRs are single-use items and are not reprocessed except in emergencies.
- FFRs require fit testing to be effective.
- FFRs are stockpiled, but inventory is not rotated.
  - Insight into burn rates and distribution of FFRs throughout the health system is limited.
  - Stockpiles contain expired products due to lack of inventory management and rotation.
- Guidelines on use of FFRs limit use to workers treating patients with COVID-19 performing specific procedures.

Future State

- There is a stable base of Canadian manufacturers producing PFE95s. These firms supply organizations across Canada through procurement contracts. PFE95s are not only accepted in Canada, but domestic manufacturers export products internationally.
  - Support Canadian manufacturers
  - Update procurement practices
  - Align regulations and standards internationally
- In addition to FFRs, there is a stable supply of surgical masks, elastomeric respirators, and other new products that are more purposefully designed for use in the health care setting. Diverse product options, including biodegradable ones, enables broader use of effective masks and FFRs.
  - Improve mask design, standards, and guidance
  - Support innovation and evidence generation
  - Design products that are recyclable/compostable/biodegradable
- Stable supply is complemented by insight into how many FFRs are being used in routine practice, and how many are stockpiled. Fluctuations in data about mask usage may be used to signal infectious disease outbreaks.
  - Invest in traceability infrastructure
  - Redesign the NESS
  - Inform demand with forecasting and scenario planning
- When demand increases are detected, procurement bodies may turn to pre-existing agreements about production capacity held in reserve and/or plan for imports under flexible arrangements such as interim orders.
  - Inform demand with forecasting and scenario planning
  - Update procurement practices
  - Align regulations and standards internationally
  - Support Canadian manufacturers

5.2 Case Study: Domestic Manufacturers Pivoting to Produce Hand Sanitizer

Current State:

- Hand sanitizer supply chains are complex. There may be multiple components in the final product that need to be shipped from different sources: the bottle, which may arrive as a pellet to be injection blown into a bottle; the sanitizer itself, which may need mixing; the sanitizer needs to be added to the bottle and the cap needs to be added, which may need moulding similarly to the bottle.
  - These activities may take place in different sites and may lead to the components travelling thousands of kilometres and requiring thousands of square feet of manufacturing sites and warehouses. The process from “pellet to pallet” may take three months, involving multiple companies and dozens of staff.
  - Materials used in the bottle and cap may not be recyclable or biodegradable.
- Canadian brewers were keen to support the COVID-19 response and many shifted to producing ethanol of the quality needed for hand sanitizer. For some producers this was the first time entering a regulated market such as medical devices, which can be an extremely large hurdle for firms to overcome.

- Uncertainty and procurement in unregulated marketplaces may lead to retail organizations engaging in price gouging, or in receiving faulty or counterfeit products [145].
- There may be some resultant quality issues and product recalls.
  - As of October 2020, Health Canada reported having to recall more than 100 hand sanitizers.

Future State:

- Vertically integrated manufacturing firms streamline the sanitizer production process into a single facility located in Canada. Ethanol is produced locally along with the bottle and cap moulded on site. This reduces the labour needs, shipping, warehousing, and manufacturing footprints, and yields environmental and cost benefits. The product can therefore be competitive on price. Production and delivery times are also shortened. Materials used in the bottle and cap are recyclable, compostable, or biodegradable.
  - Support Canadian manufacturers
  - Develop products that are recyclable/compostable/biodegradable
  - Support innovation and evidence generation
- Hand sanitizers are purchased in buy-and-sell marketplaces with appropriate oversight to ensure quality.
  - Update procurement practices
- Quality assurance testing is conducted routinely at Canadian facilities.
  - Invest in product testing infrastructure

5.3 Case Study: Sustainability in Swab Production

Current State:

- Urgent need for swabs led to high levels of procurement from foreign sources rather than domestic suppliers.
- Temporary regulatory changes enabled importation of foreign products easily; the process to gain regulatory approval for new domestically made products is more challenging. Canadian organizations are not prioritized in procurement.
- Minimum level of product criteria for swabs are not clear.
- Reliance on just-in-time procurement systems create significant shortages for critical products such as swabs [146], [147].

Future State:

- Plans are developed for regulatory requirements for critical pandemic response products that consider short-term and long-term needs for products in an emergency. Agreements are developed with Canadian SMEs and other domestic producers to understand pivoting needs and capabilities to respond to crises.
  - Support Canadian manufacturers
  - Align regulations and standards internationally
- Swabs are included in stockpiles and inventory is rotated to prevent waste. Local sourcing is prioritized.
  - Redesign the NESS
  - Develop and maintain diagnostic capacity
  - Update procurement practices

6 Discussion

This report found that support for Canadian manufacturers will be critical to ensuring a self-sufficient and sustainable domestic pandemic response products ecosystem. There are many ways to achieve this support. Simply, buying their products in large, sustained quantities as might occur through large public procurement contracts and agreements is encouraged.

It is well understood that the peak demand seen for pandemic response products will soon be slowing. What are the implications of this imminent demand shift for the nascent pandemic response products ecosystem in Canada? Manufacturers who pivoted into this space may soon return to their original core businesses. This space will continue to evolve, and it may be natural to expect that manufacturers will pivot away from pandemic response products. It will be important to maintain an understanding of what production capacity exists if rapid pivoting were to be needed again, and how best to support that pivoting.

Some of the quality infrastructure issues identified early in the pandemic have been addressed quickly. Domestic product testing capacity has been increased. Canadian standards have been developed for FFRs. In addition, regulatory changes through interim orders to facilitate imports were lauded by stakeholders.

There have also been important strides in collegiality, networking, relationship building, and data sharing. Stakeholders were keenly aware that some of this momentum may be lost once the crisis passes. Some recommendations were made on how to potentially sustain networks.

Health human resources are an important factor that received some attention in this report. Increased training needs in the laboratory and reprocessing sectors were identified. Some stakeholders further called for a full-scale review of health human resources needs along with an analysis of whether university and college training programs can support Canada's economic goals. This may be a topic for future research.

There are limitations to note in this report. As in the first report, some relevant geographical perspectives were not represented in our stakeholder interview sample. In particular, rural, remote, and Northern stakeholders were underrepresented. It is also possible that use of snowball recruitment methods led to an echo-chamber of similar-minded individuals being interviewed. It is noted, however, that stakeholders came from a diverse range of disciplines, including government, standards development, academia, and manufacturing.

It was not possible to address all domains of the feasibility framework (operational, technical, economic, schedule, and impact) for each recommendation, given their broad and diverse scopes. Action items are intended to show a pathway towards a future state; however, it is recognized that additional work is needed to fully understand the feasibility of each recommendation.

The urgency and importance rankings are to be interpreted with caution given the limited number of responses. In particular, the open text comments described that the survey's limited description of clinical integration as a key aspect of the traceability recommendation, and the vague nature of the recommendation on innovation, hindered scoring of these recommendations.

The findings of this report on action items and impact, as well as the first report characterizing the ecosystem and developing recommendations, was in alignment with the May 2021 Auditor General's report on securing PPE and medical devices [20]. It identified similar issues with the management of the NESS, particularly with respect to inventory management, as well as the positive changes made to date by Health Canada and PHAC, such as those made to the licensing process to facilitate importation of goods. It also identified a need to strengthen quality infrastructure in Canada, with particular emphasis on domestic product testing needs. It is encouraging to see alignment between the Auditor General's report, the response from Health Canada, PHAC, and Public Services and Procurement Canada, and the current report.

7 Conclusions

Support of Canadian manufacturers is critical to ensuring a self-sufficient and sustainable pandemic response products ecosystem. This support can be achieved through multiple mechanisms, including prioritizing these suppliers in purchasing, supporting innovation and development, maintaining affordable product testing capacity, and making it easier to export products by aligning on international standards and regulations. The need to maintain domestic production capacity can also be balanced with other important objectives, including reducing environmental impacts. A quote widely attributed to Winston Churchill is to "not let a crisis go to waste"; it is hoped that lessons learned from the COVID-19 pandemic lead to positive changes in the Canadian ecosystem.

References

[1] D. Breznitz, "Is This Canada's Last Chance to Revive Manufacturing and Long-term Prosperity?" *Policy Options,* Jun. 24, 2020. [Online]. Available: https://policyoptions.irpp.org/magazines/june-2020/is-this-canadas-last-chance-to-revive-manufacturing-and-long-term-prosperity/

[2] F. Graves [@VoiceofFranky], "Huge desire to shift to a made in Canada manufacturing strategy—look what tops list", *Twitter,* Aug. 5, 2020. [Online]. Available: https://twitter.com/VoiceOfFranky/status/1291196017732390914?s=09.

[3] R. Hancock-Howard *et al.,* "Envisioning a Made-in Canada Pandemic Response Products Ecosystem: Towards Self-Sufficiency and Sustainability," CSA Group, 2021. [Online]. Available: https://www.csagroup.org/article/research/envisioning-a-made-in-canada-pandemic-response-products-ecosystem-towards-self-sufficiency-and-sustainability/

[4] D. J. Bowen *et al.,* "How We Design Feasibility Studies," *Am. J. Prev. Med.,* vol. 36, no. 5, pp. 452–457, 2009, doi: 10.1016/j.amepre.2009.02.002.

[5] N. Morpus, "How a Feasibility Study Can Benefit Your Projects," The Blueprint. [Online]. Available: https://www.fool.com/the-blueprint/feasibility-study/ (accessed Jul. 21, 2021).

[6] "Type of Mask Required or Recommended for the Public to Control Transmission of SARS-CoV-2 with Consideration of Variants of Concern: Rapid Environmental Scan," Public Health Ontario, Feb. 18, 2021. [Online]. Available: https://www.publichealthontario.ca/-/media/documents/ncov/voc/2021/03/covid-19-types-of-masks-public-variant-of-concern.pdf?la=en

[7] T. Foxcroft, "As Supply of N95-style Respirators Grows, Some Say It's Time to Upgrade Our Masks," *CBC News*, Mar. 27, 2021. [Online]. Available: https://www.cbc.ca/news/health/n95-masks-health-canada-recommendations-1.5951392

[8] S. Addleman *et al.,* "Mitigating Airborne Transmission of SARS-CoV-2," *Can. Med. Assoc. J.,* vol. 193, no. 26, pp. E1010–E1011, 2021, doi: 10.1503/cmaj.210830.

[9] ASTM International, "White Paper: Global Collaboration to Advance Personal Protective Equipment (PPE) Safety, Quality, and Innovation," Feb. 2021. [Online]. Available: https://www.astm.org/ABOUT/PPE-White-Paper-R2.pdf

[10] J. R. Bentz, "Understanding ASTM's New Specification for Barrier Face Coverings," Medical Device and Diagnostic Industry QMed, Mar. 4, 2021. [Online]. Available: https://www.mddionline.com/testing/understanding-astms-new-specification-barrier-face-coverings

[11] K. Gagnon, "The N95 Must Be Worn in CHSLD, Decrees a Judge," *La Presse,* Mar. 23, 2021. [Online]. Available: https://www.lapresse.ca/covid-19/2021-03-23/le-n95-doit-etre-porte-en-chsld-decrete-un-juge.php

[12] Bureau de normalisation du Québec, "Masks Intended for Working Environments." [Online]. Available: https://www.bnq.qc.ca/en/standardization/protection-and-safety/masks-intended-for-working-environments.html (accessed Feb. 18, 2021).

[13] U. Bergeron, "Nouvelles exigences pour les masques en milieu de travail," *Le Devoir,* Jan. 21, 2021. [Online]. Available: https://www.ledevoir.com/economie/593706/travail-nouvelles-exigences-pour-les-masques

[14] Speech-Language Audiology Canada, "Update on Transparent Masks Available in Canada," Feb. 24, 2021. [Online]. Available: https://www.sac-oac.ca/news-events/news/update-transparent-masks-available-canada-0

[15] "Nike 'Just Does It'—Retail Employees Will Wear Transparent Masks," *Nat'l. Law Rev.,* vol. 11, no. 34, Feb. 3, 2021. [Online]. Available: https://www.natlawreview.com/article/nike-just-does-it-retail-employees-will-wear-transparent-masks

[16] J. Green *et al.,* "The Implications of Face Masks for Babies and Families during the COVID-19 Pandemic: A Discussion Paper," *J. Neonatal Nurs.,* vol. 27, no. 1, pp. 21–25, 2021, https://doi.org/10.1016/j.jnn.2020.10.005.

[17] A. Elassar, "The Biden Administration Launches a $500,000 Contest to Improve Face Mask Designs," *CNN,* Apr. 4, 2021. [Online]. Available: https://www.cnn.com/2021/04/04/us/biden-mask-contest-500k-trnd/index.html

[18] CSA Group, "CSA Group Becomes First Canadian Provider of Testing, Inspection and Certification for Medical-Grade PPE," Cision News Release, Oct. 27, 2020. [Online]. Available: https://www.newswire.ca/news-releases/csa-group-becomes-first-canadian-provider-of-testing-inspection-and-certification-for-medical-grade-ppe-858979921.html

[19] Office of the Auditor General of Canada, "COVID-19 Pandemic Report 10: Securing Personal Protective Equipment and Medical Devices," Independent Auditor's Report, 2021. [Online]. Available: https://www.oag-bvg.gc.ca/internet/English/parl_oag_202105_01_e_43839.html#hd2e

[20] Standards Council of Canada. "Accreditation: Lab/GLP/PTP." [Online]. Available: https://www.scc.ca/en/search/laboratories (accessed Jul. 23, 2021).

[21] Standards Council of Canada, "Directory of Accredited Product, Process and Service Certification Bodies." [Online]. Available: https://www.scc.ca/en/accreditation/product-process-and-service-certification/directory-of-accredited-clients (accessed Jul. 23, 2021).

[22] Standards Council of Canada, "Accreditation Programs." [Online]. Available: https://www.scc.ca/en/accreditation/programs (accessed Jul. 23, 2021).

[23] Standards Council of Canada, "Performance Standard for Filtering Respirators." [Online]. Available: https://www.scc.ca/en/standards/notices-of-intent/csa/performance-standard-for-filtering-respirators (accessed Jan. 20, 2021).

[24] CSA Group, "Performance Standard for Filtering Respirators, CSA Z94.4.1," (forthcoming). [Online]. Available: https://www.scc.ca/en/standards/notices-of-intent/csa/performance-standard-for-filtering-respirators (accessed July 15, 2021).

[25] Standards Council of Canada, "National Conformity Assessment Principles for Canada," Aug. 21, 2008. [Online]. Available: https://www.scc.ca/sites/default/files/liferay_files/ca_principles_e.pdf

[26] A. Snowdon, "White Paper: A Clinically Integrated Outcomes Strategy for Health Systems Globally," HIMSS Analytics. [Online]. Available: https://scanhealth.ca/images/CISOM_WhitePaper.pdf (accessed Jul. 23, 2021).

[27] T. Ebel *et al.,* "Strength in Unity: The Promise of Global Standards in Healthcare," McKinsey & Company, Oct. 2012. [Online]. Available: https://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf

[28] A. W. Snowdon and D. Tallarigo, "Leveraging Supply Chain Infrastructure to Advance Patient Safety in Community Health-Care Settings," *Leadersh. Health Serv.*, vol. 31, no. 3, pp. 269–275, 2018, https://doi.org/10.1108/LHS-03-2018-0017

[29] "Understanding Costs for Traceability Technology Implementation," Future of Fsh. [Online]. Available: https://futureoffish.org/resources/snapshots/understanding-costs-traceability-technology-implementation (accessed Jul. 23, 2021).

[30] Medtech Canada, "Position Paper: Unique Device Identifiers (UDI) for Medical Devices in Canada," Jun. 2021 (forthcoming).

[31] GS1, "Healthcare Traceability and GS1 Standards." [Online]. Available: https://www.gs1.org/industries/healthcare/traceability (accessed Sept. 15, 2020).

[32] GS1, "Global Traceability Standard for Healthcare," Oct. 2013. [Online]. Available: https://www.gs1.org/docs/traceability/Global_Traceability_Standard_Healthcare.pdf

[33] GS1, "Product Classification in Healthcare," Apr. 2015. [Online]. Available: https://www.gs1.org/sites/default/files/docs/healthcare/product_classification_in_healthcare.pdf

[34] D. Hales and P. Chouinard, "Implementing Capability Based Planning within the Public Safety and Security Sector: Lessons from the Defence Experience", December 2011. [Online]. Available: https://cradpdf.drdc-rddc.gc.ca/PDFS/unc122/p537217_A1b.pdf

[35] L. Gouzecky. "How ERP Benefits Medical Device Commercialization," StarFish Medical. [Online]. Available: https://starfishmedical.com/blog/how-erp-benefits-medical-device-commercialization/ (accessed Apr. 30, 2021).

[36] A. Caldwell, "4 Key ERP Implementation Strategies," NetSuite. [Online]. Available: https://www.netsuite.com/portal/resource/articles/erp/erp-implementation-strategies.shtml (accessed May 3, 2021).

[37] A. W. Snowdon, "Visibility: The New Value Proposition for Health Systems," SCAN Health, Oct. 16, 2018. [Online]. Available: https://issuu.com/worldhealthinnovationnetwork/docs/full_paper_-_win_visibility_thought/1?e=25657717/39177387

[38] GS1, "GS1 Global Traceability Standard for Healthcare (GTSH) Implementation Guide," Apr. 2009. [Online]. Available: https://www.gs1.org/sites/default/files/docs/traceability/Global_Traceability_Implementation_Healthcare.pdf

[39] A. Snowdon, "Exploring the Journey of Supply Chain Transformation in Three Global Health Systems," 2017. [Online]. Available: https://issuu.com/worldhealthinnovationnetwork/docs/smi_presentation.pptx

[40] A. W. Snowdon, "Study of Three International Health Systems Showcases the Benefits of Supply Chain Transformation," World Health Innovation Network, 2018. [Online]. Available: https://gs1ca.org/gs1ca-components/documents/case-studies/anne-snowdon-canada.pdf

[41] Peppol, "What Is Peppol?" [Online]. Available: https://peppol.eu/what-is-peppol/ (accessed Jul. 23, 2021).

[42] A. Correia de Brito, C. Kauffmann, and J. Pelkmans, "The Contribution of Mutual Recognition to International Regulatory Co-operation," OECD Working Paper, Jan. 26, 2016. [Online]. Available: https://www.oecd-ilibrary.org/content/paper/5jm56fqsfxmx-en

[43] Industry Strategy Council (Canada), *Restart, Recover and Reimagine Prosperity for All Canadians: An Ambitious Growth Plan for Building a Digital, Sustainable and Innovative Economy,* 2020. [Online]. Available: https://www.ic.gc.ca/eic/site/062.nsf/vwapj/00118a_en.pdf/$file/00118a_en.pdf

[44] International Medical Device Regulators Forum, "Optimizing Standards for Regulatory Use," Nov. 5, 2018. [Online]. Available: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181105-optimizing-standards-n51.pdf

[45] Standards Council of Canada, "Directory of Accredited Standards Development Organizations." [Online]. Available: https://www.scc.ca/en/accreditation/standards/directory-of-accredited-standards-development-organizations (accessed Jul. 23, 2021).

[46] Telecommunication Development Bureau, "Establishing Conformity and Interoperability Regimes," Feb., 2015. [Online]. Available: https://www.itu.int/en/ITU-D/Technology/Documents/ConformanceInteroperability/publications/Establishing_Conformity_and_interoperability_Regimes-E.pdf

[47] Health Canada, "Mutual Recognition Agreements," Government of Canada. [Online]. Available: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/international/mutual-recognition-agreements/background.html (accessed May 28, 2021).

[48] J. P. Tasker, "Federal Health Agency Wasn't Ready for Pandemic Equipment Demand, Auditor Finds," *CBC News,* May 26, 2021. [Online]. Available: https://www.cbc.ca/news/politics/ag-ness-ppe-1.6041158

[49] Australian National Audit Office, "Management of the National Medical Stockpile," Jun. 26, 2014. [Online]. Available: https://www.anao.gov.au/sites/default/files/AuditReport_2013-2014_53.pdf?acsf_files_redirect

[50] Public Health Agency of Canada. "Evaluation of the National Emergency Stockpile System (NESS)," Apr. 2011. [Online]. Available: https://www.canada.ca/en/public-health/corporate/mandate/about-agency/office-evaluation/evaluation-reports/evaluation-national-emergency-stockpile-system.html

[51] Y.-J. Chen *et al.,* "Stockpile Model of Personal Protective Equipment in Taiwan," *Health Secur.,* vol. 15, no. 2, pp. 170–174, Apr. 2017, doi: 10.1089/hs.2016.0103.

[52] Ontario Ministry of Government and Consumer Services, "Supply Chain Centralization," Government of Ontario. [Online]. Available: https://www.doingbusiness.mgs.gov.on.ca/mbs/psb/psb.nsf/English/index?openDocument (accessed Jul. 25, 2021).

[53] Health Canada. "Health Canada Procurement Plan (Assets and Acquired Services) 2019–2020," Government of Canada. [Online]. Available: https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/report-plans-priorities/2019-2020-procurement-plan.html (accessed Jul. 25, 2021).

[54] Medtech Canada, "Provincial Transformation and Centralization of Procurement – Medical Technology Industry Perspective," Position Paper, Sept. 2019. [Online]. Available: https://cdn.ymaws.com/medtechcanada.org/resource/resmgr/position_papers/positionpaper-perspective_ce.pdf

[55] Public Spend Forum, "Public Procurement Technology Landscape – Technology Landscape Guide for Public Sector Leaders," Nov. 2017. [Online]. Available: https://www.publicspendforum.net/wp-content/uploads/2020/11/Procurement-Technology-Brief_Release-2_Nov-2017_.pdf

[56] Buyandsell.gc.ca, "About Us," Public Services and Procurement Canada. [Online]. Available: https://buyandsell.gc.ca/aboutus (accessed May 28, 2021).

[57] HealthPRO, "Working with HealthPRO." [Online]. Available: https://www.healthprocanada.com/become-a-supplier (accessed Apr. 21, 2021).

[58] M. E. Pierre de la Boulaye *et al.,* "How B2B Online Marketplaces Could Transform Indirect Procurement," McKinsey & Company, Nov. 2019. [Online]. Available: https://www.mckinsey.com/business-functions/operations/our-insights/how-b2b-online-marketplaces-could-transform-indirect-procurement

[59] G. R. Shinde *et al.,* "Forecasting Models for Coronavirus Disease (COVID-19): A Survey of the State-of-the-Art," *SN Comput. Sci.,* vol. 1, no. 4, p. 197, Jun. 2020, doi: 10.1007/s42979-020-00209-9.

[60] Public Health Agency of Canada, "COVID-19: PHAC Modelling Group," Jan. 14, 2021. [Online]. Available: https://nccid.ca/wp-content/uploads/sites/2/2021/01/Modelling-Group-report-2020_01_14_Final.pdf

[61] Office of the Chief Science Advisor, "CanCOVID Network," Government of Canada. [Online]. Available: https://www.ic.gc.ca/eic/site/063.nsf/eng/h_98020.html (accessed Jul. 25, 2021).

[62] UBC COVID-19 Research, "BC COVID-19 MODELLING GROUP," University of British Columbia. [Online]. Available: https://covid19.research.ubc.ca/research/bc-covid-19-modelling-group (accessed Jul. 25, 2021).

[63] Ontario COVID-19 Science Advisory Table, "Informing Ontario's Response to COVID-19." [Online]. Available: https://covid19-sciencetable.ca/our-partners/ (accessed Jul. 25, 2021).

[64] University of Toronto, University Health Network, and Sunnybrook Hospital, "COVID-19 Modeling Collaborative." [Online]. Available: https://www.covid-19-mc.ca/ (accessed Jul. 25, 2021).

[65] K. Barrett *et al.,* "Estimation of COVID-19–Induced Depletion of Hospital Resources in Ontario, Canada," *CMAJ,* vol. 192, no. 24, pp. E640–E646, Jun. 2020, doi: 10.1503/cmaj.200715.

[66] K. Barrett *et al.,* "A Model to Estimate Demand for Personal Protective Equipment for Ontario Acute Care Hospitals during the COVID-19 Pandemic," *medRxiv,* May 2020, doi: 10.1101/2020.04.29.20085142.

[67] Public Safety Canada, "All-Hazards Risk Assessment," Government of Canada. [Online]. Available: https://www.publicsafety.gc.ca/cnt/mrgnc-mngmnt/mrgnc-prprdnss/ll-hzrds-rsk-ssssmnt-en.aspx (accessed Jul. 25, 2021).

[68] A. Russell and C. Jarvis. "Coronavirus: Inside the Supply Chain Crisis Slowing Canadian Labs," *Global News,* Oct. 20, 2020. [Online]. Available: https://globalnews.ca/news/7406308/coronavirus-inside-supply-chain-crisis/

[69] O. Vandenberg *et al.*, "Considerations for Diagnostic COVID-19 Tests," *Nat. Rev. Microbiol.,* vol. 19, no. 3, pp. 171–183, 2021, doi: 10.1038/s41579-020-00461-z.

[70] R. Graffe-McRae. "Alberta Lab Services: From Guinea Pigs to Heroes (and Back Again?)," Parkland Institute Blog, May 4, 2020. [Online]. Available: https://www.parklandinstitute.ca/alberta_lab_services

[71] Association of Public Health Laboratories, "Public Health Laboratory Workforce Needs," Mar. 2021. [Online]. Available: https://www.aphl.org/aboutAPHL/publications/Documents/QSA-2021-PHL-Workforce-Needs.pdf

[72] College of Medical Laboratory Technologies of Ontario, "Medical Laboratory Assistants and Technicians." [Online]. Available: http://www.cmlto.com/index.php?option=com_content&view=article&id=1303&Itemid=280 (accessed Jul. 25, 2021).

[73] College of Medical Laboratory Technologies of Ontario, "Careers and Specialties." [Online]. Available: http://www.cmlto.com/index.php?option=com_content&view=article&id=1309&Itemid=749 (accessed Jul. 25, 2021).

[74] Canadian Institute for Health Information, "Medical Laboratory Technologists in Canada, 2010," CIHI, 2010. [Online]. Available: https://www.hhr-rhs.ca/fr/outils/bibliotheque/english-french/medical-laboratory-technologists-in-canada-2010-technologistes-de-laboratoire-medical-au-canada-2010.html

[75] Canadian Society for Medical Laboratory Science, "Backgrounder: The Canadian Medical Laboratory Profession's Call to Action." [Online]. Available: https://csmls.org/Research/Projects,-Reports-Presentations/Backgrounder-The-Canadian-Medical-Laboratory-Prof.aspx (accessed Jul. 25, 2021).

[76] Canadian Society for Medical Laboratory Science, "Use of Simulation to Reduce Clinical Placement Hours." [Online]. Available: https://www.csmls.org/csmls/media/documents/position_statements/Simulation-and-Clinical-Placement-Position-Statement-FINAL.pdf (accessed Jul. 25, 2021).

[77] National Collaborating Centre for Infectious Diseases, "The Canadian Public Health Laboratory Network." [Online]. Available: https://nccid.ca/cphln/ (Jul. 25, 2021).

[78] Canadian Public Health Laboratory Network, "Strategic Plan 2016–2020." [Online]. Available: https://www.canada.ca/content/dam/themes/health/publications/science-research-data/2016-2020-canadian-public-health-laboratory-network-strategic-plan/CPHLN-Strat-Plan-2016-2020.pdf (accessed Jul. 26, 2021).

[79] Public Health Ontario, "Test Information Index." [Online]. Available: https://www.publichealthontario.ca/en/laboratory-services/test-information-index (accessed Jul. 26, 2021).

[80] Alberta Health Services. "Alberta Precision Laboratories Test Directory." [Online]. Available: https://www.albertahealthservices.ca/webapps/labservices/indexAPL.asp?zoneid=1&SearchText=covid&submit=Submit+Query&upperTest=-1&lowerTest=-1 (accessed Jul. 26, 2021).

[81] Association of Public Health Laboratories. "Smart Testing for Optimizing Pandemic Response," Jan. 2021. [Online]. Available: https://www.aphl.org/aboutAPHL/publications/Documents/ID-2021-Smart-Testing-for-Optimizing-Pandemic-Response.pdf

[82] Ontario Health, "Optimizing the Supply of Personal Protective Equipment During the COVID-19 Pandemic," May 10, 2020. [Online]. Available: https://www.afhto.ca/sites/default/files/2020-05/Ontario%20Health%20Recommendations%20on%20Optimizing%20Personal%20Protective%20Equipment%20During%20the%20COVID-19%20pandemic_rev10May20%20PDF_v2.pdf

[83] A. J. MacNeill *et al.,* "Transforming the Medical Device Industry: Road Map to a Circular Economy," *Health Aff.,* vol. 39, no. 12, pp. 2088–2097, Dec. 7, 2020, doi: 10.1377/hlthaff.2020.01118.

[84] J. Lagasse, "Reprocessing Single-Use Medical Devices Boosts Circular Economy for Hospitals," Healthcare Finance, Dec. 10, 2020. [Online]. Available: https://www.healthcarefinancenews.com/news/reprocessing-single-use-medical-devices-boosts-circular-economy-hospitals.

[85] This is the same as 83 above. Delete? "Transforming the Medical Device Industry: Road Map To A Circular Economy," *Health Affairs,* vol. 39, no. 12, pp. 2088-2097, 2020, doi: 10.1377/hlthaff.2020.01118.

[86] American Hospital Association, "Sustainability Roadmap for Hospitals: Reprocess Approved Single-Use Devices." [Online]. Available: http://www.sustainabilityroadmap.org/pims/27#.YO4HOOhKhyx (accessed May 28, 2021).

[87] J. M. Mansur, "Reuse of Single-Use Devices: Understanding Risks and Strategies for Decision-Making for Health Care Organizations," Joint Commission International, 2017. [Online]. Available: https://www.jointcommissioninternational.org/-/media/feature/news/jci_white_paper_reuse_of_single_use_devices2pdf.pdf?db=web&hash=6A41E61718E881E936AF4289BE36DA82#:~:text=The%20process%20of%20single%2Duse,be%20placed%20into%20service%20again

[88] "Reuse of Single-Use Medical Devices: Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)." Centers for Disease Control and Prevention. [Online]. Available: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/reuse-of-devices.html (accessed May 28, 2021).

[89] Canadian Agency for Drugs and Technologies in Health, "Reprocessing of Single-Use Medical Devices: A 2015 Update." [Online]. Available: https://www.cadth.ca/reprocessing-single-use-medical-devices-2015-update (accessed Jul. 26, 2021).

[90] CSA Group, "Certified Medical Device Reprocessing Technician (CMDRT) Certification Guide," Aug. 2020. [Online]. Available: https://www.csagroup.org/store-resources/documents/pc-programs/cmdrt/CMDRT_Certification_Guide-PCP-04-AUG-2020.pdf

[91] Public Services and Procurement Canada. "How One Canadian Company Extended the Life of Disposable N-95 Masks," Government of Canada. [Online]. Available: https://www.tpsgc-pwgsc.gc.ca/comm/aic-scr/tec-wcc/2020-08-13-00-eng.html (accessed May 28, 2021).

[92] S. A. Sanchez, M. J. Eckelman, and J. D. Sherman "Environmental and Economic Comparison of Reusable and Disposable Blood Pressure Cuffs in Multiple Clinical Settings," *Resour. Conserv. Recycl.,* vol. 155, Apr. 2020, doi: https://doi.org/10.1016/j.resconrec.2019.104643.

[93] F. McGain *et al.,* "The Financial and Environmental Costs of Reusable and Single-Use Plastic Anaesthetic Drug Trays," *Anaesth Intensive Care.,* vol. 38, no. 3, pp. 538–544, 2010, doi: 10.1177/0310057x1003800320.

[94] World Health Organization, "Circular Economy and Health: Opportunities and Risks," 2018. [Online]. Available: https://www.euro.who.int/__data/assets/pdf_file/0004/374917/Circular-Economy_EN_WHO_web_august-2018.pdf

[95] United Nations, "17 Sustainable Development Goals." [Online]. Available: https://sdgs.un.org/goals (accessed Jul. 26, 2021).

[96] Ellen MacArthur Foundation, "Towards the Circular Economy: Economic and Business Rationale for an Accelerated Transition,", Jan. 30, 2012. [Online]. Available: https://ellenmacarthurfoundation.org/towards-a-circular-economy-business-rationale-for-an-accelerated-transition

[97] Y. Kalmykova, M. Sadagopan, and L. Rosado, "Circular Economy – From Review of Theories and Practices to Development of Implementation Tools," *Resour. Conserv. Recycl.,* vol. 135, pp. 190–201, Aug. 1, 2018, doi: https://doi.org/10.1016/j.resconrec.2017.10.034.

[98] T. A. Aragaw and B. A. Mekonnen, "Current Plastics Pollution Threats due to COVID-19 and Its Possible Mitigation Techniques: A Waste-to-Energy Conversion via Pyrolysis," *Environ. Syst. Res.,* vol. 10, no. 1, 2021, doi: 10.1186/s40068-020-00217-x.

[99] J. C. Prata *et al.,* "COVID-19 Pandemic Repercussions on the Use and Management of Plastics," *Environ. Sci. Technol.,* vol. 54, no. 13, pp. 7760–7765, 2020/07/07 2020, doi: 10.1021/acs.est.0c02178.

[100] R. P. Jones. "Government Calls on Private Sector to Come Up with Compostable, Recyclable Pandemic Gear," *CBC News,* Oct. 16, 2020. [Online]. Available: https://www.cbc.ca/news/politics/ppe-waste-business-challenge-1.5765902

[101] N. J. Rowan and J. G. Laffey, "Unlocking the surge in Demand for Personal and Protective Equipment (PPE) and Improvised Face Coverings Arising from Coronavirus Disease (COVID-19) Pandemic – Implications for Efficacy, Re-use and Sustainable Waste Management," *Sci.Total Environ.,* vol. 752, p. 142259, Jan. 15, 2021, doi: https://doi.org/10.1016/j.scitotenv.2020.142259.

[102] J. Sorensen, "Canadian Wood Fibre Biodegradable COVID-19 Mask Coming in 2021." *cJournal of Commerce*, Oct. 30, 2020. [Online]. Available: https://canada.constructconnect.com/joc/news/resource/2020/10/canadian-wood-fibre-biodegradable-covid-19-mask-coming-in-2021

[103] A. Ahn, "Dr. Johan Foster & Dr. Orlando Rojas on the SDGs: Changing Canada One Biodegradable Can-Mask at a Time," BCCIC, The Blog. [Online]. Available: https://www.bccic.ca/blog-can-masks/ (accessed Jul. 26, 2021).

[104] Innovation, Science and Economic Development Canada, "Government of Canada launches new COVID-19–related challenges to help reduce environmental impact of PPE in Canada," Government of Canada, Oct. 16, 2020. [Online]. Available: https://www.canada.ca/en/innovation-science-economic-development/news/2020/10/government-of-canada-launches-new-covid-19-challenges-to-help-reduce-environmental-footprint-of-ppe-in-canada.html

[105] Natural Resources Canada, "Canada's Forest Sector Develops Made-in-Canada Biodegradable PPE Solution," Cision, Feb. 26, 2021. [Online]. Available: https://www.newswire.ca/news-releases/canada-s-forest-sector-develops-made-in-canada-biodegradable-ppe-solution-810539271.html

[106] The Canadian Coalition for Green Health Care, "The PPE-mSUP Project: A Circular Economy Model for Hospital-Generated PPE and Medical Single-Use Plastic (mSUP) Waste." [Online]. Available: https://greenhealthcare.ca/ppe-msup/ (accessed May 28, 2021).

[107] United Nations, "Five Things You Should Know about Disposable Masks and Plastic Pollution," UN News, Jul. 30, 2020. [Online]. Available: https://news.un.org/en/story/2020/07/1069151

[108] S. Clarke and L. Couture, "Real Growth of Canadian Manufacturing Since 2000," Analytical Studies Branch and Economic Analysis Division, Statistics Canada, Jun. 27, 2017. [Online]. Available: https://www150.statcan.gc.ca/n1/pub/11-626-x/11-626-x2017074-eng.htm

[109] Government of Canada, "Canadian Manufacturing Sector Gateway." [Online]. Available: https://www.ic.gc.ca/eic/site/mfg-fab.nsf/eng/home (accessed Jul. 27, 2021).

[110] M. Gingrich and M. Rowlinson, "Revitalizing Canada's Manufacturing Economy for a Post-COVID World," Public Policy Forum, Nov. 5, 2020. [Online]. Available: https://ppforum.ca/publications/revitalizing-canadas-manufacturing-economy-for-a-post-covid-world/

[111] A. Balakrishnan. "Manufacturers Hopeful COVID-19 Will Force Canada to Rethink Domestic Supply Chains," *Global News,* Mar. 20, 2021. [Online]. Available: https://globalnews.ca/news/7708899/manufacturers-coronavirus-canada-supply-chains/

[112] S. Scherer, "Canada's Slow-Burn Vaccine Roll Out Puts Pressure on Trudeau," *Reuters,* Feb. 18, 2021. [Online]. Available: https://www.reuters.com/article/us-canada-politics-trudeau-idUSKBN2AI1CO

[113] R. Tumilty, "Liberals Spending Millions on Home-Grown Industry to Shore up Canada's PPE Supply," *National Post,* Aug. 28, 2020. [Online]. Available: https://nationalpost.com/news/politics/liberals-spending-millions-on-home-grown-industry-to-shore-up-canadas-ppe-supply.

[114] S. Denney and D. Wolfe, "The Innovation Imperative: Why Canada Needs to Prioritize Scale-ups in the Face of Big Tech's Dominance," *Financial Post,* Mar. 24, 2021. [Online]. Available: https://financialpost.com/technology/the-innovation-imperative-why-canada-needs-to-prioritize-scale-ups-in-the-face-of-big-techs-dominance

[115] M. Hemmadi, "Funding Gap for Smaller Rounds Crimping Growth of Canada's Mid-Sized Firms, Federal Report Says," *The Logic,* Feb. 11, 2021. [Online]. Available: https://thelogic.co/news/funding-gap-for-smaller-rounds-crimping-growth-of-canadas-mid-sized-firms-federal-report-says/#:~:text=News-,Funding%20gap%20for%20smaller%20rounds%20crimping%20growth%20of%20Canada's,sized%20firms%2C%20federal%20report%20says&text=Mid%2Dsized%20Canadian%20companies%20face,commissioned%20by%20the%20federal%20government.

[116] Ministry of SaskBuilds and Procurement, "Guidelines to the Procurement Obligations of Domestic and International Trade Agreements," Government of Saskatchewan, 2019. [Online]. Available: http://www.saskbuilds.ca/PrioritySK/files/Procurement_Guidelines_Final.pdf

[117] D. LePage, "Exploring Social Procurement," The Canadian CED Network, Mar. 2014. [Online]. Available: https://ccednet-rcdec.ca/sites/ccednet-rcdec.ca/files/ccednet/exploring-social-procurement_asi-ccc-report.pdf

[118] *ISO 20400:2017 Sustainable Procurement — Guidance,* International Organization for Standardization, Apr. 2017. [Online]. Available: https://www.iso.org/standard/63026.html

[119] Scottish Government, "Public Sector Procurement." [Online]. Available: https://www.gov.scot/policies/public-sector-procurement/sustainable-procurement-duty/ (accessed May 21, 2021).

[120] Victoria Government, Australia, "Social Procurement – Victorian Government Approach," Buying for Victoria. [Online]. Available: https://www.buyingfor.vic.gov.au/social-procurement-victorian-government-approach (accessed Jul. 28, 2021).

[121] United Kingdom Government, "Guide to Using the Social Value Model," GOV.UK, Dec. 16, 2020. [Online]. Available: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940827/Guide-to-using-the-Social-Value-Model-Edn-1.1-3-Dec-20.pdf

[122] UK Public General Acts, "Public Services (Social Value) Act 2012," legislation.gov.uk, Mar. 8, 2012. [Online]. Available: https://www.legislation.gov.uk/ukpga/2012/3/enacted.

[123] City of Toronto, "Social Procurement Program." [Online]. Available: https://www.toronto.ca/business-economy/doing-business-with-the-city/social-procurement-program/ (accessed Jul. 28, 2021).

[124] Deloitte, "How to Eat the Value-Based Procurement Elephant? A Deloitte Point of View," Feb. 2018. [Online]. Available: https://www2.deloitte.com/content/dam/Deloitte/be/Documents/life-sciences-health-care/0000_POV_Value_Based_Procurement_HR_Final_v2.pdf

[125] Healthcare Sector Supply Chain Strategy Expert Panel, "Advancing Healthcare in Ontario: Optimizing the Healthcare Supply Chain – A New Model," Government of Ontario, May 2017. [Online]. Available: https://www.health.gov.on.ca/en/pro/ministry/supplychain/docs/advancing_hc_supplychn_expert_panel_may2017_en.pdf

[126] J. Barraket and J. Weissman, "Social Procurement and its Implications for Social Enterprise: A Literature Review," The Australian Centre for Philanthropy and Nonprofit Studies, Dec. 2009. [Online]. Available: https://eprints.qut.edu.au/29060/1/Barraket_and_Weissmann_2009_Working_Paper_No_48_Final.pdf

[127] O. Cavlan *et al.,* "The European Public-Procurement Opportunity: Delivering Value in Medtech," McKinsey & Company, Dec. 2018. [Online]. Available: https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-european-public-procurement-opportunity-delivering-value-in-medtech

[128] Government of Ontario, "Ontario Partners with Federal Government and 3M Canada on New N95 Respirator Manufacturing Facility," News Release, Aug. 21, 2020. [Online]. Available: https://news.ontario.ca/en/release/58102/ontario-partners-with-federal-government-and-3m-canada-on-new-n95-respirator-manufacturing-facility

[129] Canadian Healthcare Technology, "Medicom Signs 10-Year Agreement to Produce PPE," May 27, 2020. [Online]. Available: https://www.canhealth.com/2020/05/27/medicom-signs-10-year-agreement-to-produce-ppe/

[130] Government of Canada, "Canada's Innovation and Skills Plan," Budget 2017. [Online]. Available: https://www.budget.gc.ca/2017/docs/themes/Innovation_en.pdf.

[131] Department of Finance Canada, "Budget 2021: Building an Innovation Economy of the Future," Government of Canada. [Online]. Available: https://www.canada.ca/en/department-finance/news/2021/04/budget-2021-building-an-innovation-economy-of-the-future.html (accessed Jun. 7, 2021).

[132] Standards Council of Canada "SCC's Innovation Initiative: Empowering Canadian Innovation Where It Sparks," Jan. 25, 2021. [Online]. Available: https://www.scc.ca/en/system/files/publications/SCC_Innovation_Report_EN.pdf

[133] D. Schwanen and R. Wyonch, "Canada's 2018 Innovation Policy Report Card," C.D. Howe Institute, May 14 2018. [Online]. Available: http://dx.doi.org/10.2139/ssrn.3171145

[134] CAN Health Network, "A Platform for Canadians to Lead the New Health Care Economy." [Online]. Available: https://canhealthnetwork.ca/ (accessed Jun. 7, 2021).

[135] International Development Innovation Alliance, "Typical Actors in an Innovation Ecosystem." [Online]. Available: https://www.idiainnovation.org/ecosystem-actors (accessed Jul. 28, 2021).

[136] P. K. Lorgelly and A. Adler, "Impact of a Global Pandemic on Health Technology Assessment," *App. Health Econ. Health Policy,* vol. 18, no. 3, pp. 339–343, 2020, doi: 10.1007/s40258-020-00590-9.

[137] R. BorsukStaff, "Asia Adopts Thermal Imaging to Spot Travelers with SARS," *The Wall Street Journal,* Apr. 28, 2003. [Online]. Available: https://www.wsj.com/articles/SB105148535546154300

[138] Canadian Air Transport Security Authority, "Measures Taken in Response to COVID-19." [Online]. Available: https://www.catsa-acsta.gc.ca/en/covid19-response (accessed Feb. 21, 2021).

[139] N. Degnarain, "How UV 'Roomba' Robots Could Accelerate the Opening of Mass Transit Systems," *Forbes,* Apr. 17, 2020. [Online]. Available: https://www.forbes.com/sites/nishandegnarain/2020/04/17/how-uv-roomba-robots-could-accelerate-the-opening-of-mass-transit-systems/?sh=2cf0f9401f7f

[140] U.S. Environmental Protection Agency, "How Does Indoor Air Quality Impact Student Health and Academic Performance?" [Online]. Available: https://www.epa.gov/iaq-schools/how-does-indoor-air-quality-impact-student-health-and-academic-performance (accessed Jun. 1, 2021).

[141] L. Morawska *et al.,* "A Paradigm Shift to Combat Indoor Respiratory Infection," *Science,* vol. 372, no. 6543, pp. 689–691, 2021, doi: 10.1126/science.abg2025.

[142] R. Read. "Scientists Call for Sweeping Change in Building Design to Reduce Airborne Diseases like COVID-19," *Los Angeles Times,* May 13, 2021. [Online]. Available: https://www.latimes.com/world-nation/story/2021-05-13/covid-safe-buildings?_amp=true&__twitter_impression=true&s=09

[143] Armstrong Ceiling and Wall Solutions, "Returning Workers Seek Workspaces that Address More Than Safety: 2021 Pulse Point Occupants Survey Reveals Desires for Spaces Fit for Sustainability and Personal Well-Being," Press Release, Apr. 15, 2021. [Online]. Available: https://www.3blmedia.com/News/Returning-Workers-Seek-Workspaces-Address-More-Safety#:~:text=Returning%20Workers%20Seek%20Workspaces%20That%20Address%20More%20Than%20Safety,-2021%20Pulse%20Point&text=The%20survey%20%E2%80%9CMaking%20Space%20for,related%20health%20and%20safety%20concerns

[144] D. Kourouklis and I. Firth. "Does Government Funding Increase Public Sector Development of New Medicines?" Office of Health Economics (OHE), Mar. 5, 2021. [Online]. Available: https://www.ohe.org/news/does-government-funding-increase-public-sector-development-new-medicines

[145] T. Deschamps, "Experts Say Counterfeit Hand Sanitizer Recall at Dollarama Is a Lesson for Retailers," *Globe and Mail,* Oct. 20. 2020. [Online]. Available: https://www.theglobeandmail.com/canada/article-health-canada-recalls-counterfeit-hand-sanitizer-found-for-sale-at/

[146] J. Barocas, C. Gounder, and S. Madad, "Just-In-Time Versus Just-In-Case Pandemic Preparedness," Health Affairs Blog, Feb. 12, 2021. [Online]. Available: https://www.healthaffairs.org/do/10.1377/hblog20210208.534836/full/

[147] R. King, "Mayo Clinic CEO Blasts 'Just-in-Time' Ordering as Pandemic Changes Supply Chain," Fierce Healthcare, Jul. 7, 2020. [Online]. Available: https://www.fiercehealthcare.com/hospitals/mayo-clinic-ceo-blasts-just-time-ordering-as-pandemic-changes-supply-chain

Appendix A – Survey of the Project Advisory Panel: Prioritization of Recommendations to Improve Canada's Pandemic Response Products Ecosystem

Thank you for taking this survey to help inform prioritization of the 12 recommendations made to support the development of a self-sufficient and sustainable pandemic response products ecosystem in Canada.

We will present to you with the 12 recommendations along with a brief description of what they entail. You will then be asked to assign a score for each recommendation's **urgency** and **importance**.

A score of 1 indicates lowest urgency/importance and a score of 5 indicates highest urgency/importance. You do not have to distribute your scores (i.e., you can give all the recommendations a score of 5 if you wish).

Additional comments or feedback you may have are welcome.

Providing Quality Infrastructure

Recommendation 1: Improve Mask Design, Standards, and Guidance

Brief description:

- Develop standards for consumer masks
- Design masks that address issues including breathability, filtration efficiency, and fit
- Explore new designs to improve resiliency in mask options, and feasibility of alternatives including elastomeric respirators
- Develop guidance on mask use in health care settings that addresses aerosol transmission (i.e., better understanding of who needs to wear what mask under what conditions)

Additional Comments (open text – no word limit):

Recommendation 2: Invest in Product Testing Infrastructure

Brief description:

- Support international harmonization of standards by providing enhanced international leadership in standards development
- Create a centralized database of Canadian labs and institutions with testing capacity, both accredited (by any accreditation body) and non-accredited
- Enhance collaborations with university and college labs with product testing capacity and explore need for accreditation support

Additional Comments (open text – no word limit):

Recommendation 3: Invest in Traceability Infrastructure

Brief description:

- Adopt traceability standards in Canada, e.g., existing GS1 standards
- Implement traceability technologies, e.g., Enterprise Resource Planning (ERP), to track and trace data across supply chains, manage inventory supplies, and support quality and safety

Additional Comments (open text – no word limit):

Recommendation 4: Align Regulations and Standards Internationally

Brief description:

- Collaborate with regulatory authorities in jurisdictions outside Canada to reduce barriers to accepting Canadian products and standards
- Create pre-designed emergency interim orders to be enacted by Health Canada based on pre-defined triggers (e.g., declaration of a pandemic)

Additional Comments (open text – no word limit):

Ensuring Adequate Supply

Recommendation 5: Redesign the National Emergency Strategic Stockpile (NESS)

Brief description:

- Implement new technologies in NESS management to keep stockpiles fresh and circulating into routine inventory
- Improve coordination and communication between the NESS and provincial stockpiles
- Explore use of tiered stockpile systems and/or agreements with manufacturers about production lines held in reserve for emergency situations

Additional Comments (open text – no word limit):

Recommendation 6: Update Procurement Practices

Brief description:

- Explore adoption of social-values based procurement and movement away from lowest-price procurement
- Explore movement to centralized procurement offices for provincial health authorities, similar to practices in Alberta
- Outside of provincial health authorities, facilitate centralized open procurement marketplaces that connect buyers and sellers of pandemic products, with an oversight body to ensure safety and quality of goods in the marketplace

Additional Comments (open text – no word limit):

Recommendation 7: Inform Demand through Enhanced Scenario Planning and Forecasting

Brief description:

- Devote research funding and public sector groups to dedicated modelling of pandemic response product demand under a variety of potential disease profiles
- Model use of pandemic products to inform purchasing and stockpiling, potentially using traceability data as it becomes increasingly available and shared
- Encourage regular data collection and surveillance of emerging disease threats (e.g., by use of All Hazards Risk Assessment tools) to identify needed pandemic products

Additional Comments (open text – no word limit):

Recommendation 8: Develop and Maintain Diagnostic Capacity

Brief description:

- Address health human resource challenges in the lab sector by investing in training programs for laboratory technicians and technologists
- Create centralized database hosting information on organizations with diagnostic capacity, including tests available
- Build on collaborations and relationships developed between hospitals and public health labs during the COVID-19 pandemic, potentially creating new, recurring forums for communication
- Create framework to evaluate capacity of organizations to pivot to help produce diagnostic equipment or host testing initiatives

Additional Comments (open text – no word limit):

Supporting Economic and Environmental Sustainability

Recommendation 9: Increase Reprocessing of PPE and Medical Devices

Brief description:

- Increase adoption of existing reprocessing standards in Canada
- Analyze existing capacity for reprocessing in hospitals and examine need for further capacity and roles of third-party reprocessing companies
- Expand accredited reprocessing training programs

Additional Comments (open text – no word limit):

Recommendation 10: Develop Pandemic Response Products that are Recyclable, Compostable, or Biodegradable

Brief description:

- Invest in research initiatives to develop environmentally-sustainable PPE
- Prioritize biodegradable PPE to reduce impact of improper disposal and develop guidelines for waste management facilities
- Create guidelines to educate users on new PPE

Additional Comments (open text – no word limit):

Recommendation 11: Support Canadian Manufacturers

Brief description:

- Explore the sustainability needs of companies to continue in this space as demand shifts and ensure at least minimum levels of domestic production maintained
- Explore adoption of Buy Canadian procurement policies and agreements for virtual product stockpiles/ production lines
- Support export of Canadian products

Additional Comments (open text – no word limit):

Recommendation 12: Support Innovation and Evidence Generation for New Technologies

Brief description:

- Support evidence generation for structural changes needed to improve sanitization and ventilation advances

Additional Comments (open text – no word limit):

Appendix B – Feasibility Assessment Framework Used to Guide Stakeholder Interviews

Figure 5: Feasibility assessment framework used to guide stakeholder interviews

Operational: *Is it allowed?*	▪ Implementation ▪ Legal Implications	▪ Political Context
Technical: *Can it be done?*	▪ Identification of Lead Actors ▪ Identification of Stakeholders	▪ Complexity ▪ Maintenance/Longevity
Economic: *Is it affordable?*	▪ Costs ▪ Funding Sources	▪ Savings/Benefits
Schedule: *How long will it take?*	▪ Timelines ▪ Short Term	▪ Long Term
Impact: *What is the impact?*	▪ Minor/Moderate/Major ▪ Health/Environmental/ Self-Sufficiency	▪ Risks ▪ Equity

CSA Group Research

In order to encourage the use of consensus-based standards solutions to promote safety and encourage innovation, CSA Group supports and conducts research in areas that address new or emerging industries, as well as topics and issues that impact a broad base of current and potential stakeholders. The output of our research programs will support the development of future standards solutions, provide interim guidance to industries on the development and adoption of new technologies, and help to demonstrate our on-going commitment to building a better, safer, more sustainable world.

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