



STANDARDS RESEARCH

# Envisioning a Made-in-Canada Pandemic Response Products Ecosystem

Towards Self-Sufficiency and Sustainability

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# Executive Summary

The COVID-19 pandemic has required global mobilization of goods and supplies to help limit viral transmission and provide care for those affected. Shortages occurred for several critical products. The lack of materials was so severe that the national security exception process was invoked to facilitate acquisition of goods and services. This experience has revealed several vulnerabilities in Canada's pandemic preparedness with respect to availability of products needed to respond to a pandemic.

Many of the challenges to ensuring sufficient product availability are experienced globally, while some are unique to the Canadian context. Understanding and defining the Canadian pandemic response products ecosystem – the interconnected landscape of actors and practices in manufacturing, regulatory affairs, conformity assessment, procurement, and distribution – is the first step to identifying appropriate responses to fill those gaps. There is now a need and an opportunity for Canada to develop its own pandemic products and associated standards to improve national security via a sovereign supply of essential resources.

The objectives of this report are to answer the following research questions: What is the state of the current pandemic response products ecosystem in Canada? What is needed to create a self-sufficient and sustainable pandemic response products ecosystem in Canada? This report provides recommendations to address ecosystem gaps and will be followed by a feasibility assessment of the proposed recommendations in a subsequent report.

This work was informed by the following main activities:

1. Development of a project framework;
2. Stakeholder interviews to validate the project's scope and inform the gap analysis;
3. An environmental scan to identify papers and reports relevant to the research questions;
4. Synthesis of findings to identify ecosystem gaps and develop recommendations;
5. Development of case studies to illustrate key challenges in the current ecosystem; and
6. Review of recommendations with stakeholder roundtables.

The findings were informed by interviews with over 30 stakeholders from industry, government, health services, and academia, and a review of over 200 documents.

Pandemic response products included in the ecosystem were categorized into five functions: medical devices (e.g. ventilators), personal protective equipment (e.g., masks), testing and diagnostic equipment (e.g, swabs), air and surface sanitization products (e.g., disinfectants), and public health equipment (e.g., non-medical masks, hand sanitizer). While many of these products would be classified as a medical device in their regulatory pathway, this project considered functions separately based on their uses.

The ecosystem was further characterized into domains to facilitate identification of gaps. The domains were described as quality infrastructure, supply chain, and sustainability. **Quality Infrastructure** is the system of public and private institutions, as well as legal and regulatory frameworks and practices, that establish and implement standardization, accreditation, metrology, and conformity assessment. **Supply chain** describes the business activities and operations that integrate a continuous, seamless flow of products and services. **Sustainability** is the

ability to satisfy, among others, quality infrastructure and supply chain needs without harming the environment or well-being of those in the future, and is the domain under which second-order effects of increased domestic production are considered.

Stakeholders described several gaps in the pandemic response products ecosystem. It is clear that greater domestic production of pandemic response products is needed to improve resiliency. While increasing domestic production is critical, there are many other important aspects to becoming self-sufficient that need to be addressed. The quality infrastructure needed to create Canadian standards and perform product testing locally also requires significant strengthening. While some of these quality infrastructure and production challenges require local solutions, there is also a need to coordinate globally on standards and regulations when feasible. Adoption of global standards for traceability was encouraged. A reliance on US standards, testing, and certification for N95 masks created a critical bottleneck during this pandemic, a situation which must be avoided in the future. There is also an opportunity to develop better products, including an urgent need for more effective masks for the public, and masks that are more comfortable and recyclable. Stakeholders urged for greater collaboration between medical, standards, and manufacturing communities.

Under each domain, specific recommendations were developed:

- Quality Infrastructure
  - Improve mask design, standards, and guidance
  - Align regulations internationally
  - Invest in product testing infrastructure
  - Invest in traceability infrastructure
- Supply Chain
  - Redesign the National Emergency Strategic Stockpile
  - Facilitate an open procurement marketplace
  - Inform demand through enhanced scenario planning and forecasting
  - Develop and maintain diagnostic testing capacity
- Sustainability
  - Increase reprocessing of PPE and medical devices
  - Develop pandemic response products that are recyclable, compostable, or biodegradable
  - Support Canadian manufacturers
  - Support innovation and evidence generation for new technologies

Some limitations of this report should be noted. Some relevant geographical and disciplinary perspectives were not represented in our stakeholder interview sample. In particular, rural, remote, and Northern stakeholders were underrepresented, as well as governments at all levels.

By their nature, ecosystems are complex. The recommendations made in this report touch upon multiple complex areas that must evolve to improve future pandemic responses. Based on this report's characterization of the current state of the pandemic response products ecosystem, high-level recommendations are provided that are aimed at actors in industry, government, research, and health systems. In the next phase of this research, the feasibility of the proposed recommendations will be explored in detail. These findings will be published in a subsequent report later in 2021.



**"There is an opportunity for Canada to develop its own pandemic products, associated standards, and certification programs to ensure national security via a sovereign supply chain for essential resources."**

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## 1 Introduction

The COVID-19 pandemic has required global mobilization of pandemic response products to help limit viral transmission and provide care for those affected. Across the globe, the sudden increase in usage of personal protective equipment (PPE) – including masks, respirators, face shields, gowns, and gloves to protect health care workers, first responders, patients, and the public – resulted in shortages. Challenges related to availability of medical devices, such as ventilators, resulted in tragedy when access to life-saving interventions was inadequate and even rationed [1]. The surge in demand for sanitizers has led to quality-control issues with increased use in public areas [2], and Health Canada has recently recalled select products that did not meet requirements [3].

This experience has revealed several vulnerabilities in Canada's pandemic preparedness. Some of these challenges were experienced globally, while some are unique to the Canadian context. Strained supply chains and the lack of evaluative capacity has made it difficult to find consistent, high-quality sources to meet demand for essential pandemic response products. This shortage has been exacerbated by the fact that these products are typically manufactured, tested, inspected, or certified outside of Canada.

Canadian manufacturers have responded and many have pivoted efforts towards the manufacturing of needed products. These efforts have ranged from auto manufacturers making PPE, laboratory consumables, and medical devices to alcohol producers creating

sanitizers [3], [4]. However, the need for ongoing domestic production, as well as the testing, inspection, and certification of these products, remains high. Manufacturers need to navigate Canada's regulatory processes and connect with buyers. Procurement in health care spaces has typically been inflexible, adding challenges for inexperienced new entrants.

There is an opportunity for Canada to develop its own pandemic products, associated standards, and certification programs to ensure national security via a sovereign supply chain for essential resources [6]. Face-filtering respirators (FFRs) are a key example: many jurisdictions have their own certification bodies that reflect distinct requirements for approval, such as the US (N95), China (KN95), European Union (EU; FFP2), Japan (DS), and Australia (P2). Canadian standards and certification programs for FFRs and other pandemic response products would help reduce dependence on international certifications and imported products. High-quality jobs related to local production and evaluation have historically been a Canadian industrial policy goal and the pandemic has highlighted gaps in these areas.

Strengthening the made-in-Canada capacity also provides an opportunity to influence environmental and economic sustainability. High consumption of single-use PPE and medical devices globally results in waste [7]. Currently, reprocessing standards are not consistently applied in Canada. There is an unprecedented interest in improving the reprocessing and life-cycle management of these items [8], [9].

Pandemic preparedness plans have been developed in the past. The 2006 Canadian Pandemic Influenza Plan for the Health Care Sector stated that products and supply chain issues were largely outside of its scope; although it was recommended that a 16-week supply of laboratory products be maintained [10]. There is a need to improve the sustainability and self-sufficiency of products used to combat future pandemics in Canada [10].

The objectives of this report are to answer the following research questions:

- What is the state of the current pandemic response products ecosystem in Canada?
- What is needed to create a self-sufficient and sustainable pandemic response products ecosystem in Canada?

## 2 Methodology

This work was informed by the following main activities:

1. Development of a project framework;
2. Stakeholder interviews to validate the project's scope and inform the gap analysis;
3. An environmental scan to identify papers and reports relevant to the research questions;
4. Synthesis of findings to identify ecosystem gaps and develop recommendations;
5. Development of case studies to illustrate key challenges in the current ecosystem; and
6. Review of recommendations with stakeholder roundtables.

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

### 2.1 Development of a Project Framework

The first step of the project was to develop a framework to define a "pandemic response products ecosystem" to facilitate the identification of gaps in that ecosystem. A widely accepted business definition of "ecosystem" was adopted: *a complex network or interconnected system with dynamic interactions* [11], [12]. While this work was

motivated by the COVID-19 pandemic, the framework was designed to be relevant to future pandemics with different transmission and symptom profiles.

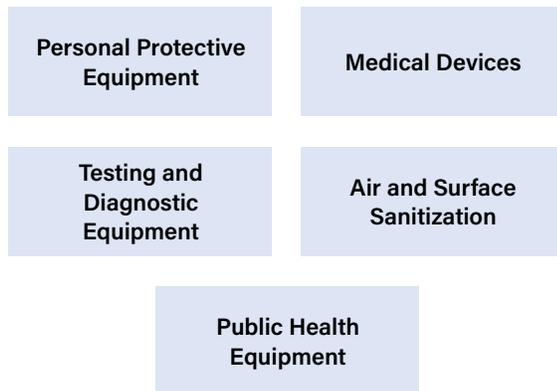
The pandemic response products included in the ecosystem were first categorized into a series of functions to distinguish needs and uses. Clear functions to be included were PPE and medical devices, but other critical goods to be included required discussion. Items included in the government Buy and Sell procurement site [13] and the National Emergency Strategic Stockpile (NESS) [14] were reviewed.

The framework also included domains for evaluating ecosystem gaps. Domains were identified through a review of guidance documents by Government of Canada agencies on pandemic response and pipeline considerations. A targeted literature scan was conducted to consolidate domains into the appropriate level of granularity, and feedback was solicited from stakeholders in the scope validation phase to ensure both completeness and consistency. The framework was treated as a living document during the project. The version adopted for use in stakeholder interviews, to inform the environmental scan and structure the report, is shown here to orient the reader to the subsequent sections.

Ultimately five material functions were included in the framework (see Figure 1). The five functions were medical devices (e.g., ventilators), PPE (e.g., masks), testing and diagnostic equipment (e.g., swabs), air and surface sanitization products (e.g., disinfectants), and public health equipment (e.g., non-medical masks, hand sanitizer). While many of these products may be classified as a medical device in their regulatory pathway, functions were considered separately based on their uses.

The setting for use was also important. It was decided that products used in health care settings would be included, except for the public health equipment function, where community settings were included. Pharmaceutical products and vaccines were purposefully excluded from the framework functions to contain the project's scope, and because some supply chain and regulatory issues for treatments were considered distinct and meriting unique consideration.

**Figure 1:** Functions of Products Included in the Project Framework to Define the Pandemic Response Products Ecosystem



Each function was evaluated across domains that describe key aspects of the ecosystem. Subdomains were assigned to further organize the framework. The three domains used to evaluate ecosystems gaps are:

- Quality Infrastructure (QI)
- Supply Chain
- Sustainability

The domains and subdomains are shown in Figure 2. The definitions of the domains and subdomains are described in Section 4 and provided in Appendix A1. The relationship between the various domains and subdomains is captured in Figure 3, which shows directional arrows between the aspects of the ecosystem as well as additional aspects of quality infrastructure.

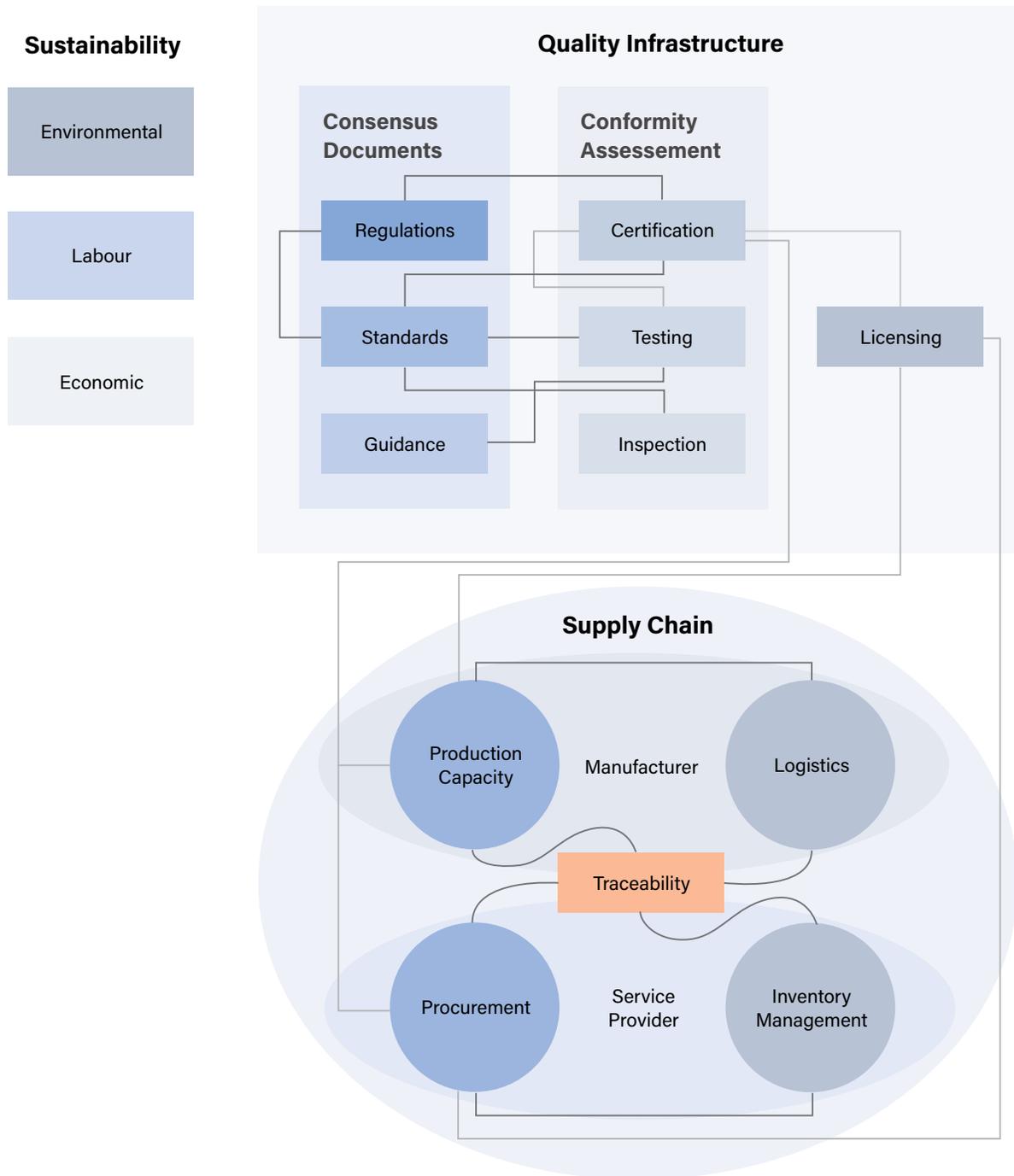
## 2.2 Stakeholder Interviews: Scope Validation and Gap Analysis

Potential participants were identified with expertise in either a framework function or domain. Broad representation in terms of sector, geographic location, and subject matter expertise was desired. This study

**Figure 2:** Domains and Subdomains Included in the Project Framework to Define the Pandemic Response Products Ecosystem



**Figure 3: Map of the Relationship Between Domains and Subdomains in the Project Framework**



received approval from the University of Toronto Ethics Review Office. Participants listed in the acknowledgements signed a written consent form. Participants' comments are anonymized.

Interviews conducted for scope validation and gap analysis used a semi-structured design with a unique interview guide. These interviews were conducted with individuals, or occasionally with two individuals from the same organization. Interviews were conducted remotely using Microsoft Teams. For interview guides see Appendix A2.

The scoping validation phase required participants to provide feedback on the project framework. Scope validation interviews took place in September 2020. Guiding questions for the scope validation interviews included:

- "Is the framework comprehensive when it comes to products needed in the COVID-19 pandemic response?"
- "Is the framework flexible enough to address pandemic responses to diseases with different profiles to COVID-19?"
- "Do the proposed case studies offer opportunities to explore relevant ideas in depth?"

In the gap analysis phase, participants were asked to reflect on their experiences and offer their insight on ecosystem gaps. Questions in the gap analysis interview guide included "Which essential resources, services, or policies were present/absent in Canada's response to COVID-19?" Gap analysis interviews were conducted between September and October 2020.

## 2.3 Environmental Scan

An environmental scan was deemed the appropriate method for gathering a broad range of evidence to inform the ecosystem assessment. The scans were conducted in conjunction with stakeholder interviews. Methods were guided in general by recommendations on the conduct of rapid reviews [15].

Given the broad scope of this project and the need to identify evidence outside of traditional scientific

databases, the searches were limited to web search engines, specifically, Google and Google Scholar. The search strategy employed an iterative approach. Since web search engines do not accommodate complex Boolean searches used for traditional databases, a traditional database search strategy was adapted to include multiple searches to ensure adequate coverage. Using the principle of saturation, no more than 100 hits from each combination of search terms were included in the review. An outline of the final search strategies for each database is shown in Appendix A3.

Articles were included if they met the following criteria: (1) the article content focused on topics related to any of the identified function categories; (2) content covered at least one framework domain; (3) content related information directly or indirectly to the current or a past pandemic; and (4) articles were focused on at least one Organisation for Economic Co-operation and Development (OECD) country. As the goal was to characterize the existing pandemic products response landscape in Canada and identify areas for improvement, literature pertaining to past emergencies (e.g., the SARS outbreak during 2003–2004) was desired. Date limits were therefore not applied.

Articles underwent two rounds of screening. The first included a title screen and an additional screening of text excerpts for Google Scholar hits. Hits that met the inclusion criteria went on to the second round of screening, which included a scan of the entire text. Data from hits were only extracted if they passed both rounds of screening. Included hits were extracted into a summary sheet in MS Excel.

## 2.4 Synthesis of Findings to Identify Ecosystem Gaps and Develop Recommendations

Data collected from the gap analysis interviews and the environmental scan were examined for consistent themes and ideas. Findings were then organized according to the domains and functions of the framework. Evidence-informed draft recommendations were developed based on identified ecosystem gaps.

## 2.5 Development of Case Studies to Illustrate Key Challenges

Topics for case studies were selected based on feedback gathered in the scope validation phase. Case studies were selected to highlight the Canadian experience of essential products that were difficult to access over the course of the pandemic. The content of the case studies was informed primarily by the experience of stakeholders interviewed and supplemented by targeted literature searches.

## 2.6 Review of Recommendations in Stakeholder Roundtables

Draft recommendations were developed by the research team and initially reviewed by the Project Advisory Panel. Recommendations were then reviewed and discussed with roundtable participants. Roundtables were organized by framework domain (i.e., quality infrastructure, supply chain, and sustainability). The policy domain was adapted to fit within the three domains rather than presented under a standalone policy domain.

Participants reviewed the draft recommendations prior to each roundtable. Some participants had taken part in previous interviews, while others were new to the project. Each roundtable included between two and six participants. Two roundtables per domain were convened, for a total of six roundtables. Roundtables

were held in December 2020. A total of 27 invitations were sent to potential participants, with 19 participating. Some participants joined multiple roundtables, depending on their expertise and availability. During the roundtables, participants were presented with the project's background, the research activities to date, and the draft recommendations. Participants were asked to discuss the recommendations and offer feedback on their relevance and accuracy, and to identify additional ideas and topics for review. A feasibility assessment of the recommendations will be performed in a subsequent report.

## 3 Summary of Results of Interviews and the Environmental Scan

### 3.1 Stakeholder Interviews

Six experts were interviewed in the scope validation phase. Three participants worked at an organization with geographical reach across Ontario, two across Canada, and one international. Four participants were employed in industry and two in health services.

During the gap analysis phase, 21 experts were interviewed. Nine participants worked at an organization with geographical reach across Ontario, one across Manitoba, nine across Canada, and two international. Ten participants were employed in industry, four in

**Table 1:** Functional Expertise of Key Informants\*

Jurisdiction	Scope Validation			Gap Analysis		
	Completed	Incomplete	Total	Completed	Incomplete	Total
PPE	3	1	4	12	18	30
Medical devices	5	2	7	7	13	20
Testing and diagnostics	1	0	1	2	2	4
Air and surface sanitization	2	0	2	1	3	4
Public health equipment	2	4	6	3	10	13
Other	0	0	0	3	12	15
<b>Total</b>	<b>13</b>	<b>7</b>	<b>20</b>	<b>28</b>	<b>58</b>	<b>86</b>

\*Data presented are not mutually exclusive as each function category reflects the overall number of participants who were able to contribute knowledge to those areas. For example, a participant with expertise in PPE and medical devices would be counted in each function category. Stakeholders who declined to participate or didn't respond to an invitation were counted as incomplete.

health services, five in academia or tertiary education, and two in government. Table 1 provides information on participant area(s) of expertise as defined by functions included in the project framework.

### 3.2 Environmental Scan

The results of the environmental scan across all functions and domains are shown in Table 2. A total of 162 and 42 hits from Google and Google Scholar, respectively, were included in the scan. An additional 35 hits were included from hand searches. Table 3 breaks down included articles by function. The functions with the highest number of hits were PPE, medical devices, and testing and diagnostics.

## 4 Characterization of Current Pandemic Response Products Ecosystem: Domains

### 4.1 Quality Infrastructure

The World Bank defines QI as “the ecosystem of public and private institutions as well as legal and regulatory frameworks and practices that establish and

implement standardization, accreditation, metrology, and conformity assessment (testing, inspection and certification)” [16]. The United Nations Industrial Development Organization uses a similar definition, and includes market surveillance as an aspect of the QI ecosystem [17]. QI is a critical business enabler; the World Bank states that “the QI system is required for the effective operation of the domestic market, and the international recognition of QI services is important to enable access to foreign markets” [16]. Effective QI helps ensure that products meet predetermined requirements during production and are manufactured in a consistent way.

The project framework breaks QI down into three subdomains: (1) consensus documents, (2) conformity assessment, and (3) licensing. The consensus documents are the regulations, standards, and guidance documents that provide requirements and the steps needed to meet those requirements. Conformity assessment encompasses testing, certification, and inspection to ensure that these requirements are met. Licensing is the seal of approval that provides a right for sale.

**Table 2:** Environmental Scan Search Results

	Search results (n)	Title/abstracts included for full-text review (n)	Articles included in review (n)
Google	1,835	399	162
Google Scholar	1,749	174	42
Hand searches	—	—	63
<b>Total</b>	<b>3,584</b>	<b>573</b>	<b>267</b>

**Table 3:** Description of Articles Included in the Environmental Scan

	PPE	Medical devices	Testing and diagnostics	Air and surface sanitization*	Reprocessing	Public health equipment	Total
Google	45	30	53	—	17	17	<b>162</b>
Google Scholar	22	6	4	—	9	1	<b>42</b>
Hand searches	12	15	2	29	—	5	<b>63</b>
<b>Total</b>	<b>79</b>	<b>51</b>	<b>59</b>	<b>29</b>	<b>26</b>	<b>23</b>	<b>267</b>

\*Upon review, the Google and Google Scholar hits under the air and surface sanitization function were more aligned to the public health equipment function. The air and surface sanitization function scan was completed using only hand searches.



include PPE, diagnostic testing devices, ventilators, monitoring devices, and sterilizing devices as well as new products entering the market [25], [26]. The IO also offers temporary product authorization for manufacturers to import, manufacture, or sell specific pandemic response products. Under the IO, Health Canada reviews the product based on a list of minimum specifications for products that are in short supply during a state of emergency [21]. The pandemic response IO was introduced in March, 2020 and was in place until March, 2021. After this point, Health Canada issued a second IO to maintain the flexibilities and regulatory oversight provided by the current IO until at least the fall of 2021" [27].

With the introduction of the IO, there are now two pathways to follow for sale of Class I pandemic-related products: (1) through an IO or (2) through an MDEL. Health Canada has recommended that manufacturers of Class I COVID-19 products interested in aiding the COVID-19 response pursue only one of these two pathways. Choosing between these two pathways is only applicable to Class I medical device manufacturers. Distributors are currently not issued IO authorizations. Each carries a set of unique benefits and risks for the manufacturer. Applicants who received an IO authorization were granted expedited review processes, where they did not require an MDEL to import or distribute their product within Canada and received exemption from the Medical Devices Single Audit Program (MDSAP) certification for Class II to IV devices [28]. Class II to IV medical devices require either an IO authorization or a full MDL prior to advertisement, importation, and sale. Importers and distributors of Class II to IV medical devices can also apply for an MDEL to *import or distribute* a Class II to IV device, provided they also hold an MDL or IO authorization for the given device.

The expedited review process included some important changes. Select medical device regulation obligations of MDEL holders were relaxed (e.g., allowing local vendors to import and sell medical gloves that do not meet labelling requirements) and application fees were reduced. Health Canada has also considered special requests to import or manufacture medical devices that were not entirely in line with current

regulations [22]. Stakeholders noted that while IOs are available for expediting approval, an organization can still choose to pursue an MDEL for the longer term. The major difference between the two authorization pathways (i.e., either obtaining an IO or the expedited MDEL pathway) is that the IOs are product specific and therefore require product and quality system performance metrics, whereas MDELs require a general application review and do not require specific metrics [29]. For this reason, many manufacturers of pandemic response products opted to apply for an MDEL [29].

While some stakeholders described a preference for the MDEL pathway, there remained some concerns with this approach. As manufacturers are only required to submit a general application, each individual product had not been vetted by Health Canada [29]. Compliance then fell on the MDEL holder. With this approach it is difficult for consumers to verify that a purchased product meets standards. In comparison, Health Canada reviews performance data for devices permitted under an IO and host IO-approved products on a database for procurement agencies.

Similarly, Health Canada has outlined pathways for fast-tracked approval of hand sanitizers and disinfectants [21]. For example, regulatory requirements were eased for facilities interested in manufacturing or distributing hand sanitizers containing 60 to 80% ethanol or 60 to 75% isopropanol, which facilitated more hand sanitizers to be licensed and additional site licences to be issued. Sanitization products such as hand and surface sanitizers undergo a similar process and require a drug identification number (DIN) to be authorized for sale and distribution within Canada [22], [30].

Health Canada is tracking imported devices under these new pathways. The imported devices approved under IOs and MDELs intended to be used during the COVID-19 pandemic and authorized by a "trusted foreign regulatory authority" are posted on the List of Medical Devices for Expanded Use from Health Canada [21]. To help address shortages in current supply and anticipated shortages for future supply, the IO also requires manufacturers and importers to report product shortages for select items [22].

Health Canada's regulatory response to the crisis has led to hundreds of devices being authorized under the IO and issuance of thousands of MDELs from March to November 2020 [31].

#### 4.1.1.2 Standards

The Standards Council of Canada (SCC) defines standards as a "document that provides a set of agreed-upon rules, guidelines or characteristics for activities or their results. Standards establish accepted practices, technical requirements, and terminologies for diverse fields" [32]. Unlike regulations, standards do not carry the force of law. Standards are developed through consensus by stakeholder committees, potentially including representatives from industry, governments, academia, and the public. These committees are organized and managed by organizations that specialize in the development of standards, called standards development organizations (SDOs) [33]. Standards have also been described as a way to make things work, or a formula that describes the best way of doing something [34].

Standards may be developed at the international level by SDOs such as the International Organization for Standardization (ISO), or domestically by organizations such as CSA Group. Canadian manufacturers often recognize and adopt international standards for the manufacture of key pandemic response products. One example is the CAN/CSA-ISO 13485 (*Medical devices – Quality management systems – Requirements for regulatory purposes*) [35]. Standards feed into the conformity assessment apparatus covering testing, inspection, and certification. These will be described further in the subsequent conformity assessment section.

#### 4.1.1.3 Guidance Documents

Guidance documents are guidelines written to give broad advice and do not have the force of law [36]. They may also support the interpretation of policies and regulations [36]. Guidance documents can be critical during a pandemic, as changes to regulations and normative standards may take longer to occur.

In August 2020, Health Canada issued FFR guidance for Canadian manufacturers [37]. The guidance was developed in partnership between the Public Health Agency of Canada (PHAC), CSA Group, and the National Research Council of Canada (NRC) [38]. This was in response to the high demand for N95 products and a lack of availability of National Institute for Occupational Safety and Health (NIOSH) certified products. Products developed using the guidance are designated with a "PFE" to denote particulate filter efficiency. The guidance for FFRs was to be in effect until the IO expired on March 18, 2021, "or until a robust accredited certification scheme is developed" [37] (accreditation and certification are discussed in Section 4.1.2, Conformity Assessment, below). The Canadian guidance on FFRs noted a brand preference for N95 certified by NIOSH, stating that "respirators meeting equivalent standards are largely not sought or found acceptable" [37].

Guidance documents have been helpful for informing the use of new technologies and products. Health Canada and the Government of Canada also produced domestic guidance for medical device reprocessing and infection control protocols [39], [40]. Health Canada has provided guidance for the evaluation of 3D-printed devices [41]. Ontario Health has offered guidance for securing alternative PPE during the COVID-19 pandemic, including reusable PPE and other sources of certified PPE [42].

#### 4.1.2 Conformity Assessment

Pandemic response products must be tested before use to show that they are able to work as intended. Conformity assessment "is the practice of determining whether a product, service or system meets the requirements of a particular standard" [43]. Conformity assessment activities may include testing, inspection, validation, certification, and accreditation [44]. The project framework describes product testing, certification, and inspection. Accreditation is the process by which a certification body proves that the products being tested are able to provide adequate services. The other aspects of the conformity assessment infrastructure, such as audits, were deemed to be less critical sources of action for review in this report.



**"Stakeholders reported difficulties early in the pandemic after key US laboratories suspended testing of foreign orders to prioritize the US market. This made testing and validation of PPE a much larger challenge for Canadian manufacturers."**

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#### 4.1.2.1 Product Testing

Product testing ensures the product works as it should and meets standards. Accreditations are provided from a third-party source and recognize the capacity of a facility to conduct specific tasks [45]. Laboratories performing product testing require necessary accreditations to ensure processes are in line with recognized standards.

Stakeholders noted several issues in the product testing landscape in Canada. Canadian testing capacity for essential pandemic response products was limited at the outset of the pandemic [46]. Canadian firms were able to rely on NIOSH testing standards, but many lacked a sufficiently large pool of testing equipment to meet domestic demands for many products, as well as local competencies to perform testing. Stakeholders reported difficulties early in the pandemic after key US laboratories suspended testing of foreign orders to prioritize the US market. This made testing and validation of PPE a much larger challenge for Canadian manufacturers.

In response to this service shortage, many testing facilities expanded their capacity to support broader product testing. This included public and private sector organizations, and university laboratories. University labs and national research facilities such as the NRC supplemented constrained testing capacity both by providing testing services and providing training to corporate labs. NRC developed capabilities in PFE

testing of N95-type respirators to meet testing demand in the short term. A stakeholder shared that, on behalf of PHAC, NRC tested imported lots procured through Public Services and Procurement Canada (PSPC), and supported domestic FFR product development for private industry. The Government of Ontario provided funding to CSA Group in June 2020 to boost testing capacity for medical-grade masks, FFRs, gowns, gloves, and other PPE [46]. One stakeholder noted that initiatives at the University of Toronto and McMaster University were created to support FFR development in the private sector while meeting international standards.

Private corporate testing facilities and university laboratories are typically not accredited, yet may have the equipment needed for testing. Stakeholders noted that labs in universities and colleges may support product testing during crises. These facilities can use available equipment to provide quality markers for pandemic response products, communicating essential information (e.g., exact filtration efficiency) for products that have already been approved. There are also many labs that are accredited by foreign certification bodies, but not domestic ones. These labs may be difficult to identify. This created confusion during the COVID-19 pandemic as it was difficult to identify available equipment necessary for product testing.

Beyond capacity, COVID-19 has revealed other challenges to product testing. Differences in standards and how they are implemented can lead to challenges

in selecting tests and understanding results. This challenge is illustrated by the standards for surgical masks. The two commonly used testing standards are defined by NIOSH and ASTM International, an international SDO [47]. For surgical masks, ASTM standards have been specified by Health Canada (specifically, ASTM F2100) [37]. There are five tests required for surgical masks, with various degrees of testing capacity in Canada [48], [49]. Surgical masks are tested for fluid penetration resistance, differential pressure, bacterial filtration, submicron particle filtration, and flame spread [50]. ASTM F2299 particle filtration tests require face velocity and neutralization subcomponents, which under the current standards have a highly variable set of acceptable parameters. This means that surgical masks with different filtration efficiencies can meet the ASTM standards required for product approval despite varying efficacy; or, that various labs could get different results for the same product, depending on how they implement ASTM standards. Stakeholders relayed that it is thought that the ASTM F2100-11 standard on submicron size (up to 0.1 micron) may be too large to effectively filter coronavirus particles [50]. As a result, NIOSH mask standards, which have a more constrained calibration requirement, have been preferred. This contributes to a product testing bottleneck as US labs have restricted foreign product testing [37].

Stakeholders familiar with testing infrastructure in Canada remarked that it was difficult to know which labs had capacity to run which tests. Testing facilities relying on the ASTM standards have at times used tests with different parameters for surgical masks. Different processes mean that results from different tests might not be comparable. Stakeholders noted that the difference in standards between ASTM and others led to a need for significant investments to compare the suitability of testing equipment at different facilities and to harmonize test methods.

In addition, equivalence across testing facilities has not yet been established, although that process has been underway since laboratory capabilities were enhanced in response to the pandemic. This lack of cross-validation between labs also led to a lack of centralized knowledge on capacity, further hindering

coordination. For FFRs, it was noted that for submicron particle filtration, the most COVID-19 relevant test, tacit knowledge, and skills required to perform testing did not yet exist in Canada early in the pandemic. A different participant remarked in a later consultation that this knowledge has been developed over the course of the pandemic and Canadian firms have expanded testing capacity to meet these needs. The learning curve was high, which limited how quickly testing capacity could scale up.

#### 4.1.2.2 Certification

Generally speaking, product certification provides assurance that the products have been tested and meet the requirements covered by the stated standards and/or regulations, with ongoing conformity assessment requirements provided through factory inspections and conformity testing. In Canada, certification bodies require accreditation to ISO 17065 from the SCC [51]–[53]. Certification bodies must also have their laboratories accredited to ISO/IEC 17025:2017, but laboratories can be accredited without being a certification body. Laboratory accreditations (ISO/IEC 17025:2017) can be provided by all International Laboratory Accreditation Cooperation (ILAC) accreditation bodies holding a valid ILAC MRA, such as the International Accreditation Service (IAS) [54]. Including CSA Group, there are currently seven domestic accredited organizations for testing and certification of FFRs, ventilators, and raw and processed materials – or input materials – used in medical device manufacturing [55]. Not all of these seven firms provide certifications.

#### 4.1.2.3 Inspection

This section reviews inspections processed by external parties rather than a certification body. Product inspection is the process of checking goods for compliance with specifications and requirements. When large quantities of items are ordered by Canadian organizations, shipments are inspected by Canadian authorities to meet specifications and requirements. Under the new IO, Health Canada and the Canada Border Services Agency are required to review the compliance of imported and exported

medical devices at the border by ensuring shipments have the necessary product licence numbers, and that import documents include an IO authorization. Inspection costs have been fairly high during the pandemic as it is more difficult to survey foreign production at the time of order, and border agencies have experienced labour constraints.

The challenges with inspection has made it more difficult to quickly obtain quality supplies. Millions of masks did not pass inspections in Canada [56]. The Canadian government did, at times, receive KN95s, an FFR that meets Chinese safety standards for COVID-19 [57]. These masks were tested in Canada by NRC on behalf of PHAC to determine if they also met North American standards [57]. Some KN95s did conform to Health Canada requirements, yet were kept in storage, as end users preferred N95 respirators, particularly in light of press coverage which noted many of the performance failures of KN95 respirators when tested in Canada and elsewhere in the world [57]. Health Canada needed to recall other pandemic response products such as hand sanitizers that were not compliant with requirements, such as the inclusion of risk information on labels [58].

### 4.1.3 Licensing

Regulated medical equipment and devices require a licence before sale. The MDL requirements for

manufacturers, importers and distributors were briefly described in section 4.1.1.1. Licensing approval for items classified as medical devices relies on certification to applicable standards. It also depends on expert testimony that the item meets industry and regulatory standards [21]. Class II to IV medical devices that are manufactured (Class II) or designed and manufactured (Class III and IV) require both an MDL and a certified ISO 13485 quality management system. A registered quality system is needed to demonstrate compliance with relevant regulatory quality system requirements [59]. Quality system certification is not needed for Class I medical devices or importers or distributors of Class II to IV medical devices.

All licensed Class II to IV medical devices are recorded in a database maintained by the Medical Devices Bureau, with Class I devices monitored by the Health Products and Food Branch Inspectorate [60]. Medical devices must have appropriate labelling that includes symbols, warnings, instructions, or control labels; the labelling should also include information displayed on the user interface. Documents should be provided with the device such as user manuals, installation, and maintenance instructions [61].

### 4.1.4 Quality Infrastructure: Summary

A summary of the key points identified in the quality infrastructure domain is shown in Table 4.

**Table 4:** Quality Infrastructure: Key Points

Quality Infrastructure: Key Points	
<b>Consensus Documents</b>	<ul style="list-style-type: none"> <li>▪ Interim orders (IOs) from Health Canada allowed for rapid changes to address critical shortages.</li> <li>▪ Canadian guidance has been developed for face filtering respirators and other devices in a collaborative effort.</li> </ul>
<b>Conformity Assessment</b>	<ul style="list-style-type: none"> <li>▪ Canadian facilities did not have adequate capacity to test many key products and historically outsourced to labs in the US.</li> <li>▪ Testing capacity and capabilities of accredited, unaccredited, public, and private facilities are unclear.</li> </ul>
<b>Licensing</b>	<ul style="list-style-type: none"> <li>▪ Medical devices must have appropriate labelling that includes symbols, warnings, instructions, or control labels; labelling requirements were relaxed to facilitate importation under the IO, e.g., language requirements.</li> </ul>

## 4.2 Supply Chain

Supply chains describe activities and operations that integrate a continuous, seamless flow of products and services for health care delivery [62]. The project framework for the supply chain domain included five subdomains: (1) procurement, (2) production capacity, (3) traceability, (4) logistics, and (5) inventory management.

The roles and responsibilities in this domain are shared among manufacturers, which are responsible for production and are tied to the rest of the chain through logistics, and service providers, which procure goods for health care clients and assist in managing inventory. Service providers can be governmental entities such as provincial health authorities, shared service organizations (SSOs), or group purchasing organizations (GPOs). SSOs and GPOs have become more prominent in the Canadian health care space since the negotiation of the Agreement on Internal Trade (AIT) that came into force in 1995 and was claimed by stakeholders to impact health care by the later 1990s. SSOs typically provide inventory management and analytic services, and GPOs use their larger purchasing power to lower procurement costs [63]. A key aspect integrating the various supply chain actors is traceability: the ability to identify, track, and validate materials and products across the entire supply chain [64].

### 4.2.1 Procurement

Many health care settings critically lacked PPE at the beginning of the pandemic and struggled to procure essential goods through service providers. Stakeholders who worked across health service delivery sectors, from hospitals to long-term care (LTC) facilities and home-care providers, noted an acute difficulty in procuring PPE from any source. Though PPE supply improved throughout the spring and summer months, many health care professions still experienced challenges acquiring PPE in late 2020 [65]. Hospitals subscribed to GPOs had standardized allotments provided based on historical demand, which failed to adapt to the changing needs of the pandemic. Stakeholders expressed that GPO agreements committing them to one vendor limited their ability

to source additional PPE. Organizations struggled to identify sources for PPE independently, and often resorted to purchasing goods of uncertain quality at much higher prices.

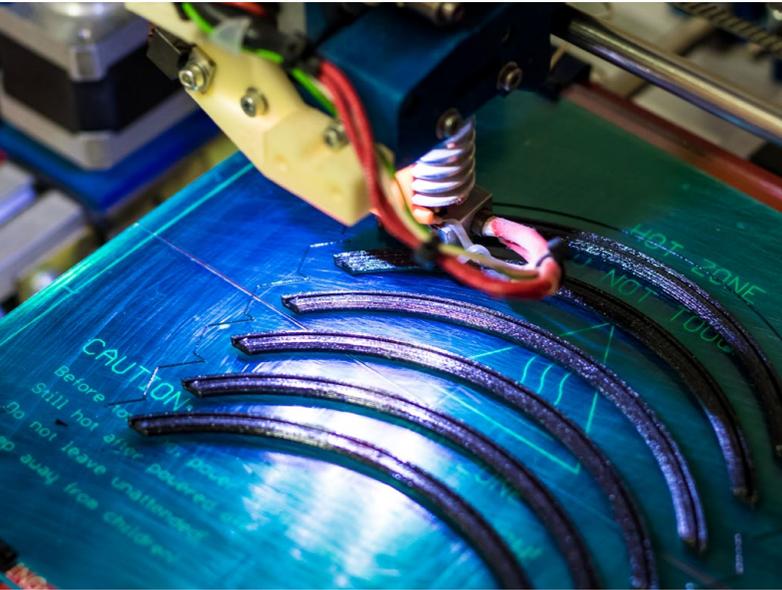
The LTC and home-care providers interviewed described an even more dire situation: having to drive their own vehicles to pick up boxes of PPE, using personal connections and donations to obtain PPE for their organizations, and resorting to reusing PPE without effective reprocessing. In Ontario, LTC and home-care providers are not associated with SSOs [66] and cannot rely on that external capacity to aid in a pandemic response. Many health care workers were also asked to practise extended use of disposable FFRs and to reprocess their PPE [67]. Some resorted to creating PPE using plastic film and photographic film [68].

In response to uncertainty across international markets, the Government of Canada was able to arrange for the procurement of ventilators and other medical devices such as PPE and testing kits from domestic suppliers. In March 2020, the Public Services and Procurement minister stated that “the government has placed orders from a variety of different companies for 157 million surgical masks, 60 million N95 masks, and 1,570 ventilators, as well as preparing to order another 4,000 ventilators” [69].

On an international scale, Canada has entered a joint declaration with six other countries (Australia, Brunei, Chile, Myanmar, New Zealand, and Singapore) to facilitate easier trade flows, allowing for the cross-border movement of necessary materials and goods [70].

### 4.2.2 Production Capacity

Stakeholders noted that manufacturing of new products in Canada was difficult for several reasons. Participants reported that domestic manufacturing is costly, with most manufacturers declining to produce small runs because of high fixed costs and a lack of capital coming from a small overall domestic market limiting the opportunity to scale. To increase domestic production capacity, the federal government issued a call for companies to aid in Canada’s COVID-19 response [71]. This initiative, referred to as the “Call to Action” plan, requested businesses in Canada with



"Manufacturing is costly, with most manufacturers declining to produce small runs because of high fixed costs and a lack of capital coming from a small overall domestic market limiting the opportunity to scale."

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available equipment or facilities, skilled workers, and the ability to provide PPE and medical supplies to offer manufacturing assistance. By late March 2020, more than 3,000 companies had responded, including those not previously manufacturing pandemic products [71]. For example, a winter clothing company began manufacturing scrubs and gowns to be distributed to hospitals across Canada [72]. Other companies made shifts in day-to-day production: distilleries produced hand sanitizer, medical device manufacturers built alternative ventilators, and plastics companies made face shields.

It was also noted that, despite Canada's rich raw material resources, limited refinement activities are conducted domestically to produce inputs to pandemic response products. Most raw and processed materials, such as polypropylene used to make PPE, come from Asian distributors [73], [74]. This has constrained domestic production capacity as imports fell due to global logistics bottlenecks [75]–[77].

Diagnostic testing capacity was also challenged by lack of materials. Some of the key material challenges encountered during the ramping up of diagnostic testing were collection swabs, transport media, reagents, and lab consumables. Reagents are used for the amplification of the viral materials in the samples collected and are a key input component of the testing apparatus. The lack of availability of reagents for Reverse Transcription Polymerase Chain Reaction

(RT-PCR) testing represented a major setback for the testing effort as most of the reagent manufacturing capacity is based in China and the pandemic has made access to this more difficult.

Proprietary testing kit manufacturers witnessed a dramatic spike in demand for their high throughput machines across the globe and, consequently, their supply chains were placed under immense stress. Specifically, Ontario's testing system relies heavily on instruments from a major European pharmaceutical giant. Their machines use a proprietary reagent chemical resulting in the company struggling to keep up with demand [78]. A New Brunswick company signed a deal with the government in April to provide reagents for up to 500,000 tests per week, however intellectual property protections prevents the use of domestic reagents in the machines from the European manufacturer.

Lab consumables such as deep well plates, transfer pipettes, and tubes were also identified as being at-risk of critical shortage. Difficulties in procurement were exacerbated by skyrocketing prices owing to an increased demand for these consumables and a dependence on supply chains in Asia [79]. Stakeholders reported that, while companies have pivoted to ramp up supply for deep well plates, pipette tips prove to be an ongoing bottleneck with domestic production still being an estimated 12 to 18 months away as of October 2020 [79].

The scientific community has already begun work on cutting-edge solutions to fill testing gaps. In a collaboration with McGill University and with support from the NRC Pandemic Response Challenge program, NRC scientists are working on solutions that would enable efficient, low-cost, and large-scale biomanufacturing of testing equipment [80]. A research team at the University of Calgary has been working on a rapid diagnostic test that uses protein-based screening and mass spectrometry to detect the virus directly from swabs [81]. A BC-based company is developing a one-minute COVID-19 antibody test to help broaden the extent of Canada's testing capabilities [82]. Health Canada has approved another company's RT-PCR test strips that deliver diagnostic results within an hour [83]. One other BC-based company is in the process of developing a 15-minute point-of-care (POC) antigen test in partnership with Next Generation Manufacturing Canada (NGen) [84]. Hospital laboratories may have not historically received sufficient funding for upkeep and maintenance, but these could have been leveraged to satisfy the testing backlog during the peak of the pandemic [78]. There is an urgent and pressing need for a greater focus on public health and hospital labs to help decentralize and supplement the national testing effort.

### 4.2.3 Traceability

Traceability concerns were noted as a major barrier to effective response by most stakeholders interviewed; however, it was difficult to identify solutions to respond to this gap. Participants familiar with supply chain challenges suggested that barcodes or similar technologies could be expanded and used for pandemic products. Such technologies store essential data on products that can be made accessible to buyers and sellers. The International Medical Device Regulators Forum (IMDRF) has published harmonized guidance on the use of such technologies [85]. GS1 is a non-profit organization that develops business communication for global standards, such as traceability infrastructure, and manages barcodes on products distributed along the international supply chain [86]. Existing IMDRF guidance and GS1 standards may provide a good foundation for improving global traceability infrastructure, and Health Canada is currently evaluating the use of IMDRF.

Participant interviews shed light on major challenges surrounding traceability of pandemic response products. Stakeholders relayed that cloth materials are typically not traceable or labelled, making it difficult to assess the filtration efficacy of locally made cloth masks. Stakeholders described outdated inventory management systems in the health sector, making it difficult to keep track of items. Stakeholders relayed that some health care organizations did not have sufficient information on lot numbers and expiry dates for key pandemic response products, such as N95 masks. Some orders are tracked by lot number, making it difficult to identify whether an individual item came from a small, contaminated batch. Better traceability infrastructure would improve inventory management.

### 4.2.4 Logistics

Prior to the COVID-19 pandemic, Canada had become increasingly reliant on China for multiple categories of manufactured products. Products developed in China are relied on for both their price and the quality of goods [74]. This reliance along with the US export ban on shipments of PPE and medical devices in the early stages of the pandemic, left Canada vulnerable to medical device shortages [87]. Stakeholders mentioned common occurrences of shipments being diverted or unfulfilled as a result of logistical challenges. There were also instances of incomplete shipments arriving, with boxes of goods having been removed at stops along their route to Canada.

The lack of coordination across international players, and the breakdown of trust in international markets as the pandemic progressed introduced significant supply chain challenges for countries with limited domestic production capacity such as Canada, spurring interest in a made-in-Canada approach

### 4.2.5 Inventory Management

Managing product inventories is a critical challenge for bodies overseeing stockpiles and health facilities. Many issues stem from an undeveloped traceability infrastructure, creating difficulty ensuring that product levels are adequate, products are used before their expiration date, and products are able to be tracked

once they have been used. A key component of inventory management for essential goods has been the just-in-time system, which seeks to reduce the amount of inventory immediately accessible for goods with high usage patterns [74], [88]. The just-in-time approach meant that, particularly early in the pandemic, supplies were rapidly depleted when consumers’ needs increased simultaneously and distributors could not rapidly adapt to meet rising demand.

The NESS was meant to fill this gap in times of crisis, but this did not occur as intended. A large portion of PPE in the NESS had expired years prior to the pandemic and was destroyed [89]. The NESS has not historically flowed its stock to end users during non-urgent times. In Ontario, the provincial government stockpiled millions of face masks several years after the SARS outbreak to prepare for a future pandemic [90]. In 2017, the Auditor General of Ontario found

more than 80% of the province’s stockpile had expired [90]. The provincial stockpile has been underfunded for some time and lacked mandates to meet the demand of a pandemic of this size [91]. In fact, the stockpile budget covered only the cost of storage and not the management of goods [90].

In addition, lack of communication between federal and provincial/territorial governments added further difficulties to coordinating pandemic resources. Federal agencies rely on provinces to manage PPE in their own stockpiles and provide assistance if additional aid is required [92]. The federal government did not coordinate its stockpile system with provincial and territorial governments in a timely manner [92]. These concerns were echoed in many stakeholder interviews.

#### 4.2.6 Supply Chain: Summary

A summary of the key points identified in the supply chain domain is shown in Table 5.

**Table 5: Supply Chain – Key Points**

Supply Chain: Key Points	
<b>Procurement</b>	<ul style="list-style-type: none"> <li>Procurement organizations have been unable to keep pace with the demands of the pandemic due to reliance on historical needs.</li> <li>Procuring sufficient products was difficult. Health care organizations experienced issues with distribution, purchasing decisions, and timely deliveries, among others.</li> </ul>
<b>Production Capacity</b>	<ul style="list-style-type: none"> <li>Canadian industries are not currently capable of sustaining long-term production due to high manufacturing costs and relatively low investment in domestic capacity.</li> <li>Most manufacturers are reliant on China for raw and processed materials used in production.</li> <li>Businesses required additional financial resources to pivot manufacturing to essential pandemic resources.</li> </ul>
<b>Traceability</b>	<ul style="list-style-type: none"> <li>Inability to trace certain products used to manufacture pandemic response products has proven challenging.</li> <li>Most stakeholders consider traceability an important issue but were unsure how to address it.</li> </ul>
<b>Logistics</b>	<ul style="list-style-type: none"> <li>Products distributed globally were not well-coordinated between countries during the COVID-19 pandemic.</li> </ul>
<b>Inventory Management</b>	<ul style="list-style-type: none"> <li>The NESS was underfunded and some contents expired. Federal and provincial governments did not coordinate on who was responsible for management, upkeep, and distribution of stockpile contents.</li> <li>Provincial stockpiles have been unevenly maintained and resourced.</li> <li>Inventory management practices in health care need modernization to move towards dynamic systems that can monitor inventory in real time.</li> </ul>

## 4.3 Sustainability

Sustainability is the ability to satisfy present needs without harming the well-being of those in the future [93]. The project framework identified three key subdomains of sustainability: environmental, labour, and economic sustainability. Environmental sustainability represents the need to take into consideration the ecological impact of input materials and building reusability into the design and manufacture process. Labour sustainability relates to bridging gaps in training and skill development that are needed for manufacturing of pandemic response products and services such as materials testing and diagnostic equipment. Crucial to the made-in-Canada ecosystem are the capital and capabilities to sustain long-term production and the economic sustainability subdomain tackles the key challenges and opportunities towards this.

### 4.3.1 Environmental Sustainability

#### 4.3.1.1 Waste

The COVID-19 pandemic increased reliance on single-use PPE that risk additional burdens for waste management systems. Increases in total waste have been reported in Canada. One medical waste processing company has reportedly experienced more demand for medical waste processing but not to the point of stalling operations [94]. Since single-use PPE are currently essential to a pandemic response, proper intake management of waste disposal systems over the long-term must be ensured.

The PHAC recommended that waste management systems follow routine practices [94]. This may include incineration or disinfecting PPE before moving items to a landfill [94]. Used PPE are given special treatment to avoid infecting workers along the waste management line [94]. Major cities in the US faced identical concerns and introduced temporary changes to their recycling system to avoid further exposures from contaminated products [95]. Reusable PPE offer an alternative to single-use items and can be used over longer periods of time, reducing waste production. Reusable elastomeric masks are already normalized in some occupations and are commonly relied on by industrial workers and miners

[96]. The benefits and drawbacks of elastomeric masks and other reuseable products will be further explored in a subsequent report.

The COVID-19 pandemic has not yet presented a significant challenge for the disposal of biohazardous waste in Canada. Future pandemics with different infectious profiles may present more challenges if materials that come into contact with infected individuals need more specialized handling. Despite the 2006 Canadian Pandemic Influenza Plan detailing corpse management procedures with recommendations such as maintaining a rotating six month inventory of body bags [10], stakeholders reported that early in the pandemic, no protocols existed for the management of deceased individuals, and sometimes corpses retrieved for burial were wrapped in sheets. This presented challenges in other jurisdictions, and it may be important to address these activities in future pandemic response plans.

#### 4.3.1.2 Reprocessing

Reprocessing refers to the “cleaning, sanitization, disinfection, decontamination, and/or sterilization of devices and equipment in health care settings” [42]. Due to a lack of clear evidence on efficacy and safety, reprocessing of single-use isolation gowns, surgical/procedural masks, and gloves has not been recommended by certain health authorities, including Ontario Health [42].

There is a lack of coordinated formal training and accreditation within reprocessing specializations for single-use medical devices in particular. Although a stakeholder mentioned that courses, programs, and certifications are offered by post-secondary institutions and standards organizations like CSA [97], other stakeholders noted that training for reprocessing staff is not standardized across the medical sector, leading to variations in quality.

There are many concerns over the use of reprocessed single-use products [98]. Most of the recent reprocessing literature has focused on reprocessing FFRs, such as N95s, for reuse and conservation [99]. Though this area is rapidly evolving, currently there is a lack of scientific evidence supporting the efficacy



"The shortage of face-filtering respirators led to industry actors across Canada leveraging existing technologies, typically used for other purposes, to reprocess materials products for reuse."

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and safety of reprocessing methods for single-use FFRs [100]–[102]. In the literature, maintaining material functionality was described as the most prominent challenge associated with reprocessing FFRs. Stakeholders also noted that inventory management issues, such as tracking products at the unit level, contributed to reprocessing challenges. Despite this, reprocessing was adopted as a crisis management tool to address critical PPE shortages during the pandemic [103].

Guidance on reprocessing has been provided by regulators. Health Canada and the Centers for Disease Control and Prevention (CDC) have provided guidance regarding reuse of N95 FFRs [40], [104], [105]. Health Canada requires reprocessing methods to meet several criteria, including evidence of reduced pathogenic burden. A reprocessing method must demonstrate a sterility assurance level (SAL) of  $10^6$  through bacterial sporicidal testing as well as viral inactivation [40]. Guidance on reprocessing from the CDC indicates ultraviolet germicidal irradiation (UVGI), vaporous hydrogen peroxide (VHP), or moist heat as the most promising technologies for decontaminating FFRs [106]. These technologies had also been described as the most safe and effective reprocessing methods for FFRs throughout the grey and academic literature. Other technologies such as autoclaving were also mentioned, but to a lesser extent [107], [108]. CSA Group has developed a standard for medical device reprocessing [109], but stakeholders relayed that compliance with standards could be improved.

Stakeholders described an interest in further research on the use of UV technology in reprocessing.

The shortage of FFRs led to industry actors across Canada leveraging existing technologies, typically used for other purposes, to reprocess materials or products for reuse [110]–[112]. For example, Quebec and Ontario manufacturers adapted technology, originally intended for other purposes, to sanitize N95 respirators after receiving approval from Health Canada [110], [111]. This pivot enabled other jurisdictions to purchase and use this technology to reprocess PPE for health care workers [112].

The nuclear industry also pivoted their operations to support reprocessing. As almost 50% of the world's Cobalt-60 is provided by Ontario's nuclear reactors operated through Ontario Power Generation (OPG) and Bruce Power, the Canadian nuclear industry was able to play a role through supplying nuclear technologies such as isotope Cobalt-60 to sterilize medical devices [113].

Assessments of the environmental impact of reprocessing methods are a clear gap in the literature. One article described that biobased or reusable medical devices are not necessarily associated with a lower environmental impact [114]. The same study emphasized market diversification as important for not only reducing supply chain disruptions but for facilitating greater flexibility to implement solutions with a lower life-cycle energy consumption. However, a better understanding of when environmental benefits of reprocessing are optimized (i.e., when benefits are outweighed by environmental risks) is needed.

### 4.3.2 Labour

Despite Canada's highly skilled labour force, there were skills gaps identified in the response to the pandemic. Stakeholder consensus mentioned that the absence of an expert database contributed to delays in the setup of the COVID Task Force. The inability to rapidly identify where skills were located across the country hampered coordination efforts.

Across the various domains, a lack of pre-existing, standardized skill sets produced hurdles in ramping up capacity, most notably in product development and testing, diagnostic testing, and reprocessing. A participant with reprocessing expertise noted how a lack of formal training programs in reprocessing resulted in varying quality. The product testing infrastructure to validate the quality of PPE and other medical devices similarly suffered due to a historical outsourcing of these tasks. Stakeholders noted that in key tests, such as submicron particle filtration, much of the process is not explicitly delineated, requiring years of experience to perform well. This requirement of tacit knowledge could not easily be accelerated during the pandemic.

The testing and diagnostics effort to identify COVID-19 cases not only centred on the availability of diagnostic test kits and equipment but also on the trained personnel who would be able to process the tests to provide the results. Many provinces, especially Ontario, have faced an acute shortage of trained testing personnel, resulting in laboratories being overwhelmed and scrambling to reach out across provinces to offset the gap for labour [115]. The Ontario government urged hospitals and labs to shift to the province's case management system to better allocate testing personnel from units with lower rates of infection to higher rates of infection [115]. While this is a good resource allocation strategy when resources are constrained, it does expose a dire need for a greater emphasis on training and skill development of testing personnel in the long term.

### 4.3.3 Economic Sustainability

As described in the production capacity section, Canada has increasingly relied on international manufacturing for the production of a wide range

of goods. Manufacturing makes up approximately one-tenth of Canada's gross domestic product, and this value has been shrinking for decades [116]. A leading manufacturer and distributor of medical goods headquartered in Canada does not yet have a domestic factory to manufacture essential PPE [57]. A representative from the same manufacturer said there is a preference to manufacture products internationally in countries where there are existing facilities [57]. Once the pandemic began, prices for raw materials used in essential items and shipping costs rose considerably [57]. Several participants also remarked that the Canadian market is relatively small, and firms would have difficulty sustaining sales volumes by relying solely on the domestic market. Canada's reliance on international manufacturing has exposed the country to substantial risks.

To bridge this gap, funding from federal, provincial, and local governments was provided to support domestic firms. Examples of current investments include:

- The Ontario government launched the \$50 million Ontario Together Fund to support businesses with manufacturing essential medical supplies and equipment and providing innovative solutions in response to the COVID-19 pandemic [117].
- The Ontario and federal governments invested \$23.33 million in a large local firm to expand their manufacturing facility in Ontario and produce N95 respirators [118].
- A Quebec-based medical equipment manufacturer signed an agreement with the Canadian government to manufacture 20 million N95 respirators and 24 million surgical masks per year for the next 10 years [119].
- The Ministry of Natural Resources invested \$1.3 million in a private not-for-profit Research and Development (R&D) organization to begin developing a biodegradable filter for single-use face masks [120].
- NGen announced a \$50 million COVID-19 program to support organizations with manufacturing necessary technologies, equipment, and pandemic response products [121].

- The NRC Industrial Research Assistance Program (NRC IRAP) collaborated with Innovative Solutions Canada (ISC) and Innovations, Science and Economic Development Canada (ISED) to launch challenges seeking solutions that address a pandemic-related need from small and medium-sized enterprises (SME)'s needing financial support [122].
- The Department of National Defence and Defence Research and Development Canada launched the Innovation for Defence Excellence and Security (IDEaS) program that requested proposals addressing issues resulting from the COVID-19 pandemic [123].

While the increased funding in the wake of the pandemic indicates a step in the right direction towards economic sustainability, the road to preparedness for future pandemics will require a continued emphasis on bolstering domestic manufacturing. Sustained policy efforts are needed to ensure that procurement from Canadian manufacturers becomes a key priority in the health care sector.

#### 4.3.4 Sustainability: Key Points

A summary of the key points identified in the sustainability domain is shown in Table 6.

**Table 6:** Sustainability – Key Points

Sustainability: Key Points	
<b>Environmental</b>	<ul style="list-style-type: none"> <li>▪ Waste management systems have seen increases in waste but not to the point of stalling operations. PHAC has recommended routine practices for handling waste.</li> <li>▪ Reusable PPE offer an alternative to single-use; however, a lack of guidance for developing reusable PPE, ensuring appropriate timing for disposal, and smoothly tracking frequency of reuse remain challenges.</li> <li>▪ The lack of Canadian standards for reprocessing single-use FFRs, absence of formal and standardized training for reprocessing staff, and inventory management challenges added to difficulties for reprocessing.</li> <li>▪ Industry actors, including the nuclear and medical technology industries, pivoted their operations to reprocess products to support FFR shortages.</li> <li>▪ Better understanding of the environmental impact of reprocessing methods, including when the environmental benefits are optimized, is needed.</li> </ul>
<b>Labour</b>	<ul style="list-style-type: none"> <li>▪ Provinces faced shortages of trained testing personnel, resulting in laboratories relying on reactive resource allocation strategies.</li> <li>▪ There is a need for a greater emphasis on training and skill development of testing personnel including a “learning-by-doing” training model.</li> <li>▪ The inability to rapidly identify where skills and expertise were located across the country hampered coordination efforts.</li> </ul>
<b>Economic</b>	<ul style="list-style-type: none"> <li>▪ Canada relies heavily on international manufacturing, mainly due to associated cost savings and a relatively small domestic market.</li> <li>▪ Governments in Canada are now investing more in innovation and local pandemic response product infrastructures.</li> <li>▪ Public procurement may not be sufficiently prioritizing products that are made-in-Canada or implementing values-based procurement models, which makes it difficult for Canadian manufacturers to be sustainable.</li> </ul>

## 5 Case Studies of Key Products Illustrating Critical Challenges

### 5.1 Case Study: N95 Masks for Health Care Workers

Protection of health care workers has been a top priority during the COVID-19 pandemic. The priority of protecting health care workers led to restrictions on the use of N95s, the go-to FFR on the market in health care settings [124]. The demand for FFRs exploded early on in the pandemic. However, the NESS was not able to meet this demand in a sustained way, as much of the stock had expired [125].

The shock to demand exacerbated shortages. Customers expected to need a lot more than they ordered, even as those orders could not be filled. Interview participants shared that orders jumped to much higher levels when health care facilities needed to stock their inventories. Prior to the pandemic, just-in-time demand had been the historic norm. The change in ordering habits added to the difficulty in procurement, and the lack of internal procurement teams in health care and LTC settings made it difficult for them to access N95s from other channels in an affordable manner with adequate quality controls. The strains on global supply chains deprioritized the small Canadian market, leading to orders being either diverted or showing up with reduced quantities. In April 2020, the US government invoked the Defence Production Act, which would have halted exports of N95 masks from a US company's production facilities [126]. Soon after, the same company and the US government quickly agreed on a plan to continue distribution to Canada and Latin America [127].

Procuring N95 FFRs for hospitals continued to be a challenge throughout the early months of the COVID-19 pandemic given that FFRs were a low-margin product that had no domestic production until the summer of 2020. Outside of hospitals, the availability of N95s was even more dire. Outbreaks in LTC facilities were common and catastrophic, particularly in Ontario, Quebec, and British Columbia [128]. A stakeholder noted how procurement in LTCs was difficult, and LTCs' lack of coordination and lobbying power made them less

effective at securing emergency equipment than hospitals. Even more alarming was the situation among home-care professionals, with stakeholders describing significant restrictions on their use of N95s even when FFRs were available.

It was announced in August 2020 that a large US multinational company would open a plant in Brockville, ON, to produce N95s and supply hundreds of millions of FFRs to the Canadian market by March 2021 at the latest [129]. The federal and provincial Ontario governments each contributed \$23.3 million to secure the arrangement and launch domestic production [129]. While domestic production of N95s was a critical gap to fill, there were concerns that the selection of a US company would hamper efforts of Canadian organizations. Stakeholders relayed that within health care settings there was a strong preference for a US brand of masks tested by NIOSH.

FFRs are tested for submicron particle filtration efficiency, inhalation, and exhalation resistance and fit tests. In addition, the following tests are also conducted for medical FFRs: fluid penetration resistance, flammability, biocompatibility with skin, and mechanical strength of headstrap [130]. The most relevant test to COVID-19 is the submicron particle filtration test, which is performed for both surgical masks and FFRs. It has proven to be the most difficult to perform as it requires specialized, calibrated, and standard equipment that was not readily available in Canada at the outset of the pandemic. It has been suggested that significant investments are needed to compare the calibration of testing equipment at different facilities. As NIOSH prioritized product testing for firms in the US, restricting access for Canadian firms, product testing became a significant bottleneck to increasing domestic FFR production.

Significant initiatives are underway to provide guidance for Canadian manufacturers pivoting to FFR production. The ultimate objective will be to harmonize the performance and testing requirements with established standards such as NIOSH, as well as standards currently under development by the ISO [37], [131]. Stakeholders also mentioned that many provincial authorities are reluctant to purchase FFRs that were not certified by NIOSH.



"The priority of protecting health care workers led to restrictions on the use of N95s, the go-to face-filtering respirator on the market in health care settings."

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Upstream standards also do not exist for essential components of FFRs, such as for melt-blown polypropylene or melt-blown manufacturing equipment, which makes the supply chain more dependent on foreign imports. Early in the pandemic, it was not possible to source melt-blown polypropylene from within Canada. Stakeholders relayed that transporting melt-blown production machines to Canada from Germany or Asia was delayed due to demand.

The challenges in sourcing and producing FFRs illustrate several key issues. At the beginning of the pandemic, FFRs were not manufactured in Canada. In addition to manufacturing challenges, NIOSH standards had been typically relied upon along with product testing and certification in the US. Local stockpiles were insufficient and typical procurement processes were strained. After NIOSH certification became unavailable to Canada, local guidance for FFR production and testing needed to develop rapidly. Large government contracts for mask production were given to large multinational companies, which stakeholders relayed may discourage smaller firms from scaling up. The production and supply of melt-blown fabrics, a key input material to FFRs, was also challenging. Despite these challenges, as of December 2020, there are 10 Canadian SMEs authorized under the IO to manufacture FFRs and three melt-blown polypropylene manufacturers.

## 5.2 Case Study: Keeping Air and Surfaces Clean – Understanding Sanitization Needs and Solutions

Transmission of respiratory viruses primarily occurs through four routes of transmission: direct contact, indirect contact, droplet, and airborne [132]. Direct contact transmission occurs when coming into direct physical contact with an infected person. Indirect contact involves touching a contaminated surface (fomites). The primary mode of SARS-CoV-2 transmission is through direct contact. Respiratory droplets containing the virus can spread by an infected person. Sneezing and coughing may project droplets onto nearby uninfected people and expose them to the virus. This is called droplet transmission. Airborne transmission occurs when smaller droplets and particles are suspended in the air, exposing those who are not physically close to the infected person. The risk of infection is much lower with adequate ventilation [132]. Though indirect transmission is less common, proper sanitization of surfaces has a role in containing spread [133].

Prior to the COVID-19 pandemic, Canadian guidance on the use of household cleaners and disinfectants was variable [134]. Disinfectants are classified based on their use for either food-contact surfaces (e.g., counter tops, appliances) or high-touch (e.g., door handles, light switches) and low-touch (e.g., walls, floors, windows) environmental surfaces [134]. In Canada,

regulatory requirements for disinfecting environmental surfaces, medical devices, and inanimate objects depend on their use and purpose [135]. The Medical Devices Directorate (MDD) licenses disinfectants for devices [136], whereas the Natural Health Products Directorate (NHPD) issues NPNs for certain hard-surface disinfectants [137]. Disinfectant products are evaluated in accordance with the Food and Drugs Act and Medical Devices Regulations [138], [139].

The COVID-19 pandemic has brought special interest to ultraviolet (UV) radiation, which can be used to decontaminate medical devices and surfaces. Health Canada has developed a notice outlining safety and efficacy requirements for manufacturers using UV radiation devices to reprocess or decontaminate other medical devices [140]. For consumer products used on household items, Health Canada has not yet received sufficient evidence to support the use of UV light against COVID-19 [141]. Nonetheless, many businesses have installed self-cleaning technologies in high-touch areas and are offering UV disinfection as a customer service [142]. UV light products aimed at consumers have proliferated and are not currently regulated; concerns have been raised about their safety and efficacy in reducing the viral burden and their marketing claims. UV radiation is considered a carcinogen, with the Ontario government recently highlighting its hazardous effects [143].

Prior to the pandemic, the use of UV disinfection in health care settings had not been widespread. A 2018 health technology assessment by Health Quality Ontario did not recommend the use of UV disinfection devices, citing a lack of evidence of superiority over standard cleaning disinfection and sanitization, and practical implementation concerns [144]. This illustrates a common challenge in evidence generation and application of existing and emerging technologies. Stakeholders reported that robotic cleaning practices are commonly used in Asia, and that increased use of robotics can reduce potential workplace exposures.

In July 2020, over 200 scientists called for a greater acknowledgement of the growing evidence on the airborne transmission of COVID-19 [145]. More recently on January 4, 2021, 363 Canadian experts

signed an open letter urging Canadian leaders to also recognize the importance of aerosol spread and to update guidelines, regulations, and communication as a result [146]. The letter stated: “The evidence is now overwhelming — aerosol transmission of COVID-19 is common and is an important route of transmission” [146]. The use of appropriate ventilation along with airborne infection controls (e.g., proper air filtration and germicidal UV lights) are important for reducing airborne transmission [145]. This has resulted in greater demand for heating, ventilation, and air conditioning (HVAC) companies to upgrade and provide high-quality filtration systems, air filters, and air purifiers [147]. Air filters, in particular, are made from similar material used for PPE, which has further complicated supply constraints [147].

Toronto’s Medical Officer of Health advised businesses to review their HVAC systems for efficacy, efficiency, and optimized air-exchange settings in November 2020 [148]. The American Society of Heating, Ventilating, and Air-Conditioning Engineers (ASHRAE), the Federation of European Heating, Ventilation and Air Conditioning Associations (REHVA), and the Chartered Institution of Building Services Engineers (CIBSE) developed guidance for minimizing viral spread using HVAC systems [149]. Public Services and Procurement Canada also developed guidance intended for PSPC real property inventory, which included general information about HVAC system maintenance [150]. Most recently, the CDC and PHAC released guidance on indoor ventilation needed to reduce COVID-19 spread [151], [152].

As knowledge of the SARS-CoV-2 transmission improved, concerns about surface transmission diminished while those associated with airborne transmission increased, as did attention being paid to HVAC systems. Nevertheless, significant public and private investments have been made in improving disinfection of surfaces. Understanding the most efficient and effective air and surface disinfection and sanitization practices, and embedding them into health care settings, businesses, workplaces, schools, transit, and other congregate settings requires further investigation. This presents an opportunity for Canada to improve overall health and to innovate.

### 5.3 Case Study: Understanding and Meeting the Need for Ventilators

Early on in the pandemic, the fallout of COVID-19's spread in Italy had caught global attention, with a focus on the acute impact of the country's ventilator shortage [1]. Fortunately, Canada has not faced the same ventilator need to date. Of the 12,029 hospitalized cases in Canada at the end of September 2020, less than 4% (469 cases) have required ventilators [153]. Despite this, early fears of shortages prompted significant efforts to boost ventilator stock, with varying success.

Prior to the COVID-19 pandemic, intensive care unit (ICU) resources in Canada were limited and costly. Critical care services are one of the most expensive aspects of the health care system [154]. In 2015, the Canadian Critical Care Trials Group conducted a national survey of all acute care hospitals to determine the number of critical care beds, mechanical ventilators, and availability of specialized support for respiratory failure in critically ill adults and children following the 2009 to 2010 influenza A (H1N1) pandemic [154]. This investigation determined that there was substantial variation of medical devices and care required for the support of respiratory failure and that the variation of supply was not completely due to population size. Both the H1N1 and COVID-19 pandemics highlight the absence of knowledge regarding Canadian critical care capacity. This includes a lack of targets for population-based critical care resources at the provincial, national, or international levels, as well as insufficient attention to ensuring the optimal distribution across regions. It is important to understand these needs to better plan for the demand of medical devices, including ventilators.

At the start of the pandemic there were approximately 5,000 ventilators in hospitals nationally, with another 500 in the NESS [155]. Many of these were from an Alberta provincial stockpile which was procured in December, following early warning signs of the outbreak in Wuhan, China [156]. Federal initiatives to boost ventilator stocks began in March, in response to news about Italy's experience, leading to \$1.1 billion in spending to order 40,000 new ventilators for hospitals nationwide, less than 3% of which had

been delivered by the end of August 2020 [157]. The world's market leader in ventilator production is an international medical device manufacturer, with one factory in Ireland producing all of its ventilators globally. The manufacturer made the design specs and software codes for one of its ventilators publicly available in April 2020. This was done so that others can manufacture devices to increase the global supply of ventilators. In two days, over 500 organizations in Canada downloaded the intellectual property for this product [158]. Stakeholders called for consideration of standardizing ventilator models for ease of use and training, and to minimize human error.

Manufacturers entering the ventilator market have not been able to move as quickly as they would have preferred. A government-backed domestic ventilator project set to produce 7,500 ventilators submitted a design for a made-in-Canada ventilator in June 2020, and received its Health Canada approval on September 25, 2020 [159], [160]. Even when products were approved relatively quickly, production was slow to ramp up, according to stakeholders. The consortium Ventilators for Canadians (V4C) adopted an open-sourced design from an international medical device manufacturer. V4C received approval on June 17, 2020 for manufacture and delivery [161]. Stakeholders reported slow production ramp up due to a lack of domestic sources for pressure controllers, an essential ventilator input to ensure safety. This input is typically used by specialized labs and had not previously been produced or procured domestically.

While the need for ventilators may have been overestimated, fears of unmet needs during the second wave were rising. Efforts to increase local production during the pandemic were slowed at both the regulatory phase and in sourcing input materials, much like with N95 mask manufacturing. The inability to readily deliver on the assessed need is an indication of gaps in Canada's medical device ecosystem. These gaps include Canada's small stockpile of ventilators, a lack of readily available data displaying where equipment is most needed, and potentially inequitable distribution of existing critical care resources across the country.

## 5.4 Case Study: Domestic Manufacturers Pivoting to Produce Hand Sanitizer

The spread of COVID-19 relies heavily on human-to-human transmission in community settings. Measures such as proper hand hygiene, physical distancing of at least one metre, appropriate indoor ventilation, widespread testing and contact tracing, and quarantine and isolation measures play a large role in controlling the spread of the virus [162]. Many of these activities do not specifically rely on the availability of materials or products, although hand hygiene is supported by hand sanitizer.

Hand sanitizers are typically subject to regulatory requirements from Health Canada before companies can legally produce and distribute products. Depending on their ingredients, hand sanitizers are classified as natural health products (NHPs) or non-prescription drugs. Hand sanitizers classified as NHPs are regulated under the Natural Health Products Regulations (NHPR) in Canada.

During the early stages of the pandemic, the supply of hand sanitizer was limited. Health Canada's interim measure enabled businesses to pivot to or scale up production of hand sanitizers to meet consumer needs [163]–[166]. For example, upon requesting approval from Health Canada, multiple distilleries in Alberta began producing hand sanitizer in early spring at the peak of the pandemic [163]. Despite a large number of Canadian distilleries pivoting their operations to supply large quantities of hand sanitizers for hospitals and government offices across the country, a CBC News investigation found only 52% of hand sanitizer procured by the federal government were being produced by Canadian suppliers [167]. Many hand sanitizers have been recalled by Health Canada, including some made by domestic distillers [168]. This illustrates the many challenges faced when manufacturers pivot to new products.

Rising demand also led to supply hoarding and price gouging for hand sanitizers and other essential products. Price gouging was a particular issue on e-commerce platforms. Many independent retailers introduced products to the market and regulatory bodies were unable to properly monitor them all.

In response to these challenges, provincial governments across Canada were able to control pricing by using revised powers that came after declaring multiple states of emergency [169].

## 5.5 Case Study: Sustainability in Swab Production

Nasopharyngeal swabs are used in the RT-PCR test to diagnose COVID-19. In the RT-PCR test, a machine located in a laboratory or at a POC, runs a series of reactions by cyclically changing temperature to detect the genetic material from the sample collected on the swab [170]. These swabs are long and thin – to retrieve a specimen sample from the upper part of the throat – and made of synthetic fibre. Swabs are a weak link in the supply chain since they are low-margin products that historically fail to attract much investment capital [171]. The shortage of swabs in Canada has brought to the forefront issues surrounding material capacity and production sustainability. Nasopharyngeal swabs are used in the RT-PCR test to diagnose COVID-19. In the RT-PCR test, a machine located in a laboratory or at a point-of-care POC runs a series of reactions by cyclically changing temperature to detect the genetic material from the sample collected on the swab [170].

Procurement of swabs has been almost entirely dependent on two major manufacturers. One of the manufacturers has facilities located in the Lombardy region of Italy, which happens to be one of the worst hit areas during the initial phase of the pandemic [172]. This resulted in major labour and processing issues due to workers becoming infected, which caused the manufacturer to struggle to keep pace with demand. The problem of material shortages has been compounded by issues with quality assurance, as evidenced by reports of large shipments of contaminated or unusable swabs arriving at ports of delivery [173].

The shortage of swabs has also given rise to at-home collection kits which attempt to collect saliva samples without clinical supervision. The swabs available in the at-home collection kits are shorter than those used in the RT-PCR test and may carry greater risk of generating a false negative result [174].

New initiatives to increase sustainable domestic swab production have begun. In July 2020, an advanced manufacturing firm was granted Health Canada approval for its proprietary 3D-printed swab [175]. Primarily an additive manufacturing services company before the pandemic, the company pivoted to producing plastic nasal swabs and other critical pandemic response products. The company is investing over \$2 million in a facility that will have a throughput of eight million swabs per month, with production anticipated to begin early in 2021 and employment expected to reach at least 50 people once operations get underway [176].

## 6 Recommendations to Move Towards a Self-Sufficient and Sustainable Ecosystem of Pandemic Response Products in Canada

Four draft recommendations under each domain were developed following completion of the environmental scan and gap analysis that informed the characterization of the domains and case studies. The next section presents the final recommendations, each

incorporating feedback from the six roundtables. The roundtables hosted panels of diverse stakeholders from industry, academia, and health services to discuss the draft recommendations. The 12 recommendations are summarized in Figure 4.

### 6.1 Providing Quality Infrastructure

#### 6.1.1 Improve Mask Design

Medical and non-medical masks have issues with fit, filtration efficiency, and reusability. It is imperative that mask design be improved to address these issues. It is important to convene a space for dialogue between experts, including engineers, designers, health care professionals, and the standards community. The appropriate mechanism for this collaboration requires further thought.

It is important to think beyond the N95 mask type. The prioritization of the N95 mask for aerosol generating procedures in health care settings led to overwhelming demand for this mask. We also heard of a strong brand preference in health care for certain brands of N95 masks. This reliance on a specific type and brand of mask is a vulnerability.

**Figure 4:** Overview of Recommendations to Move Towards a Self-Sufficient and Sustainable Ecosystem of Pandemic Response Products in Canada

<p><b>Providing Quality Infrastructure</b></p>	<ol style="list-style-type: none"> <li>1. Improve Mask Design, Standards and Guidance</li> <li>2. Invest in Product Testing Infrastructure</li> <li>3. Invest in Traceability Infrastructure</li> <li>4. Align Regulations and Standards Internationally</li> </ol>
<p><b>Ensuring Adequate Supply</b></p>	<ol style="list-style-type: none"> <li>1. Redesign the National Emergency Strategic Stockpile</li> <li>2. Facilitate an Open Procurement Marketplace</li> <li>3. Inform Demand Through Enhanced Scenario Planning and Forecasting</li> <li>4. Develop and Maintain Diagnostic Capacity</li> </ol>
<p><b>Supporting Economic and Environmental Sustainability</b></p>	<ol style="list-style-type: none"> <li>1. Increase Reprocessing of PPE Medical Devices</li> <li>2. Develop Pandemic Response Products That Are Recyclable, Compostable, or Biodegradable</li> <li>3. Support Canadian Manufacturers</li> <li>4. Support Innovation and Evidence Generation for New Technologies</li> </ol>



**"Open-source projects are critical as intellectual property issues around masks can act as barriers to ramping up production and global cooperation."**

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As mentioned previously, there are already alternatives to FFRs in existence, such as elastomeric respirators. During the pandemic, elastomeric respirators were presented as a substitute during FFR shortages by health agencies such as the CDC and Ontario Health [42], [177]. There is potential for elastomeric fitted masks to become alternative fitted respirators, with greater capacity for reuse and similar or better efficacy as N95s. This is likely due to the presence of a replaceable filter and a separate exhale vent that prevents release of viral particles [178]. However, their broader adoption would require addressing some logistical challenges relating to reuse and disinfection as well as the possibility of viral transmission through the exhalation valve if the user themselves is infected [177]. Issues with fit, comfort, and training would also need to be addressed [179]. There would also be a need to educate and communicate with health care workers about different mask types and their efficiencies, to ensure they feel safe and protected even when not using a favoured N95 mask brand. Acceptance and use of a broader range of masks may help reduce restrictions on use such that high efficiency masks could be more widely available outside of hospitals. The general public should also receive education on mask types to prepare for pandemic diseases that spread through communities.

With community transmission being such a critical feature of the COVID-19 pandemic, use of masks outside of medical settings is receiving unprecedented attention. While mask mandates are now common

globally, the masks being used by the public vary highly in quality. The ROSE (Reusable Open-Source Equipment) Project is an initiative aiming to fill a need for increased availability of effective, reusable masks. The ROSE Project is working towards designing a medical-grade mask that can be sewn from commonly available fabric materials [180]. It plans to provide open-source plans for the mask once complete. This would enable local production of effective, reusable masks. Support must be given to organizations working on open-source solutions for mask design. Open-source projects are critical as intellectual property issues around masks can act as barriers to ramping up production and global cooperation. While the ecosystem project focused on PPE use in health care settings, the question of mask use in workplaces, schools, and public spaces was repeatedly raised as a key issue. Use of masks in non-medical settings has been addressed by authorities recently: in November 2020, PHAC recommended the general public wear three-layer masks, among other specifications [181]. The French standard development organization, Association française de normalisation (AFNOR), also released guidelines establishing minimum requirements for the production of non-medical masks [182]. The specifications were released during March 2020, in various languages, including English [182].

Additional issues with mask design were raised by stakeholders, such as breathability. Breathability remains a challenge. Filtration efficiency should be balanced with breathability to maximize effectiveness

and practicality. Common mistakes in mask wearing, such as wearing them upside down, could be addressed with design fixes such as adding arrows to indicate which part goes over the nose.

### 6.1.2 Improve Mask Standards and Guidance

Who needs to wear what mask and under what conditions? This is a question of fundamental importance, yet it is still unclear. Predefined algorithms for PPE use should be defined for both health care settings and the public. The World Health Organization (WHO) has recently provided guidance on this, and it will be important to review and integrate this guidance into scenario planning, forecasting, and local communications [162]. Stakeholders working in health care settings early in the pandemic recalled that advice on PPE protocols and procedures changed almost daily.

The efficacy of masks used by the public has become an issue of utmost concern. Members of the public rely on masks with a wide range of filtration efficiency, and users may not know how effective they are. Recent work performed by CBC's *Marketplace* and the Dalla Lana School of Public Health revealed that masks available to consumers vary considerably in their efficacy depending on the fabric and materials used [183], which is information typically not available to the consumer (and as noted in the discussion on traceability in Section 3.2.3, fabric components may not be known by manufacturers either).

There is a need for refined standards for consumer masks. These could look like a set of minimum standards for consumer mask production or an introduction of a tiered system. Unlike Class I FFRs, non-medical and industrial-use masks are not Class I medical devices [184]. Non-medical masks therefore differ widely in terms of material, quality, efficacy, function, and fit, with a lack of prescriptive and comprehensive standards guiding their production. It was proposed by stakeholders that, rather than introducing a minimum standard of filtration for non-medical masks, standardization bodies could instead introduce a quality marker to identify filtration capabilities. Masks may be marked accordingly to help consumers make informed choices about the masks they buy. Specifics of these recommendations should

be coordinated with certification bodies to ensure standards are enforceable. Guidance on consumer masks could be a shorter-term goal with standards as a longer-term goal. Recently it has been reported that NIOSH and ASTM are working on developing standards for consumer masks [185]. The Bureau de normalisation du Québec (BNQ) released requirements for masks used in workplaces that are unable to meet physical distancing measures [186], [187]. Non-medical masks produced in factories should also prioritize a balance between filtration, breathability, and fit and avoid the use of exhalation valves that obstruct source control [162].

Consumer masks may alternatively fall under a tiered system where products are classified based on performance measures (e.g., particle filtration efficiency). Tiered standards introduce a hierarchy of products ideal for fighting different diseases. Introducing tiered standards for consumer masks, rather than recommending use of medical masks, allows manufacturers to continue relying on materials and supply chains currently used for these products. The pragmatics of a tiered system may be investigated in the subsequent report.

The COVID-19 pandemic has highlighted that Canada relies on standards and certifications developed externally. In the summer of 2020, NIOSH announced suspension of new applications for N95 certification by manufacturers outside the United States [37]. Domestic production of FFRs became a national priority. However, the level of confidence in FFRs that are not certified by NIOSH is low and, consequently, FFRs that meet equivalent standards are largely not sought after or found acceptable. This need led Health Canada – in partnership with PHAC, the NRC, and supported by research and foundational work by CSA Group – to develop guidance to fill a gap for Canadian manufacturers seeking to create alternative solutions to N95 respirators in Canada [130]. The development of the Canadian guidance should be reviewed to understand the lessons learned. What elements are needed for a Canadian conformity assessment program is an important question for future consideration, and will be discussed further in the next section.

One participant recommended a transition towards objective-based standards. This would permit the use of any materials or processes as long as a set of predetermined objectives are met. Objective-based standards are expected to facilitate flexibility in manufacturing. An outcomes- or performance-based approach could help to balance between standardization and innovation, especially for new entrants into the PPE space that may need to diversify in the future. Objective-based standards will be further investigated in the subsequent report. Lastly, participants suggested that standards be developed for inputs and machines used in manufacturing pandemic products to increase product confidence.

### 6.1.3 Invest in Product Testing Infrastructure

Canadian testing infrastructure requires more investment to evaluate the quality of pandemic response products. Canada currently relies on infrastructure from NIOSH. Many interviewees shared that Canadian firms would benefit from a set of national Canadian testing standards. The need for Canadian performance and testing requirements for FFRs standards has been identified by the SCC [131].

Conformity assessment has emerged as a key gap in the Canadian ecosystem during the COVID-19 pandemic. The need for an enhanced conformity assessment program in Canada should be explored, with consideration given to existing models in comparable jurisdictions such as the United States and the European Union, although notably these jurisdictions are much larger than Canada. As discussed in Recommendation 4, Canadian standards would ideally be harmonized with international bodies to reduce hurdles to exporting and importing products. The logistics of creating a new set of Canadian standards is beyond the scope of this report; however, stakeholder groups should host dialogues to explore routes for harmonizing performance and testing requirements with far-reaching SDOs such as ISO. As a starting point, stakeholder groups should review the process of developing the Canadian guidance for domestic FFR production and evaluating what lessons can be learned from that process.

Information on Canadian labs should be centralized to improve accessibility. This could look like a database describing labs in Canada as well as facilities with the capacity to pivot and run tests during emergencies. The database could host information on the testing approaches, such as the equipment the labs and facilities use, their calibration, and their specific implementation of standards, to ensure that they are using procedures ideal for buyers and to cross-validate methods between them. Stakeholders identified significant capacity in universities and colleges to supplement testing needs during a state of emergency. Databasing efforts should include a broad sweep of organizations, both accredited and non-accredited, and those accredited to a foreign standard, to maximize the amount of information available to the public in an easily accessible format. Potential stakeholders that could oversee and maintain the database will be reviewed in the subsequent report.

University labs, while typically not accredited, can perform a variety of roles. Whether they should be supported in gaining accreditation, or whether the need for accreditation can be altered under emergency situations by having a list of requirements, should be further explored to help expand the role university labs can play in product testing. One participant noted that university labs have built partnerships with corporate labs to develop long-term capacity and testing innovations. These corporate partnerships could be encouraged more broadly to build a sustainable infrastructure in non-pandemic times.

### 6.1.4 Invest in Traceability Infrastructure

The pandemic has shown us the complexity of global supply chains. Moving forward, traceability infrastructure will need greater public investments to track goods used in health care settings across their entire life cycles. Canadian traceability standards can be formalized through compliance with existing GS1 standards [188], [189]. The IMDRF is leading work in this area and these initiatives have also been endorsed by MEDEC [190]. Stakeholders described an industry desire for better traceability and a desire for leadership on this from regulators.

Distributors and health care providers would also benefit from standardized enterprise resource planning (ERP) processes. ERP systems can facilitate a digitized supply chain by ensuring data fidelity and integration across the value chain. Specifically, ERP integrates business processes into a shared software system and translates to better forecasting, improved visibility and collaboration, and enhanced operational performance. Using ERP systems also requires digitization of other key functions of pandemic planning such as the NESS and procurement systems. ERP systems typically come with built-in data security systems that provide access controls and ensure data security [191], and they can be used to centralize and manage procurement, manufacturing, and distribution data.

Higher up the supply chain, incentives can be provided to raw materials manufacturers or refiners to leverage finer grained identifications, such as QR codes or blockchain IDs, to ensure dynamic visibility as they are moved around. Increasing the granularity of identification for items by introducing new information for each component, as well as taking further steps in the supply chain such as integrating information about the testing lab used and its results, would enable improved quality management. The more uniquely identifiable an item, the easier it is for distributors and users to identify bad batches of items, and reorder appropriate quantities from more reliable sources. The subsequent report will explore institutions that could manage product information.

Inventory management has proved one of the major challenges to reprocessing efforts of pandemic response products, which stakeholders identified would be resolved by improving integration of data across departments to track item usage. Inventory management of reprocessed products require approaches distinct from other products in part due to the logistical challenges of counting reuse.

### **6.1.5 Align Regulations and Standards Internationally**

Regulation frameworks vary between jurisdictions and this affects the distribution of pandemic response products and confidence in their quality. Manufacturers

could also face additional hurdles when meeting diverse requirements across international borders. It is recommended that Canadian regulatory bodies work to align regulations with other countries to move closer towards globally harmonized standards. Health Canada could play a significant role in the movement to engage international organizations on regulatory cooperation. Standards may be developed to suit the needs of the Canadian marketplace and those of other countries interested in participating. The ISO is an important international SDO and Canada could play a more active role in technical standards development at the ISO in addition to governance leadership.

Participants proposed developing transfer standards, which are used to calibrate equipment and ensure comparable quality between jurisdictions [192]. This would allow Canadian manufacturers to build domestic testing equipment that meet international standards and would improve domestic approval times for products available in foreign markets, especially for critical components such as materials testing equipment.

Emergency IOs played a large role in Canada's COVID-19 response and allowed for flexibility in established regulations. It is recommended that Health Canada review the effectiveness of these IOs both in terms of how well they worked to facilitate greater flow of safe and effective goods, and in terms of whether or not the approach of using IOs as a pandemic response action is efficient. Stakeholders reflected on delays in government circles to issue a plan of action for the COVID-19 pandemic. To avoid this, the Canadian government and regulatory bodies should consider the benefits of developing predesigned emergency preparedness plans that can enact IOs immediately at the start of a pandemic (e.g., relaxing language requirements on labelling or authorizing emergency use of unapproved products [193]). This would involve coordination between government, industry, and academia. An industry stakeholder suggested that a preparedness plan also include tiered standards for pandemic response products and processes (e.g., reprocessing). In cases where there are insufficient production materials during a pandemic emergency, tiered standards can identify the next best option.



"Canadian products should be prioritized in National Emergency Strategic Stockpile procurement policies to support domestic manufacturers and suppliers."

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## 6.2 Ensuring Adequate Supply

### 6.2.1 Redesign the National Emergency Strategic Stockpile (NESS)

To address challenges with the NESS, a top-down analysis of the stockpile is recommended. The NESS has multiple functions, and the suitability of included items for pandemic responses specifically may need to be reconsidered. Further key changes to the stockpile could include dedicated funding from the federal government to perform necessary upkeep, and the introduction of a sophisticated inventory management system to track items in the stockpile, quantities, and expiration dates. The NESS should rotate stockpiles to ensure items are fresh, up-to-date, and in proper quantities. This could be done by rotating supply regularly where new inventory is received routinely and old stockpile items are distributed into public and commercial settings before expiry. The federal and provincial governments could coordinate this with GPOs or distributors and health care facilities to integrate items from the NESS with local supplies. Other researchers have proposed that a prime vendor, which could be a Crown corporation or a not-for-profit, be given responsibility for management of integration of the NESS with the commercial supply [194]; however, this would be a major change from its current structure.

Interview participants identified several opportunities to improve domestic stockpiles to better serve Canadians. First, more attention could be given to local stockpiles, including provincial stockpiles and those held by large hospitals. This could be done in collaboration with

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. Second, the use of virtual stockpiles was proposed, which would involve designing agreements so that production capacity could be held in reserve for emergency situations, rather than stockpiling physical items. Lastly, Canadian products should be prioritized in NESS procurement policies to support domestic manufacturers and suppliers (see Section 6.3.3). In doing so, procurement officials must account for procurement-related obligations outlined in existing domestic or international trade agreements (see, e.g., Government of Saskatchewan [195]).

### 6.2.2 Facilitate an Open Procurement Marketplace

Emergency marketplaces have emerged during the pandemic to connect buyers with vendors selling pandemic response products. This includes the Rapid Response Platform Canada and COVID PPE Help [196], [197], both of which were financially supported by government bodies. It is recommended that investments be made to expand emergency platforms into an open procurement marketplace to facilitate purchasing from smaller and more varied suppliers, assure quality of goods and vendor credentials, and fast-track sales for pandemic response products. The purpose of this would be to create more competitive market prices for essential goods,

reducing the overhead created by necessitating large purchasing organizations, and enabling flexibility in times of sudden changes in demand. The new open procurement system must be evaluated to determine effective methods of implementation. Further recommendations about procurement are made in the sustainability discussion in Section 3.3.

### 6.2.3 Inform Demand Through Enhanced Scenario Planning and Forecasting

Formal scenario planning teams should be developed to create strategic action plans for potential shocks to demand for medical supplies. The team would make use of available data on trends during emergency scenarios to forecast when and which medical supplies might be needed [198]. This recommendation is currently at a high level and will be further explored in the subsequent report. Stakeholders noted that creative, extreme scenarios are needed to ensure future preparedness. Further, in the past, supply chain risk analysis and forecasting has been better handled for pharmaceutical products, and materials supply chains require similar analysis and forecasting to improve their resilience and preparedness.

Scenario planning and forecasting efforts would be facilitated by better data on supply and demand for pandemic response products in Canada. Introducing a digitized supply chain accessible to Canadian and international pandemic-relevant industries would be expected to improve efficiency day-to-day and during a future emergency. This would require health care networks and manufacturers to shift logistics towards a digital medium. ERP systems (see Section 6.1.4) can be leveraged to help meet this objective since these systems update data in a dynamic fashion ensuring accurate forecasts and agile scenario planning.

### 6.2.4 Develop and Maintain Diagnostic Capacity

Throughout the COVID-19 pandemic, Canadian labs have struggled to meet demand for diagnostics. Moving forward, government bodies can support training initiatives through universities and colleges to create a sustainable labour force able to carry out diagnostic testing. Similarly, further investment in

domestic diagnostic systems and identification of actors who could pivot during a state of emergency is needed. Expansion of university and hospital labs to supplement testing capacity is also recommended. Expansion of testing capacity should be coupled with greater accessibility of resources (e.g., swabs, laboratory consumables, reagents). Like the recommendation for product testing, a centralized database summarizing diagnostic lab capacity would be beneficial. The centralized database would aggregate diagnostic testing data ensuring visibility in case testing capacity. This may also provide leaders with accurate information on suppliers and total resources available for a pandemic which can be factored into supply chain risk analyses and help plan for redundancies.

## 6.3 Supporting Economic and Environmental Sustainability

### 6.3.1 Increase Reprocessing of PPE and Medical Devices

Health Canada has issued guidance on the reprocessing of reusable medical devices [40], [104], [199], [200]. Reprocessing of medical devices that are labelled as single-use pose regulatory, ethical, medical, legal, and economic challenges [201]. The pandemic has provoked increased attention to reprocessing, particularly as reprocessing of items labelled as single-use has been seen as a potential safeguard against severe shortages [40], [103]. The logistics and regulatory framework for reprocessing of single-use and non-single use medical devices and PPE should continue to evolve.

Canadian SDOs and regulatory bodies should champion reprocessing standards development and use of existing standards for PPE and medical devices [109]. The advantages of greater adoption of reprocessing standards are multifold: they improve equipment security, improve confidence in reprocessing methods, and reduce unnecessary environmental waste. The use of existing standards should be promoted in industry and expanded upon through a consensus-based process involving a variety of actors across sectors. Research should be

a key focus of developing reprocessing standards to fill in knowledge gaps where they exist (e.g., effective reprocessing methods).

Increased reprocessing would also require enhanced capacity. While hospitals typically have in-house reprocessing sites, these sites may require expansion. Consideration would need 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 United States [200].

### **6.3.2 Develop Pandemic Response Products That Are Recycle, Compostable, or Biodegradable**

Environmentally friendly materials should be used to manufacture pandemic products. Research initiatives should further investigate the safety, efficacy, and application of these materials in pandemic response products. Efforts are underway in Canada to develop biodegradable products, including the recent development of a single-use biodegradable face mask [202]. Guidelines should accompany the materials being used in these products to ensure that users are aware the products are either compostable or recyclable. Similarly, guidelines are needed for waste management facilities to follow proper protocol and be able to maintain activities and minimize any infection risks during pandemics [203], [204]. Innovation such as building reusability into the product design process, material science to ensure safety and efficacy of input materials, increased attention to product life-cycle management, and a greater emphasis on compostable, biodegradable, and recyclable materials is required.

### **6.3.3 Support Canadian Manufacturers**

Currently, manufacturing is largely done overseas where the cost of production is cheaper. Canada needs to invest more in its local capacities to sustain domestic production over the long term. This includes government commitments to buying local and to providing skill development for essential workers. Initiatives such as the Ontario Together Fund should be monitored and evaluated to build on potential successes.

Governments are key actors in taking the first steps, particularly with respect to domestic procurement. Canadian decision-makers should introduce a strong commitment to local manufacturers to bolster and maintain capacity. Government leaders and decision-makers can play a crucial role in supporting domestic industries by introducing “Buy Canadian” practices that mandate quotas of Canadian goods and are compatible with existing international trade agreements and provincial procurement agreements. According to interviewed stakeholders, many domestic producers have had success with designing and producing needed goods but have struggled to gain contracts. Stakeholders described that despite efforts to produce FFRs equivalent to N95s in Canada, many requests for proposals still require that FFRs be certified by NIOSH. One stakeholder highlighted values-based procurement, in which proposals are scored not only on price but also on their life-cycle management and labour practices; such initiatives have been gaining ground in the UK and Europe. A holistic approach to procurement has previously been recommended by experts and by the Ontario Health Innovation Council in “The Catalyst” report published in 2014 [205], [206].

Many firms that aimed to rapidly pivot during the pandemic encountered challenges. Regulatory pathways must be redesigned to ease the burden on manufacturers of new technologies. This may provide a clear set of requirements needed to develop innovative technology and support efforts to pivot production.

### **6.3.4 Support Innovation and Evidence Generation for New Technologies**

Innovative technologies offer new approaches to mitigate pandemic impact and improve health outcomes, safety, and convenience. Emerging technologies face additional burdens between inception and introduction to the market. There must be widespread support for facilities manufacturing and distributing nascent technologies that make it easier to find useful products, aid development, scale products, and introduce them to marketplaces. This recommendation also builds on those included in the Ontario Health Innovation Council’s “The Catalyst” report [205].

Stakeholders emphasized specific technologies and innovative ideas for addressing future pandemics. Among other emerging technologies, pooled sampling, large-scale genome sequencing, and use of CRISPR-based technologies in diagnostic testing must be the focus of continued research. 3D-printed PPE and medical device components offer promising solutions to product shortages but require guidelines and/or standards. The quality control process for products made using open-source designs (e.g., medical masks stemming from the ROSE project) may require unique considerations. There is some potential overlap for the need to create regulatory and market access pathways for products that are based on open-source designs with a movement towards performance-based standards. Objective-based standards, as described in Section 6.1.2, can support flexibility and innovation [207].

Many technologies are used in other jurisdictions but have not yet been widely adopted in Canada. For example, thermal scanning has only been implemented in some Canadian airports following the onset of the pandemic, while this practice had been widely adopted in Asia following SARS in 2003 [208], [209]. The effectiveness of thermal scanning in travel hubs or congregate settings may vary depending on the symptom profile of the virus [210]. UV robotic sanitization is also more widely used outside of Canada [211]. Additional evidence generation regarding the effectiveness of thermal scanning and broader use of UV sanitization in the Canadian setting may be needed to inform health technology assessment and policymaking processes, and should 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.

Innovation support and incubation has been an area of policy focus in recent years [212], [213]. By building on these initiatives, funding opportunities could be introduced to those facilities that manufacture and/or distribute nascent technologies to aid development and scaling. High-fixed costs for new facilities or prototyping new products make it difficult

for production to get off the ground. Technology incubators and accelerators have directed more attention towards the medical sector in the wake of the COVID-19 pandemic. Continued support should be considered.

## 7 Conclusions

This report characterized the existing pandemic response products ecosystem in Canada and aimed to develop recommendations to strengthen the self-sufficiency and sustainability of this ecosystem. Ideas have been synthesized from relevant literature and expert insights. The ecosystem encompassed domains of quality infrastructure, supply chain, and sustainability. The pandemic response products included were PPE, medical devices, testing and diagnostic equipment, air and surface sanitization, and public health equipment.

It is clear that greater domestic production of pandemic response products is needed to improve resiliency. In the year since the COVID-19 pandemic was declared in March 2020, many Canadian manufacturers, governments, researchers, institutions, and agencies have acted to fill these gaps. While increasing domestic production is critical, there are many other important aspects to becoming self-sufficient that need to be addressed. The quality infrastructure needed to create Canadian standards and perform product testing locally also requires significant strengthening.

There is a need for local solutions relating to production and supply chains. However, there is also a corresponding need to coordinate globally on standards and regulations when feasible. A reliance on NIOSH standards, testing, and certification for N95 masks created a critical bottleneck during this pandemic, a situation which must be avoided in future. Greater international cooperation on regulations and standards is needed.

There are several limitations to this report worth highlighting. First, the participants were not geographically representative of all Canadian provinces and territories. In addition to gaps in stakeholder

geographies, there were also some gaps in stakeholder expertise. Individuals working in industry and not-for-profit organizations were typically able to be interviewed, while individuals working in government settings were less able to participate. Trade experts were not interviewed. As research progressed, it became clear that expertise on how made-in-Canada procurement policies relate to international trade agreements is needed. Stakeholders highlighted the potential for values-based procurement to incentivize responsible manufacturing practices and encourage domestic procurement. These activities have important implications but did not receive substantial attention in this report.

In developing this report, many stakeholders were consulted, and the findings are aimed at multiple stakeholders as well. This report did not take a health systems or public health perspective. Recommendations in this report have implications for these systems, particularly with respect to digitizing supply chains, inventory management, and enabling forecasting and scenario planning with better data.

Stakeholders urged for greater collaboration between medical, standards, and manufacturing communities.

By their nature, ecosystems are complex. The recommendations made in this report touch upon complicated areas that must evolve to improve future pandemic responses. Based on the characterization of the current state of the pandemic response products ecosystem, this report provides specific recommendations at a high level. In the next phase of this research, the feasibility of the proposed recommendations will be explored in detail. These findings will be published in a subsequent report later in 2021.

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# Appendices

## A1. Definitions Used in the Project Framework

### Quality Infrastructure

A quality infrastructure is the consortium of public, private, and citizens' initiatives and institutions that ensures that products or services meet the needs of their consumers [214].

- 1. Standards:** A document that provides a set of agreed-upon rules, guidelines, or characteristics for activities or their results. Standards establish accepted practices, technical requirements, and terminologies for diverse fields. They can be mandatory or voluntary and are distinct from acts, regulations and codes, although standards can be referenced in those legal instruments [32].
- 2. Guidance:** Published documents that provide information to organizations from authoritative sources on compliance with governing statutes and regulations, as well as on how mandates and objectives should be implemented in a manner that is fair, consistent, and effective. Guidance documents do not have the force of law and, as such, allow for flexibility in approach [215].
- 3. Regulation:** Rules that carry the force of law. Regulations are developed and enforced by a regulatory body which administers legislation under a direct mandate over a certain domain [18].
- 4. Evaluation:** The review of a products' safety and efficacy by a regulatory authority to approve its ability to be sold in a jurisdiction [216]. The evaluative capacity of a regulator refers to its ability to conduct evaluations and the speed at which these are conducted.
- 5. Assessment:** New technologies are assessed on clinical and cost-related dimensions and may take into account ethical, social, and legal implications [217].
- 6. Conformity Assessment:** The practice of determining whether a product, service, or system meets the requirements of a particular standard or regulation [218], [219].
- 7. Certification:** A formal confirmation that the standards and/or regulations covered by the certification have been tested for and met. Certification is performed by third parties to provide an independent quality check on work being done. As a result, certifications are a hallmark of trust in production [219].
- 8. Inspection:** Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements [219].
- 9. Testing:** Determination of one or more characteristics of an object of conformity assessment, according to a procedure. Occurs through logical, physical, or process inspection, allowing for validation of quality.
- 10. Licensing:** The process of approval for goods to be sold conditional on their meeting relevant standards and passing evaluations for safety and effectiveness. For new goods that exist outside of existing recognized standards, the regulator must test the item and provide a licence; otherwise, independent certification from an accreditation body is sufficient [215].

### Supply Chain

The term "supply chain" is used to describe the business activities and operations that integrate a continuous, seamless flow of materials and services for health care delivery [62].

1. **Procurement:** The act of obtaining goods or services, typically for business purposes [220]. Procurement involves activities such as (but not limited to) identifying and specifying the need, acquiring and managing the supply of goods from a third party, purchasing, contracting, and contract and supplier management [221].

Procurement can be classified as direct or indirect procurement. Direct procurement involves the process of purchasing components, raw materials, or services that a manufacturer then uses to produce finished goods [222]. Procurement of goods at hospitals is usually done through group purchasing organizations (GPO) that realize savings by aggregating purchase volume and leveraging discounts from manufacturers [64]. This is referred to as indirect procurement. Procurement can be classified as direct or indirect procurement.

2. **Production Capacity:** The effective volume of a particular product that is made available to a country subsequent to being manufactured within the country, which is subject to the availability of productive resources, entrepreneurial capabilities, and production linkages [223].
3. **Logistics:** The overall process of managing how resources are acquired, stored, and transported to their final destination [224].
4. **Inventory Management:** The branch of business management concerned with planning and controlling inventories with the objective of maintaining desired stock levels of desired products/items [225].
5. **Traceability:** Traceability in health care enables the tracking of movement of prescription drugs or medical devices across the supply chain. Products can be tracked backwards to identify the history of the transfers and locations of a product and tracked forwards to see the intended route of the product towards the point of care. Tracking products across the health care supply chain helps eliminate counterfeit health care products, increases patient safety and compliance with regulations [188].

## Sustainability

Sustainability is the ability to satisfy present needs without harming the well-being of those in the future [93].

1. **Economic:** The ability for a given economy to support a given level of income indefinitely, generated from a constant or growing capital stock. For an economy to be sustainable, it is necessary that it has, at the minimum, constant human, manufactured, natural, and social capital [226].
2. **Labour and Skills:** The ability for an economy to supply sufficient skilled labour to meet the demands of employers and provide high quality jobs to the workforce [227]. Sustainability of labour requires accessible education and training, as well as lifelong learning opportunities for workers, informed by the present and expected needs of industry [228].
3. **Environmental:** The minimization or elimination of production and processing wastes through eco-efficient practices and the adoption of new environmental technologies [229].

## Policy

Policy is the suite of actions and practices by a governing body to achieve a given outcome [230].

## A2. Key Informant Interview Methods

### Interview Guides

#### Introduction (used for both scope validation and gap analysis)

1. Thank them for their time. Provide brief personal introduction, invite interviewee to introduce themselves and have team introduce themselves.
2. Request permission to record interview.
  - a. Standard text: "Your name, job title, and organization will be referenced in a list of key informants, however **none of the content will be identifiable or attributed to you directly.** The report will be published on the CSA group website."
  - b. If they prefer not to be recorded, do not record.
3. Outline structure of the talk: We will describe the project and ask you specific questions.
  - a. Standard text: "Do you have any questions before we begin?"

#### 1. Scope Validation

##### A. Guiding Questions

1. Which resources, services, or policies should be included in the ecosystem analysis?
2. Is the framework comprehensive when it comes to addressing the COVID-19 pandemic response?
3. Do the proposed case studies offer opportunities to explore relevant ideas in depth?
4. Are the definitions accurate and categorizations reasonable?

##### B. Discussion Questions

1. Does our framework encompass all areas relevant (e.g., resources, services, policies) to Canada's pandemic response? What is missing?
2. Does our framework and accompanying materials maximize both breadth and depth in identified areas? What is missing?

3. Are the definitions accurate? What is missing?
4. In your opinion, how well do the categories/ domains/functions capture the relevant aspects of the COVID-19 pandemic?
5. Do you think there is an overlap between stated domains/functions/categories? Can any of these domains/functions/categories be merged together?

### 2. Gap Analysis

#### A. Project Overview

1. Describe the overall project.
  - a. Standard text: "The project goal is **to identify essential gaps in Canada's pandemic response materials ecosystem.** The research aims to explore the following questions:
    - i. What is the state of the current pandemic response materials ecosystem in Canada?
    - ii. What is needed to create a self-sufficient and sustainable pandemic response materials ecosystem in Canada?"
  - b. Standard text: "Your responses will help to inform recommendations to support a made-in-Canada pandemic response materials ecosystem and improve resilience when faced with future pandemics."
2. Describe the project organization:
  - a. Standard text: "The project is being conducted in partnership with CSA Group, NGen, and NRC. We have an advisory committee including representatives from government, industry, and the U of T."
  - b. Standard text: "We are currently conducting interviews to inform our gap analysis. In the future we will conduct small group discussions regarding recommendations stemming from this research. We are also conducting an environmental scan."

3. Show the framework and describe it.
  - a. Standard text: "This is how we are conceptualizing the 'ecosystem' and it will help us to frame our questions." Verbally describe the ecosystem.
  - b. Where is the interviewees area of expertise?

## B. Specific Questions

1. Which essential resources, services, or policies were present in Canada's response to COVID-19?
  - a. What organizations were key enablers of this response?
2. Which essential resources, services, or policies were absent in Canada's response to COVID-19?
  - a. Who would be well positioned to lead this work, or is a new entity required?
3. Quality infrastructure:
  - a. What were the problems?
  - b. What are potential solutions?
  - c. What are the barriers?
  - d. Who are the key actors to enable solutions?
4. Supply chain:
  - a. What were the problems?
  - b. What are potential solutions?
  - c. What are the barriers?
  - d. Who are the key actors to enable solutions?
5. Sustainability:
  - a. What were the problems?
  - b. What are potential solutions?
  - c. What are the barriers?
  - d. Who are the key actors to enable solutions?

6. Policy:
  - a. What were the problems?
  - b. What are potential solutions?
  - c. What are the barriers?
  - d. Who are the key actors to enable solutions?

## C. WRAP UP

1. Don't interrupt flow but bring up wrap-up questions with 5-10 minutes remaining to be respectful of time limits:
  - a. Is there anything else you would like to add or any points you would like to clarify before we wrap up?
  - b. Is there anyone else who you would recommend we speak with for this project? Are there any relevant resources you could direct us to?
  - c. Would you be open to participating in future small group discussions about potential recommendations stemming from this research? Would you like to receive a copy of the final report? Would you be willing to participate in any future discussions towards this project should they arise?
2. Conclusion

## A3. Environmental Scan Methods

### A3: Environmental Scan Methods

Function	Quality Infrastructure	Supply Chain	Sustainability
<b>Google</b>			
<b>PPE</b>	Pandemic PPE standards Canada	Pandemic PPE ("supply chain" OR supply) Canada	Pandemic PPE economy Canada
<b>Medical Devices</b>	Authorization medical devices Canada	Medical devices supply chain pandemic Canada	Medical devices Canada sustainable
<b>Testing and Diagnostic Equipment</b>	Pandemic (viral OR antibody) test* rule* OR guideline* Canada	Pandemic (viral OR antibody) test* supply chain Canada	Pandemic (antibody OR viral) test* sustainable manufacturing Canada
<b>Reprocessing</b>	Pandemic PPE (reprocess OR sterilize) standards Canada	Pandemic (reprocess OR sterilize) supply chain Canada	pandemic (reprocess OR sterilize) economy Canada
<b>Air and Surface Sanitization</b>			
<b>Public Health Equipment</b>	Pandemic (sanitizer OR purifier) AND (regulations AND requirements) Canada	Pandemic sanitizer (supply chain) Canada	Pandemic (sanitizer OR purifier) AND (costs OR economy) Canada
<b>Google Scholar</b>			
<b>PPE</b>	Pandemic PPE standards Canada	Pandemic ppe ("supply chain" OR supply) Canada	Pandemic PPE economy Canada
<b>Medical Devices</b>	Authorization medical devices pandemic Canada	Medical devices supply chain pandemic Canada	Medical devices Canada sustainable
<b>Testing and Diagnostic Equipment</b>	Pandemic (viral OR antibody) test* rule* OR guideline* Canada	Pandemic (viral OR antibody) test* supply chain Canada	1) Pandemic (antibody OR viral) test* sustainable manufacturing Canada 2) Pandemic (antibody OR viral) test* environment* (impact OR footprint) Canada
<b>Reprocessing</b>	Pandemic (reprocess OR sterilize) standards Canada	Pandemic (reprocess OR sterilize) supply chain Canada	pandemic (reprocess OR sterilize) economy Canada
<b>Air and Surface Sanitization</b>			
<b>Public Health Equipment</b>	(Pandemic sanitize*) AND standards AND Canada	Supply chain AND PANDEMIC AND (sanitize*) AND Canada	Sustainable* AND (pandemic sanitize*) AND Canada

## CSA Group Research

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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.