



EVERGREEN KEY MESSAGES

2019 Novel Coronavirus (COVID-19) – Wuhan, China

Issue Statement: On December 31, 2019, the Wuhan Municipal Health Commission in Hubei province, Central China, issued a public statement that they had identified an outbreak of pneumonia of unknown cause. China has made a determination that a novel coronavirus (referred to as COVID-19) is responsible for cases of pneumonia in the Wuhan outbreak.

For the latest and most up-to-date information about COVID-19, including the latest number of confirmed cases, visit Canada.ca/coronavirus.

These media lines have been prepared for use by media relations and senior officials to respond to requests for information.

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Foundations for Living with COVID-19

- We recognize that we will continue to see the transmission of COVID-19 in the community as things start opening up again. That is why we need to move slowly, cautiously, as we live through the next phases of this pandemic, until such time as we have a vaccine.
- Most people infected with COVID experience mild symptoms. During this reopening phase, we will do our utmost to protect those at most risk of severe illness due to the virus. Our goal is to minimize overall illness and death from COVID and non COVID related illnesses. There are key steps all Canadians can take in this.
- Continue to practice the critical measures to limit transmission: physical distancing, frequent hand-washing, and staying home if you're sick.
- If you suspect you have illness due to COVID, get tested. This will help us identify any outbreaks in the community and put in place measures to prevent further spread.
- By opening up health services for all conditions again, and allowing for some social and economic activity, we hope to reduce the overall burden of disease and illness in the community, COVID and non-COVID related.
- People with chronic disease, people over the age of 60 and anyone at higher risk should maintain a high-level of vigilance. We need to support these most-vulnerable members of the community to continue to stay home as much as possible, avoid situations where non-home contacts might be and/or where adequate physical distancing is not possible.
- Remember that each of us can still infect others, even if we have no symptoms. It will be critical to continue practicing fundamental infection prevention measures, as well as to ensure that anyone with symptoms contacts goes to a testing centre right away.
- If you are experiencing even mild symptoms, stay home from work and other community settings until you are better. Employers and employees alike need to support each other on this front so that we can track the rate of transmission and keep it under control. Remember that the science tells us it's possible to be spreading the virus before, during and even without any symptoms.
- We know many Canadians want to mark important ceremonies, funerals and other important rites and rituals. It will be important to follow your local guidance on number of participants, infection prevention measures.

Interim Report on the WHO's Response to COVID-19 from January-April 2020

- The ever-evolving COVID-19 pandemic has created an unprecedented situation where global cooperation on health has never been more important.
- Canada values the WHO's leadership and coordination role in the COVID-19 response, including their role overseeing the International Health Regulations, driving collaborative global research efforts towards new vaccines and effective treatments, working with all actors to

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address shortages of critical medical supplies and personal protective equipment, and supporting the most vulnerable countries in their preparedness and response efforts.

- Canada thanks the Independent Oversight and Advisory Committee for its timely interim review of the WHO's response and recommendations for the WHO and Member States, which will be helpful to further strengthen the global response to this health emergency and those in the future.
- The entire global community, including the WHO, is learning more about the virus and the effectiveness of measures to address the pandemic every day.
- There will be many lessons that the global community will learn from this pandemic, and to this end Canada would support a review of the global response post-crisis.
- The Government of Canada will review the recommendations with interest.

Keeping Canadians Informed

Situational Awareness Dashboard Update (Phase 2)

- The Public Health Agency of Canada has released an updated [Canada COVID-19 Situational Awareness Dashboard](#).
- The dashboard provides Canadians and researchers with the latest COVID-19 data in a user-friendly format online so that they can better understand how the outbreak of COVID-19 is evolving in Canada.
- In addition to providing an interactive overview of the number of cases and deaths in Canada, the updated dashboard now provides information at the health region level on recovered cases, testing, and the percentage of cases resulting in death, hospitalization or ICU visits, by age and gender.
- Our collective efforts in gathering, sharing and analyzing data have allowed Canada to monitor and report on numbers and trends, and make evidence-based public health decisions at all levels to respond to this pandemic.
- The Government of Canada will continue to work collaboratively with partners at all levels of government to share and provide timely evidence that can inform and support the public health response.

COVIDTrends Dashboard

- The Public Health Agency of Canada has released a new online tool, called COVIDTrends, that provides Canadians with the number of cases of COVID-19 and deaths in their area within last 14 days, as well total counts since January 2020.
- This is another way that Canadians can stay informed about COVID-19 activity in their area or another region of Canada.

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- The COVIDTrends also provides Canadians with a direct link to the website of their local public health authority so they can get even more information.
- Staying up to date on COVID-19 in their local area, as well as understanding the risks associated with different activities and settings, can help Canadians make informed choices to keep themselves, their families and their communities safe.
- Our collective efforts in gathering, sharing and analyzing data have allowed Canada to monitor and report on numbers and trends, and make evidence-based public health decisions at all levels to respond to this pandemic.
- The Government of Canada will continue to work collaboratively with partners at all levels of government to share and provide timely evidence that can inform and support the public health response.

NARRATIVE Public Health Data in Canada

Current situation

- Canada has undertaken a number of activities to monitor COVID-19 trends and provide critical information to both decision-makers as well as the Canadian public.
- Canada successfully put public health surveillance in place for COVID-19 in very short order, creating the ability to monitor the number of cases, trends over time, severity of cases and demographics of cases.
- Canada has been actively sharing this information publically and with decision makers through many venues, including regular updates on the Canada.ca website.
- All levels of government are working closely together to share information and provide timely evidence that can inform and support the public health response.
- Most public health surveillance in Canada includes a system of data collection beginning with case information collected by local public health. This information flows from local, to provincial and territorial public health authorities.
- The Public Health Agency of Canada receives data per the national case report form, without any personal identifiers. This allows for all levels of public health to monitor the number of cases over time, as well as the geography, severity, demography of the cases, and mode of transmission (e.g., travel vs. community exposures).
- For greater depth of knowledge, public health surveillance is supported by a number of other sources of data, including; enhanced surveillance initiatives to gather intelligence on particular

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populations (such as children) and settings (such as acute care hospitals); clinical information; health system administrative data; and research and special studies.

- The COVID-19 pandemic has shed a light on needed improvements related to public health data and systems in Canada. This includes timeliness, completeness, and granularity of data as well as rapid analysis for data to intelligence and appropriate access to data by multiple parties.
- Systemic and long-standing challenges affect Canada's health data system including resources and capacity, IT infrastructure, and clarity in data governance.
- Healthcare is a provincial and territorial jurisdiction, and Canada does not have a single data solution for public health surveillance and health data.
- While many jurisdictions have invested in solutions that are appropriate for their conditions, this has resulted in a patchwork of newer and legacy systems of varying capabilities.
- Details on individual COVID-19 cases are collected through interviews with patients conducted at the local public health level, usually by a public health professional. This places significant pressure on the front line staff who are asking patients to disclose personal information that some may find to be sensitive in nature.
- Since public health collects the information when individuals are diagnosed, which is typically early in the illness, information on what happens to that individual later in the course of illness, whether it be hospitalization, ICU admission, death or recovery, may take some time to be available and updated.
- The information is then submitted to the province or territory, which shares it electronically to the PHAC, via a case report form. These forms are received in varying states of completeness, depending on how much information is available at the time as well as willingness of the patient to disclose information at the interview.
- All efforts are made to have timely reporting, however, given the heavy burden on our healthcare systems due to COVID-19, there are some delays in reporting and receiving detailed data.
- Despite some of the challenges to collecting information, provinces and territories share data on new cases with the PHAC every day. There is basic information on 99% of all cases of COVID-19 in Canada with over 90,000 cases nationally, this is a huge achievement. Federal, provincial and territorial public health representatives meet regularly to discuss technical and strategic issues for the response, and share information to help one another meet this unprecedented challenge.

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- In the face of a pandemic, our collective efforts in gathering, sharing and analyzing data has allowed Canada to monitor and report on numbers and trends, undertake and report publically on modelling and forecasting work, and make evidence-based public health decisions at all levels.
- Collaboration with the provinces and territories, such as agreement on national data elements and the development of a case report form, supported these efforts.
- Based on lessons learned, we have now reached the stage where we need to discuss how to enhance our common data system to better support public health and policy decision-making through timely and appropriate data and intelligence.

Need for Greater Depth of Information

- As the pandemic has developed across the country, it has become clear that we need more information on certain high-risk groups.
- Some occupations, such as healthcare workers, or specific circumstances such as people living in congregate settings, such as long-term care, and certain ethnic groups are more likely to face circumstances or settings that can increase their vulnerability to COVID-19 and its related impacts.
- Healthcare workers face greater exposure to COVID-19 every day, and congregate living can make it more difficult to practice public health measures, such as physical distancing, that affect the risk of infection and community spread. Further, certain ethnic groups have a higher prevalence of underlying medical conditions associated with more severe complications from COVID-19. Social and economic inequalities may also contribute to higher risk of exposure and infection.
- The national COVID-19 case report form includes a section to self-identify as Indigenous (First Nations, Metis, Inuit). Data in this section are often incomplete or missing. The case report form currently does not include any questions on race or ethnicity, occupation, or dwelling type. Proposed changes to the national case report form to address these issues are underway via an FPT advisory committee.
- PHAC is committed to working with partners, including Indigenous organizations and provincial and territorial counterparts, to look at ways to improve the collection of race and ethnicity, Indigenous identity, occupation, and socio-economic data such as dwelling type.

Path forward

- Ongoing conversations are taking place at federal/provincial/territorial levels to consider and identify both short- and long-term health data system needs in Canada.



- At the beginning of the pandemic, we could not anticipate all the data we would need. Our data systems must be nimble and adaptive and draw information from many sources, not only health.
- Having the data needed to respond to this unprecedented challenge will require all the tools at our disposal, and the creation of new ones. Federal, provincial, and territorial jurisdictions must renew our commitment to working together to create and share the information for this response. It is a complex and difficult problem, but it can be done.
- Our goal is to ensure that Canada has the data and intelligence needed to identify, prevent, monitor and respond to current and future health issues, protect the health of Canadians and support the economy.

COVID-19 Dataset

- The Public Health Agency of Canada (PHAC) is committed to providing Canadians with access to accurate and up-to-date information about the COVID-19 pandemic.
- PHAC works collaboratively with the provinces and territories to gather epidemiological data so that Canada's public health response to COVID-19 is based on the most accurate information and best evidence available.
- The dataset now includes additional details, including provincial and territorial location (grouped into regions), symptoms and occupation.
- To ensure the protection of personal information, Statistics Canada is recoding some data to prevent identification of cases. For instance, instead of listing the date of onset of illness, the data table now shows the week of onset. In addition, provinces and territories that have few cases are grouped into regions. These methods ensure that the data release complies with the requirements of the Privacy Act.

Canadian Institute for Health Information (CIHI) report on infections among healthcare workers

- The Government of Canada is collaborating with the Canadian Institute for Health Information (CIHI) to address data gaps in our understanding of the impacts of COVID-19 among healthcare workers.
- The data from the CIHI's report will help inform local and pan-Canadian public health decision-making and support policy development to further protect Canada's healthcare workers.
- All levels of government need to continue to work together to protect our frontline healthcare workers.
- The Government of Canada will continue to work with the provinces and territories to support frontline healthcare workers. This includes:

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- ensuring they have the personal protective equipment and medical supplies they need. We are doing this through collaborative bulk procurement with the provinces and territories, building domestic production capacity and identifying potential alternatives and ways to extend product life;
- providing guidance, based on evolving science, to inform policies and practises in acute healthcare settings;
- increasing testing of people who present with symptoms and those in high-risk situations such as people working in healthcare settings, long-term care facilities, correctional facilities and situations where a positive case is connected to a high-risk setting that could lead to an outbreak;
- working with provincial and territorial public health laboratories to ensure high-quality diagnostic testing for COVID-19.

If pressed on the over-representation of racialized healthcare workers:

- Healthcare workers face greater exposure to COVID-19 every day. Further, certain ethnic groups have a higher prevalence of underlying medical conditions associated with more severe complications from COVID-19. Social and economic inequalities may also contribute to higher risk of exposure and infection.
- The Public Health Agency of Canada (PHAC) is working with provinces and territories to promote better analysis and understanding of COVID-19 in specific populations and settings. This fall, the new national COVID-19 case dataset will collect data on new variables including race. Other variables such as occupations and exposures will be better defined and standardized.
- The Government of Canada is committed to working with partners, including Indigenous organizations and provincial and territorial counterparts, to look at ways to improve the collection of race and ethnicity, Indigenous identity, occupation, and socio-economic data such as dwelling type.

If pressed on PHAC's infection prevention and control guidance for acute healthcare settings:

- PHAC's guidance, published April 30, 2020, emphasized the need for environmental and administrative controls in facilities to protect persons working in healthcare settings and patients, as well as the fundamental importance of training in the use of personal protective equipment (PPE).
- PHAC continues to recommend that all persons working in acute care hospitals wear medical masks and eye protection/face shields for the full duration of a shift in acute healthcare settings.
- Persons working in healthcare settings should refer to their province or territory's guidance, as well as facility policies on the use of masks, eye protection, and other PPE (including any PPE conservation strategies that are in place).

Virtual Health Tools

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- More than ever, Canadians need to have tools and resources to support their health and wellbeing, including readily available information, mental health supports, alerts, and screening tools.
- May 3rd's announcement of \$240.5 million will help Canadians access credible health information and needed health services through virtual tools and approaches.
- Virtual tools enable Canadians to engage safely with their regular health providers via phone, text or video-conference. They also enable patients to continue to access specialist services during this time of uncertainty.
- Improving access to virtual tools will also help Canadians to access trustworthy information, including via the Canada COVID-19 mobile app, so that they can understand and track their symptoms and learn more about how to stay safe during the pandemic.
- We recognize that Canadians are coping with the effects of COVID-19 and are facing different degrees of stress. This investment will support Wellness Together Canada, a new free online portal that offers virtual mental health, wellbeing and substance use supports.
- The Government of Canada is working closely with provinces and territories, innovators and others to support rapid expansion of virtual care services and make these tools widely available to Canadians and their families.
- Supporting the expansion of virtual care and providing digital solutions to Canadians will help reduce pressures on health systems and provide Canadians with needed health services and authoritative information in a safe and secure manner.
- Our government recognizes that this is an unprecedented time. We are continuing to work with provinces and territories, innovators and others to take action and support Canadians.
- Enabling Canadians to access credible information and needed health services virtually and securely is key to the government's work to keep Canadians safe and informed.

Canada COVID-19 app

- Canadians need easy access to digital tools and resources to help them get the information they need about COVID-19.
- The Canada COVID-19 mobile application allows users to access trusted health resources and track COVID-19 symptoms daily.
- The latest updates about COVID-19 and how Canada is responding are available in real-time through the app with recommendations and resources that are personalized.
- This app builds on what provinces and territories are doing and provides another valuable resource for Canadians.
- Health Canada is continuing to work closely with provinces and territories, vendors and stakeholders to make additional tools widely available to Canadians and their families.

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- The Canada COVID-19 app is a central resource to be used for accessing trusted, evidence-based information about the COVID-19 pandemic across Canada. It does not track personal information, nor is it a surveillance tool.
- The protection of Canadians information is a priority for the Government of Canada and any tool used to collect health care information would need to undergo a rigorous privacy assessment.

COVID Alert: Exposure Notification App

- The Government of Canada, in collaboration with other orders of government and across sectors, has developed a new nation-wide mobile app to let users know if they may have been exposed to COVID-19.
- The app, called COVID Alert, is available to all Canadians for free download, in the App Store and Google Play.
- The app uses strong measures to protect the privacy and confidentiality of any data it collects. The app does not track a user's location or collect personally identifiable information.
- COVID Alert is another tool Canadians can use to help slow the spread of infection, prevent future outbreaks, and protect our communities as we ease restrictions and restart the economy.
- While the exposure notification app is voluntary, the more Canadians who use it, the more useful it will be in protecting our loved ones and limiting further infection.
- During this first phase, people in Ontario who get a positive COVID-19 test result will be given a one-time key from health authorities in Ontario.
- When the one-time key is entered in to the app, COVID Alert will notify other users who may have come in close contact with that person.
- The government is working with provinces and territories to have COVID Alert implemented in all jurisdictions so that all Canadians can benefit from the exposure notification app. The timeline for implementation will depend on the circumstances and contexts in each jurisdiction.
- COVID Alert is just one tool among a suite of tools and guidance being used by the Government of Canada to help slow the spread of COVID-19.
- The Government has created the COVID-19 Exposure Notification App Advisory Council to provide advice and guidance as the mobile app is rolled out across the country.

Assessment and recommendations from OPC on exposure notification app

- Health Canada welcomes the OPC's finding that the app's design includes strong privacy protections, as well as the OPC's reference to the Government's ongoing efforts to ensure public transparency.



- Health Canada and the several other federal institutions collaborating on the COVID Alert initiative would like to thank the Privacy Commissioner and his office for their assessment of and recommendations on the app.
- The app uses strong measures to protect the privacy and confidentiality of any data it collects. The app does not track a user's location or collect personally identifiable information.
- The app's privacy protections and our continued transparency with Canadians are priorities of Health Canada and the institutions collaborating on this important initiative.
- The Office of the Privacy Commissioner (OPC) has been actively engaged on this issue.
- The assessment noted that exceptionally strong measures have been adopted by the Government of Canada to ensure that the identity of users is protected and not disclosed to the Government.
- While experts generally agree that there is no such thing as zero risk of the re-identification of de-identified data, the OPC felt that, with this app, the risk of re-identification is very low in light of the security and other safeguards adopted.
- The exposure notification approach used by Apple and Google is a secure system, designed to work without storing personally identifiable information.

COVID Alert security vulnerability

- COVID Alert is built with strong privacy protections and is a highly secure system. We remain confident that the app protects the privacy of Canadians.
- It is extremely unlikely that COVID Alert users could be identified while using the app. The risk of re-identification is very low in light of the security and other safeguards that have been adopted.
- We are aware of a Bluetooth vulnerability with the Google/Apple Exposure Notification Framework that impacts a small subset of Android-based phones and we have notified Google. This vulnerability does not lie with the COVID Alert app.
- This vulnerability could potentially allow a malicious actor to track a user's location using the random codes that are generated by the app. It would be a very difficult, time consuming, and costly to exploit this vulnerability.
- We continue to work with our government and industry partners to ensure that COVID Alert protects every user's privacy and that any potential cyber security risks continue to be properly mitigated.
- The Office of the Privacy Commissioner has previously conducted assessments of the app and noted that exceptionally strong measures have been adopted by the Government of Canada to ensure that the identity of users is protected and not disclosed to the Government.

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- The app's privacy protections and our continued transparency with Canadians are priorities of Health Canada and the institutions collaborating on this important initiative.

COVID Alert One-Time Keys

- Canadians who test positive for COVID-19 get a one-time key from onboard provinces but the process to obtain the one-time key may vary.
- Individuals should contact their local health authorities for more information about the process for getting a one-time key in the province or territory they currently reside in.
- We continue to work with our partners to increase awareness of the app as well as with onboard provinces to make sure everyone in Canada who tests positive for COVID-19 has access to a one-time key.

Panorama Health Surveillance Data Tools

- In Canada, the Public Health Agency of Canada (PHAC) and provincial and territorial public health authorities share responsibility for public health surveillance.
- Panorama is a digital health solution to help public health professionals:
 - conduct communicable disease case management,
 - track vaccine inventory,
 - manage immunization programs,
 - manage disease outbreaks, and
 - manage public health workloads.
- Panorama was funded through Canada Health Infoway, which was established in 2001 by the Government of Canada as an independent, not-for-profit organization to help public health professionals have access to modern, effective digital health solutions.
- Not all provinces or territories use Panorama to perform every one of these functions. It is used by jurisdictions in different ways, depending on their contexts and priorities.
- Though information is not being shared through a single software platform, provinces and territories have been sharing data on cases since the COVID-19 pandemic began in Canada. All provinces and territories have been working closely with PHAC to leverage data systems and mechanisms to respond to the COVID-19 pandemic.
- The federal, provincial and territorial Special Advisory Committee on COVID-19 is the vehicle through which Canada's national COVID-19 surveillance decisions are made during the pandemic. The committee institutes additional data collection mechanisms as required to ensure consistency and to eliminate potential data gaps.
- PHAC is continually working with provinces and territories to improve the way surveillance information is shared across jurisdictions in Canada. This is complex, as surveillance systems, practices, standards, policies and legislation vary significantly from one jurisdiction to another.

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- PHAC conducts surveillance activities on specific diseases and threats to public health, from setting up systems to analyzing and reporting on data on emerging trends and relevant issues with input from across the country.
- PHAC works with provincial and territorial partners through established committees and communities of practice to advance national surveillance initiatives, get a clear understanding of the issues.
- PHAC's goal is to ensure an effective national framework for public health surveillance; one that is based on common principles and standards and that allows us to collect, analyze and share standardized information across jurisdictions appropriately.
- The Government of Canada continues to provide leadership and coordination by supporting the development of standards for the collection of national data and to guide the development of immunization registries and other vaccine-related technologies.

Annual report from the Office of the Privacy Commissioner: COVID Alert

- Health Canada welcomes the annual report from the Office of the Privacy Commissioner (OPC). The OPC continues to be consulted and engaged on COVID Alert, and supports its use by Canadians.
- In his annual report, the Privacy Commissioner highlighted COVID Alert as an example of how respectful privacy practices can be built into the design of an initiative to achieve public health goals.
- Health Canada would like to thank the Privacy Commissioner and his office for their ongoing assessment and recommendations on the app.

On evaluating the app's success...

- Health Canada regularly conducts evaluations to ensure effectiveness and proper management of the public funds administered by the Department. An evaluation of COVID Alert will be undertaken in consultation with the OPC.
- The Government of Canada also recognizes the benefit of independent oversight and guidance from a variety of private sector and academic experts, which is why a COVID-19 Exposure Notification App Advisory Council was established.
- The Advisory Council consists of eleven members, including two co-chairs, and reflects both the diversity of Canada and the varied regional perspectives and challenges from coast to coast. These experts will provide advice and guidance on the implementation of COVID Alert. These experts will provide advice to help ensure the app meets the highest standards with respect to public health outcomes, technology and privacy.

Marketing Partnership | Entertainment Software Association of Canada



- The Public Health Agency of Canada (PHAC) and Entertainment Software of Association of Canada (ESAC) are joining forces to reach millions of Canadian gamers with messaging about public health measures they can adopt to help minimize the spread of COVID-19.
- Video games have helped many youth and young adults stay connected with friends and family while maintaining physical distancing during the pandemic.
- Young people, especially those living with older or high-risk family members, or who work in customer service settings, have a critical role to play in reducing the spread of COVID-19.
- This in-kind marketing partnership is part of the Government of Canada's effort to engage with youth aged 13 to 19 and young adults aged 20 to 29 returning to school, work or extra curricular activities this fall.
- ESAC is the national voice of Canada's video game industry representing some of the most prominent leaders in the industry including Microsoft, Warner Brothers, and Gameloft.

If pressed on specific aspects of the marketing campaign:

- Canadian gamers can expect to see social media posts, videos and links to Canada.ca/coronavirus during the campaign.
- This marketing collaboration with ESAC is an in-kind partnership, meaning that no funds were provided to ESAC or its members.
- PHAC incurred some costs developing the campaign materials, as part of its COVID-19 public education budget to ensure that all content under this partnership is consistent with other COVID-19 material. This will help Canadians identify ESAC as a trusted source and know that the information is evidence-based and reliable.

If pressed on increased COVID-19 infections among youth and young adults:

- Since the initial wave of COVID-19 in Canada, the infection rates among younger age groups has grown substantially.
- Since late August, the highest infection rates for COVID-19 have been among those aged 20 to 29 years. Recent national surveillance data indicate that young people are getting infected more than others.
 - Youth aged 13 to 19 years of age accounted for **9%** of total cases but account for only **7.73%** of the Canadian population.
 - Young people 20 to 29 years of age accounted for **28%** of total cases but account for only **13%** of the Canadian population.
- Most young people will experience milder illness with COVID-19, but not all. Some have or will experience prolonged symptoms or develop serious illness requiring hospitalization and others have or will pass on the illness to family members and contacts.

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- The Public Health Agency of Canada is committed to finding innovative ways to target young people and help protect the health and safety of those at higher risk for severe illness.

If pressed on gaming disorders as a growing public health concern:

- We are committed to communicating public health and mental health resources with all Canadians.
- While gaming disorders continue to be a growing concern in Canada, it is important to reach young Canadians where they are congregating virtually, with important public health messaging and mental health resources.
- We know that 65% of Canadians play video games, and more than 90% of teens play video games. It is essential for the Government of Canada to engage with Canadians in a timely and innovative way at this critical point in our fight against COVID-19.
- We understand these are unprecedented times and parents may find it difficult to limit screen time for their children. As with all entertainment, we encourage moderation. We support the use of healthy game play tools, such as parental controls.
- Together, families can choose the right games, set house rules and set parental controls. Canadians can find tips on how to set parental controls on the [Entertainment Software Association of Canada's website](#).

National PPE and Medical Supplies Dashboard

- In support of the response to COVID-19, the Public Health Agency of Canada (PHAC) is collaborating with provinces and territories on bulk procurement of critical supplies of personal protective equipment (PPE) such as masks, gloves, face shields and gowns for front-line healthcare workers.
- The majority of these supplies are allocated to provinces and territories when received. Some surge capacity is retained in the National Emergency Strategic Stockpile (NESS) to address urgent needs identified by the provinces and territories.
- The NESS usually supplies provinces and territories with assets that they don't normally stockpile, such as, rare pharmaceuticals for biological threats. In the past, the PHAC has not disclosed the specifics of these holdings for security reasons.
- While historically PHAC has not disclosed the inventory of the NESS for security reasons, we are now disclosing the quantity of critical PPE in the NESS—specifically, masks, gloves, face shields, gowns, and ventilators —along with information about the quantities of PPE ordered, received and shipped to provinces and territories to help them with their preparedness and response activities for COVID-19.
- This is an exceptional circumstance and we all benefit from greater transparency to support the pan-Canadian COVID-19 response.

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Preparing Canadians for seasonal return indoors

- We know that weather, holidays and other activities traditionally bring people indoors more often this time of year. As provinces and territories continue to adjust public health measures, we have to think about the risks associated with different settings and activities.
- Canadians are used to adding layers of clothing for protection against the elements. This year, we also encourage Canadians to use multiple layers of protection against the virus.
- Inside or outside, Canadians should continue to maintain a 2-metre distance from people who are not part of their household or part of their small, consistent and trusted close contact bubble. A non-medical mask is an extra layer of protection that you can use to reduce the risk of spread, but it doesn't replace physical distancing.
- Other layers of protection that should be combined with physical distancing are:
 - staying home if you have symptoms, even if mild;
 - maintaining good hand and respiratory hygiene;
 - cleaning and disinfecting frequently touched surfaces;
 - maintaining a small, consistent and trusted in-person close contact bubble; and
 - wearing non-medical masks or cloth face covering, if able and appropriate (according to age, ability and setting).
- We are still learning about how forms of ventilation affect transmission, but do suggest open windows will benefit airflow in indoor spaces. Some fresh air is better than none, but we know that it's not always possible to be outside or keep windows open. As new evidence emerges, and as we learn from the experiences of other jurisdictions, our guidance will continue to evolve.

Considerations for hosting

- If you're planning to host an event or activity, remember that there are actions you can take to reduce the risk for yourself, your household and your guests..
- Gathering limits and restrictions vary across the country. Follow your local public health advice on how best to stay healthy indoors.
- Some quick questions to ask when considering hosting guests are:
 - Is there enough space for guests from different close contact bubbles to keep 2 metres apart from each other?
 - Am I, or is someone in my household, my contacts bubble or my guest list at risk of more severe disease or outcomes?
 - Will I keep a list of guests and their contact information for potential contact tracing?
- Next, consider how many additional measures you can put in place to reduce the risk for your household and guests:
 - Would it be possible to host this event virtually?
 - Can I host this activity in a venue other than my home—where space, ventilation and other features might allow my guests to gather more safely?
 - Will I check in with guests before their arrival to confirm they're feeling well and don't have any symptoms or recent contact with a confirmed case?

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- Will I ask guests who are feeling ill or experiencing even mild symptoms not to attend?
 - Am I able to offer my guests somewhere to wash their hands with soap and water?
 - Can I make hand sanitizer readily available for guests, especially at the door when they enter?
 - Can I arrange seating at adequate distance ahead of guest arrival?
 - Will I promote physical distancing and ask guests to avoid physical greetings and contact, like handshakes and hugs?
 - Am I able to host this event outside?
 - Are there windows I can open to increase ventilation?
 - Will I frequently clean high-touch surfaces like counters, doorknobs, and faucets while guests are here?
 - Can I turn music off or down—so that guests do not have to speak loudly to be heard?
 - Will I limit how many people handle or serve food and provide non-medical masks for anyone preparing or serving food?
 - Will I limit the self-serve food and drink options to prevent utensils and dishes from being shared?
 - Am I comfortable asking my guests to wear a non-medical mask?
 - Can I provide non-medical masks for guests who don't have one?
- It is important to remember that just because you know the people at an event outside your household and contact bubble, does not reduce the risk. Don't let your guard down. Keep following good public health practises.
 - This is not a comprehensive checklist, but a reminder that we can take steps to reduce risks of spreading COVID-19.
 - On the Government of Canada website, Canada.ca/coronavirus, there is a risk mitigation tool that can provide further advice for people to consider. We must also follow local public health guidance and adjust environments so that we can reduce the risk of spread.
 - Not everyone will be able to follow every recommendation, but it is our shared responsibility to take all the precautions that we can.
 - Consider the risks of each setting and activity, and make informed decisions to keep yourself, your family and your communities safe. If a planned activity puts you at higher risk of getting COVID-19, consider adjusting your plans to make it safer for all.

Assessing personal risk

- No individual, and no family, faces the same set of circumstances. Regardless of the temperature, weather or location, each of us has to think about the risks for any activity and make an informed choice.
- You cannot eliminate all risks, but there are things you can do to reduce your risk, and the risk to your loved ones:
 - if you have any symptoms, even mild ones, stay home, stay away from others and get tested;
 - keep up with effective public health practises such as physical distancing, hand-washing and wearing non-medical masks or face coverings; and

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- limit the number of locations and events or activities you attend in the days and weeks before a planned important activity.

Thriving in the cold

- The outdoors has been a refuge for many during the pandemic. Canadians have been getting outside for exercise, lower-risk socializing and positive mental health and well-being.
- This can still be the case even in colder temperatures, as long as we continue practicing physical distancing and other public health measures.
- Part of our Canadian identity and spirit is braving the outdoors in the winter. Let's roll **down** our sleeves, put on our toques, mittens and masks, and keep COVID-19 outside of our homes.

Mental health impacts

- As colder weather sets in, parks, patios and other outdoor places will be less accessible. Often in the colder months, we're inside for longer periods, which can cause feelings of sadness, stress, confusion and worry.
- These feelings may be especially strong, since many of us have already experienced them throughout the pandemic.
- The COVID-19 pandemic has resulted in many changes.
- If you're in crisis, or need urgent medical support, call 911 or your local emergency help line. You can also get support from a local crisis centre, @CrisisCanada (1-833-456-4566), 1 866 APPELLE (Quebec residents) and @KidsHelpPhone.
- The Hope for Wellness Help Line (1-855-242-3310) offers immediate mental health counselling and crisis intervention to all Indigenous Peoples, including an on-Line Chat Counseling Service: <https://hopeforwellness.ca>
- Canada.ca/Coronavirus has a wide range of immediate mental health and substance use resources and supports for Canadians, including the online Wellness Together Canada portal. This portal can help those experiencing a range of common feelings like:
 - a sense of being socially excluded or judged;
 - concern about your children's education and well-being;
 - fear of getting sick with COVID-19 or of making others sick;
 - worry about losing your job, not being able to work or finances; or
 - fear of being apart from loved ones due to isolation or physical distancing.
 - new or increased desire to use alcohol or other substances

Canada's success so far

- It is expected that we will continue to have COVID-19 cases, given that the virus is circulating across Canada and worldwide. But Canada has increased capacity across our health, public health and laboratory systems and made adaptations to social and economic spaces to tackle these cases as they come—if we can all keep working together to keep the infection rate at a manageable level.

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- In order to keep the infection rate to a manageable level, particularly during the fall and winter when colder weather shifts our activities indoor, Canadians will need to be even more vigilant about following public health guidance.
- It is important that we maintain proven effective public health measures and keep our number of in-person close contacts low. This will keep the COVID-19 infection rate to a manageable level, so that local public health authorities do not become overwhelmed with too many cases and too many contacts. This is the only way to control epidemic growth and maintain the slow burn that we need to protect the health of all Canadians. .
- We can all do our part by continuing with our collective efforts, safely apart.

Keeping your own space safe

- There is no one-size-fits all approach at home, as some Canadians need to take extra precautions if they live in multi-generational households or with people who may be at risk of more severe disease or outcomes from COVID-19.
- When returning home from an outing, it is strongly encouraged to:
 - wash your hands with warm water and soap for at least 20 seconds, or use a Health-Canada approved hand sanitizer, as soon as you return home;
 - put possibly exposed laundry including non-medical masks and face coverings in plastic-lined laundry bin or a plastic bag;
 - do laundry with regular laundry soap by putting it directly into the washing machine, using a hot cycle and drying it well;
 - clean or disinfect regularly used electronics such as mobile phones, keyboards, tablets and smartboards by following the manufacturers instructions; and
 - avoid touching your face, mouth, nose or eyes to reduce the likelihood of exposure and keep you and others safer..

Federal funding

- On March 11, the Prime Minister, Justin Trudeau, announced Canada's more than \$1- billion whole-of-government COVID-19 Response Fund.
- Funding provided to PHAC and Health Canada includes:
 - \$50 million for the Public Health Agency of Canada to support ongoing communications to keep Canadians informed and a national public education campaign to encourage the adoption of personal protective behaviours.
 - \$100 million to support federal public health measures such as enhanced surveillance, increased testing at the National Microbiology Laboratory (NML) and ongoing support for preparedness in First Nations and Inuit communities.
 - This is in addition to an initial \$50 million that was provided to support the immediate public health response.
 - \$275 million to enhance our capacity to explore antivirals, develop vaccines and support clinical trials.

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- This is in addition to the \$27 million for coronavirus research announced in early March through the Canadian Institutes of Health Research, which will support 47 research teams from across Canada.
- \$50 million to the Public Health Agency of Canada to support the purchase of personal protective equipment—such as surgical masks, face shields and gowns—and medical supplies to address federal needs and supplement stocks of the provinces and territories that require it.

Q4 Proactive Disclosure of Contracts

- The Public Health Agency of Canada has taken unprecedented actions to respond to the rapidly evolving COVID-19 epidemic. For example:
 - The Canadian Red Cross Society, Nav Canada and Voyageur Transportation contracts relate to the large-scale repatriation of Canadians from affected areas outside the country and their temporary housing at designated quarantine sites, to prevent the import of COVID-19 into their home communities.
 - The Stevens Company Ltd and Amazon Services LLC contracts relate to our strategy of purchasing and delivering unprecedented quantities of personal protective equipment (such as surgical masks, face shields and gowns) to provinces and territories to protect the health and safety of Canadians, particularly frontline healthcare workers
 - The Spartan Bioscience contract reflects our efforts to accelerate diagnostic testing capacity in order to detect cases of COVID-19 more quickly.
 - The contract with BlueDot enhances our ability to collect the infectious disease data we need to inform our public health planning.

Key Messages from PSPC on Proactive Disclosure of Contracts Related to COVID-19

- The Government of Canada is engaged in an unprecedented effort to acquire supplies and equipment to ensure that Canada's front-line healthcare workers stay safe and healthy.
- We are aggressively procuring in the global marketplace, while facing the risks posed by fragile supply chains, the fluidity of the current situation, and a surge in demand.
- The global nature of this pandemic and demand for supplies means that we face severe competition for goods and a highly volatile supply chain.
- With this in mind, in order to protect the integrity of our procurement processes and global supply chains, it is necessary to delay the proactive disclosure of contracts related to COVID-19 response.
- In line with our ongoing commitment to transparency, this information will be made publicly available as soon as our procurement of vital personal protective equipment (PPE) is no longer at risk.

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Mental Health Support for Canadians

Wellness Together Canada portal

- Canadians need easy access to digital tools and resources to provide them with the information they need during COVID-19.
- During these difficult times, it is critical that Canadians have access to effective tools to support their mental health and wellbeing, obtain credible and reliable information about mental health and substance use, and access services.
- That's why the Government of Canada is launched the Wellness Together Canada mental health and substance use support portal. It is a central resource for accessing confidential mental health and substance use support with respect to COVID-19.
- Health Canada was pleased to work with a wide variety of organizations who have a long history of providing top quality mental health and substance use care to Canadians, including Stepped Care Solutions, Kids Help Phone, Homewood Health, Greenspace Health, the Mental Health Commission of Canada, and the Canadian Psychological Association.
- This web-based portal provides Canadians with a virtual network of psycho-social information services and supports, and is available on Canada.ca/coronavirus and the [Canada COVID-19 app](#).
- The Wellness Together Canada mental health and substance use support portal is meant to support existing provincial and territorial services.
- Health Canada is working closely with provinces and territories, vendors and stakeholders to make additional tools widely available to Canadians and their families.

Funding to Kids Help Phone to meet increased demand for mental health services for children and youth in relation to COVID-19

- The COVID-19 pandemic is new and unexpected. It is having a major impact on Canadians, including children and youth. Supporting the mental health and well-being of Canadians during the COVID-19 pandemic is a priority for the Government of Canada.
- With school closures and reduced access to community resources, Kids Help Phone is experiencing increased demand for its confidential 24/7 crises support services, which are available online, by telephone, and through text messaging.
- In response, the Government of Canada is providing \$7.5 million to Kids Help Phone to meet this increased demand and provide young people with the mental health support they need during this difficult time.
- This additional support will provide English and French e-mental health services to children and youth across Canada who are feeling the social and financial impacts of the COVID-19 pandemic. It will ensure that vulnerable Canadian youth and children can find the help they need when they need it most.

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This investment is an important first step in connecting Canadians to the mental health resources they need across the country.

Promoting Health Equity: Mental Health of Black Canadians Fund

- Racism and discrimination can create barriers to essential conditions for good health, like adequate housing, jobs, and education. Within the COVID-19 pandemic context, these barriers can be even greater for Black and other racialized Canadians.
- The Government of Canada recognizes these systemic challenges and barriers, and is taking steps to address them through supports for young Black Canadians to improve their mental health and well-being through culturally appropriate programs.
- The Promoting Health Equity: Mental Health of Black Canadians Fund (MHBC) provides support to community-based organizations for the development of more culturally focused programming, capacity, and knowledge to improve the mental health of Black Canadians.
- The Government of Canada recognizes the significant and unique challenges faced by Black Canadians and other racialized populations during the COVID-19 pandemic. Our community-based programs will continue to take into account these unique needs throughout the pandemic and its recovery.

IF PRESSED ON THE NEED FOR RACE-BASED COVID-19 DATA

- We are working to better understand the impacts of COVID-19 among culturally diverse groups through research and community-based programs.

Government of Canada's Research Response to COVID-19

- Our top priority is the health and safety of Canadians.
- Canada is home to some of the most skilled and recognized researchers in the world, who are working hard to support international efforts to fight this pandemic.
- Every day, we are adding to our knowledge of COVID-19, keeping pace with the rapid growth of new scientific evidence as it emerges.
- In order to slow, and eventually stop, the spread of COVID-19 infection we need to mobilize Canada's research and scientific communities to advance research and technology development.
- That's why, in March 2020, the Government of Canada announced a \$1 billion government-wide COVID-19 Response Fund, which includes \$275 million to enhance our capacity to test antivirals, develop vaccines and support clinical trials.
- Through the Canadian Institutes of Health Research (CIHR) Rapid Research Response program, the Government of Canada has invested a total of \$54.2 million to support 99 research teams from across the country. These teams are focusing on developing and implementing measures to rapidly detect, manage and reduce the transmission of COVID-19. This includes research into a vaccine, as well as the development of strategies to combat stigma, misinformation and fear.
- In addition to CIHR, funding for the Rapid Research Response was provided by the Natural Sciences and Engineering Research Council of Canada, the Social Sciences and Humanities Research Council, the Canada Research Coordinating Committee, the International Development Research Centre, Genome Canada, as well as contributions from Research Manitoba, Research Nova Scotia and Alberta Innovates.

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- The report released today highlights the critical and innovative research taking place across Canada, including tools and solutions being developed to combat and treat COVID-19.
- This includes leveraging capacity and expertise from the Government of Canada's research facilities and making strategic investments to support and boost Canadian research capacity in both academia and industry.
- Many of these funded projects have international collaborations and partnerships with academia, government departments as well as industry.
- Together, we are working to turn significant findings and research into actions that will save lives across the country.

Canada's Support of the Global Solidarity Trial and Solidarity II Study for COVID-19

- COVID-19 is a global pandemic that requires a global solution.
- The participation of researchers around the world in these initiatives to combat COVID-19 is truly a new model for global collaboration.
- Canada is home to some of the most skilled and brightest researchers in the world who are working hard to support domestic and international efforts to fight this pandemic.
- Through international collaboration efforts like the Solidarity Trial, discoveries made through Canadian research will benefit not just Canada, but the global community as a whole.

On Canada's support of the Solidarity Trial

- This global trial, coordinated by the World Health Organization, will test multiple potential drugs to treat COVID-19. By using a common study design across countries, it ensures that results can be obtained more rapidly and be more robust.
- As with any unproven therapy, there are potential harms as well as benefits. Therefore, all potential therapies are best accessed through a clinical trial.
- The Government of Canada has invested nearly \$4.5 million through the Canadian Institutes of Health Research to support university- and hospital-based researchers in their project, Canadian Treatments for COVID-19 (CATCO). This is part of our more than \$1 billion commitment towards a national medical and research strategy for the COVID-19 pandemic.
- The researchers conducting the Canadian trial intend to recruit up to 80 sites across Canada.
- Data from CATCO research efforts will be shared with the Solidarity Trial to contribute to global efforts to help find an effective treatment for COVID-19.

On Canada's contributions to the Solidarity II Serological Study

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Canada's COVID-19 Immunity Task Force is leading the pan-Canadian effort to understand how widespread exposure to the COVID-19 virus has been. Connections with international studies are important and plans for linkages with Solidarity II will be considered as Canada's studies get underway.

- Serological testing identifies antibodies in the blood that indicate if a person has already been infected.
- Solidarity II is a global collaboration of serological studies among different populations around the world.
- Understanding what proportion of the population has been infected with COVID-19, and what proportion may be immune from infection in the future, will inform how local, national and international decision-makers respond collectively to the pandemic.

New Research Studies

- This latest study on COVID-19 is one of many of an increasingly large number of studies being published at a rapid pace. It is important for us to carefully review and consider the value of its findings, and how these might contribute to the scientific landscape.
- It is important to recognize that the SARS-CoV-2 virus is new, so our knowledge of COVID-19, though growing, is incomplete. We will learn more as the science continues to evolve.
- While our understanding of the virus and how it behaves can advance based on new research findings, I would caution against drawing firm conclusions on the basis of a single study.
- Canada is very much a part of the global research network learning more about the disease and how we can address it. The Government of Canada's National Microbiology Laboratory is one of the global leaders in infectious disease research, working tirelessly with many other Canadian and international research facilities.

Canada's public health advice will continue to be informed based on trusted and expert science that will ensure the health and safety of the Canadian population in the face of this unprecedented pandemic.

Examples of projects

- The Government of Canada is investing \$150 million to support federal public health measures such as enhanced surveillance, increased testing at the Public Health Agency of Canada's (PHAC) National Microbiology Laboratory and ongoing support for preparedness in First Nations and Inuit communities.
- This important work will support diagnostic testing across Canada, research, testing and implementation of new diagnostic tests and methods, and coordination of the supply and distribution of reagents and lab supplies with provincial and territorial authorities to increase testing capacity across the country.
- The Public Health Agency of Canada's National Microbiology Laboratory is improving its understanding of the epidemiology of COVID-19 across Canada, which will help us to improve our response. Part of this work includes evaluating and establishing blood test methods to determine the immune status of Canadian populations and modelling work to

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- assess different projections that will inform the actions we need to take to minimize the impact of the virus.
- The National Research Council of Canada's (NRC) Pandemic Response Challenge Program will bring together the best Canadian researchers from government, academia, and the private sector to develop important medical countermeasures to address COVID-19. Working with Canada's health experts to identify the most pressing needs, the program will target tools to rapidly diagnose and detect the virus, drugs and vaccines to treat and prevent the illness, and digital health solutions to help manage Canada's response to the pandemic.

COVID-19 Duration of Infectivity NML Research Study

- New information on COVID-19 emerges every day. Researchers and scientists in Canada and around the world are working hard to better understand the virus, and its impacts on people and communities.
- Scientists from the Public Health Agency of Canada's National Microbiology Laboratory, along with collaborators from Manitoba's Cadham Provincial Public Health Laboratory, have found that patient samples did not contain infectious material after eight days following the onset of symptoms.
- The evidence gained through this research study will help determine how many days after infection that patients may be able to spread the virus to others. This knowledge will help to better protect the health of Canadians.
- Our government has invested heavily in science and medical research. Evidence gained through this research project is proof we are seeing results from those investments and are learning critical information about the virus that causes COVID-19.
- The duration of infectivity, or how long someone can spread the virus, is critical knowledge needed to inform public health guidelines and interventions. Before this research study, there was a lack of laboratory data to understand this very important factor in the spread of COVID-19.

On the specifics of the research study:

- NML scientists examined 90 samples from laboratory-confirmed COVID-19 patients and made two important findings.
- While samples still contained the genetic footprint (RNA) of the virus that causes COVID-19, they found that the samples did not contain infectious material after eight days following the onset of symptoms. This suggests that COVID-19 patients should not be infectious beyond eight days after symptom onset.
- They also found that samples with low levels of RNA (or viral genetic material) were not able to grow in the laboratory. This means patients whose lab tests show levels of viral RNA within a certain threshold should not be contagious.

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- While there was still genetic material (RNA) in the samples, they were unable to cause infection and therefore symptomatic patients who are beyond 8 days post symptom onset should not be able to spread COVID-19 to others.
- This information can inform current public health policy and guide clinical, infection control, and occupational health decisions.
- This is the largest cross-sectional research study of its kind that explored infectivity of COVID-19 that included patients of all ages and backgrounds.
- Further studies of larger sample sizes are needed to confirm findings. Targeted studies of patients with specific conditions, such as weakened immune systems, are also needed.

Collaborative work to develop a vaccine:

- Currently, there is no vaccine to protect against COVID-19. Research supporting the development of COVID-19 vaccines is in various stages around the world, including in Canada.
- We are taking appropriate action to secure the availability of a vaccine or drug to prevent or treat COVID-19 to Canadians, once it is developed.
- This includes investments to:
 - Medicago (Quebec City): for pre-clinical and clinical testing of a plant-based, virus-like particle vaccine, with expansion of manufacturing capacity;
 - The University of Saskatchewan's Vaccine and Infectious Disease Organization – International Vaccine Centre's (VIDO-InterVac): to strengthen VIDO-InterVac's existing expertise on coronavirus research and upgrade its manufacturing facility to meet good manufacturing practice (GMP) standards; to support this effort, the NML and the Canadian Food Inspection Agency (CFIA) are collaborating with the University of Saskatchewan's VIDO-InterVac and with the National Research Council to develop and test vaccine candidates against COVID-19; and,
 - National Research Council (NRC): to upgrade the Human Health Therapeutics Research Centre in Montreal to meet GMP standards. This biomanufacturing facility will be available to produce clinical trial lots as soon as vaccine candidates become available, beginning as early as late spring 2020.
- Health Canada is also working with vaccine developers and manufacturers to help expedite the assessment of vaccines to prevent COVID-19. This includes supporting clinical trials and preparing for expedited reviews, once they are developed.
- The Government of Canada will continue working with international health product regulators—including the European Medicines Agency, the United States Food and Drug Administration, Australia, Canada, Singapore and Switzerland partners, and other organizations such as the International Coalition of Medicines Regulatory Authorities and the World Health Organization (WHO)—to support and coordinate rapid regulatory responses for potential vaccines and other medical countermeasures.
- The NRC is also working with a number of companies in the development of vaccine candidates.
- Canada is participating in the SOLIDARITY trial—a multinational trial coordinated by the WHO that is testing multiple potential drugs for the fight against COVID-19. The Canadian arm of this study has already begun enrolling patients. This global trial plans to recruit up to 20 sites across Canada.



- This unprecedented mega-trial to test potential treatments for COVID-19 is truly a new model for global collaboration, with the goal of being able to quickly identify treatments that could reduce the toll of COVID-19.

Working with industry to advance research and bring innovative products to market

- The Government of Canada is also working with industry to support research and manufacturing capabilities through Innovation, Science and Economic Development Canada and the National Research Council of Canada.
- This includes funding to develop patient monitoring systems and home diagnostic kits.
- The Government of Canada is also providing funding to help Canadian small and medium-sized businesses to increase their capacity to innovate and take ideas to market, including manufacturing personal protective equipment and sanitation products.

Collaboration with the global research community

- The Government of Canada is also connected to the global research effort to respond to COVID-19, working with international partners, including the WHO through its Collaborating Centres and Blueprint R&D Initiative, to coordinate efforts and share research data and findings to collectively build knowledge around the world.
- Some examples include collaboration between the Canadian Food Inspection Agency (CFIA), Defence Research and Development Canada (DRDC) and PHAC to establish the Biosafety Level 4 Zoonotic Disease Network (BSL4ZNet).
- This network consists of 15 government organizations from five countries (Canada, the US, the UK, Germany and Australia), each with a responsibility over the regulation of human, animal and zoonotic pathogens with pandemic potential.
- The BSL4Znet has been conducting COVID-19 emergency meetings since early January with international partners to facilitate the sharing of scientific information and research capacity needs to enhance global efforts to respond to the spread of COVID-19.
- PHAC and DRDC are also members of the Medical Countermeasures Consortium, in partnership with the Department of National Defence, where they engage with the US, the UK and Australian governments to promote collaboration in research, development and acquisition.
- GAC, NRC, PHAC and CFIA regularly engage with the Coalition for Epidemic Preparedness and Innovation (CEPI), which is a key international funding mechanism for vaccine development. Canada has provided \$54 million to CEPI, which is leading efforts to have COVID-19 vaccine candidates ready for clinical trials by late spring 2020.
- CIHR's response to the COVID-19 pandemic is being informed by international partners, including the WHO and the Global Research Collaboration for Infectious Disease Preparedness (Glo-PID-R).
- CIHR, in partnership with PHAC, is leveraging the existing Canadian Immunization Research Network (CIRN) to address the COVID-19 pandemic. CIRN has received \$1 million through a direct grant to gather data related to COVID-19 symptoms, as well as possible treatments and risk factors, which will inform Canada's public health response to COVID-19.
- Health Canada is engaged with other international regulators to monitor any impacts on global supply as a member of the International Pharmaceutical Regulators Programme.

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National Microbiology Laboratory scientists conduct research to develop COVID-19 vaccine

- While no vaccine currently exists for COVID-19, global efforts are underway to develop a COVID-19 vaccine and work is progressing at an unprecedented pace through significant investments in every stage of the vaccine development cycle.
- Scientists at the Public Health Agency of Canada's (PHAC) National Microbiology Laboratory (NML) are conducting research to develop in-house vaccine candidates, as well as assisting external collaborators in evaluating candidates developed by academia and industry.
- NML scientists are researching a variety of different approaches and have at least 10 separate projects currently underway, with more in the planning stages.
- NML scientists are world leaders in vaccine research. They developed the lifesaving ERVEBO Ebola vaccine—the first approved vaccine to protect against one of the world's most deadly diseases.
- The Government of Canada has made significant investments in science and research related to COVID-19. Our scientists are working diligently to find a vaccine to protect Canadians and the global community from COVID-19.

How do vaccines work?

- A vaccine is usually a pre-exposure measure that is used to prevent a virus or bacteria from infecting an individual. Vaccines contain antigens, which are harmless substances associated with the bacteria or virus. When these antigens are injected into the human body, they trigger the body's natural immune response to protect an individual against the disease.
- In certain circumstances, vaccines can be used immediately post exposure to a virus or bacteria to stimulate an immune response before the infection becomes established in the body.

NATIONAL MICROBIOLOGY LABORATORY

- The NML employs some of the best vaccine researchers in Canada and the world.
- The NML houses the country's only Level 4 laboratories for human health. These state-of-the-art laboratories are essential for developing vaccines to protect against infectious disease threats like Ebola and other highly infectious respiratory pathogens, such as COVID-19.
- The NML has unique capacity to conduct pre-clinical research in animal models to ensure that vaccine candidates are of high quality, safe and effective.

TYPES OF VACCINES

- The NML is creating vaccines that can be grouped into five main categories:

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- **Live replicating viruses** that would not normally cause infection in humans to act as the delivery system for the vaccine. This is the same approach used for creating the Ebola vaccine.
- **Replication-deficient viruses** are viruses that cause mild illness in humans, but the vaccine is manipulated so as not to cause illness in humans. This is the same approach used for the small pox vaccine.
- **Incremental doses of live virus**, which is an innovative approach using small incremental amounts of the live SARS-CoV-2 virus to stimulate an immune response in individuals without causing disease.
- **Nucleic acid-based vaccines**, such as DNA vaccines that contain the genetic codes for specific proteins (antigens) of viruses so that an immune response is triggered.
- **Protein-based vaccines** that use purified proteins from the virus as a vaccine. There are a number of different technologies that can be used to create these types of vaccines, which would allow for mass production and distribution.

LIVE REPLICATING VIRUS VACCINATION APPROACHES

- Live viruses provide a convenient method to deliver harmless components of the virus, also known as antigens, to select target cells or tissues to cause an immune response. Live viruses used for this type of approach often do not cause disease in humans that are exposed to the virus, such as the Ebola vaccine developed at the NML.
- NML scientists developed the ERVEBO Ebola vaccine by “changing the coat” of the virus. This is done by replacing a surface protein in an animal pathogen, called vesicular stomatitis virus, with a surface protein from Ebola. This results in a benign virus wearing the “Ebola coat”, allowing the immune system to target the Ebola virus glycoprotein without having to be infected with the natural Ebola virus. This has proven to be a game changer in the fight against Ebola.
- For COVID-19, NML researchers and collaborators are exploring three live replicating virus vaccine platforms, including ones using diseases commonly found in wild birds and domestic fowl.
- Some of these platforms are well established already for vaccine use, such as the vesicular stomatitis virus vaccine platform, while others like Newcastle Disease virus platform are more experimental but show good promise.

REPLICATION DEFICIENT VIRUS APPROACHES

- An innovative approach to developing vaccines is to use other human viruses that have been re-engineered so they are defective and cannot replicate and cause human infections. Scientists then manipulate the vaccine to include antigens for SARS-CoV-2 to cause an immune response to protect against COVID-19.
- NML scientists are exploring several replication deficient viruses using adeno virus, adeno-associated viruses, and poxvirus platforms.
 - **Adenoviruses** are a family of small DNA viruses that cause a variety of diseases in humans. They have been used in vaccine development since the late 1980s. They are relatively safe, well tolerated, and easy to manufacture.

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- **Ad5-nCoV** is an adenovirus-based vaccine. With this vaccine, the gene encoding the SARS-CoV-2 spike protein is added to an adenovirus (one of the types of viruses that cause the common cold) that's been genetically modified so it does not make you sick. The aim of this approach is that, following intramuscular injection, the viral spike protein should be produced and our immune system should recognize this foreign protein and begin manufacturing antibodies to protect against a COVID-19 infection.
- **Adeno-associated viruses** are non-replicating viruses, meaning they enter a cell once but then cannot make more copies. NML scientists are exploring if they are capable of delivering components of the SARS-CoV-2 virus to stimulate the immune system and provide protection. Vaccines created using this approach are generally well tolerated and safe. NML scientists are currently testing vaccines using this approach on animal models.
- NML researchers have developed a vaccine to protect against COVID-19 based on **recombinant pox vaccinia virus**, which is the same platform used in the small pox vaccine. NML researchers reformulated the small pox vaccine to make it safer and better able to induce an immune response.

INCREMENTAL DOSES OF LIVE VIRUS

- Scientists at the NML are working on developing a vaccine using a novel innovative approach using small, incremental amounts of live SARS-CoV-2 virus as a protective vaccine.
- Scientists are exploring if a very small amount of the virus that will not cause infection can kick start the immune system to provide long-lasting immunity and protection from COVID-19.

NUCLEIC ACID-BASED VACCINES

- The field of DNA vaccines is a new rapidly developing approach that shows promising results.
- With this approach, a key portion of the genetic sequence from the SARS-CoV-2 spike protein is injected. The body creates the spike protein and allows the immune system to respond to the virus protein to get rid of it. This approach is considered safe as it does not use live viruses, only genetic data to create a vaccine and should be easy to mass-produce if effective.

PROTEIN-BASED VACCINES

- Protein-based vaccines are one of the most well established approaches to vaccine development. They are easy to produce and safe as they do not use live viruses to provide protection.
- Common vaccines, such as the human papillomavirus and pertussis are protein-based vaccines.
- NML scientists, in collaboration with scientists from the Canadian Food Inspection Agency, are producing a vaccine for SARS-CoV-2 that uses an engineered spike protein from the virus that

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is expressed in and purified from insect cells. The purified spike protein will be used to hopefully trigger an immune response that should provide protection against infection.

VACCINE DEVELOPMENT

- Vaccines typically take several years to develop because they are complex products that require significant investment.
- There are several steps in the development process of vaccines that can fail once a candidate vaccine is identified, such as vaccine efficacy in animal models, preclinical safety, clinical safety and efficacy in people, and the feasibility of manufacturing to a large enough scale to supply the market.
- At present, there are more than 100 COVID-19 candidate vaccines globally at different stages of development by academia and industry, with about 10 in clinical evaluation. At this time, it is not possible to determine which one(s) will be successful in preventing COVID-19 infection.
- Determining the efficacy of a vaccine candidate is a lengthy process.
 - First, animal trials are run to determine if a vaccine is effective in animals. With that knowledge, researchers are able to determine the type of administration or delivery required to generate an immune response.
 - Next, a series of challenge tests are run against various new strains of the virus from across the globe.
 - Then, clinical trials begin, which on average take at least six months. They involve three phases, which ensures efficacy and safety in a large cohort of people.
 - Following release, further monitoring is performed to ensure that there are no unforeseen, very rare issues that might arise (this is known as post-marketing surveillance or Phase 4).
- These important steps are one of the reasons vaccine development takes so long. As the virus evolves, we have to test the vaccine against several strains and wait for the immune response to it, on both animals and humans. All of this is done to ensure vaccines are not only effective, but also safe and not toxic.

Russia's "Gam-COVID-Vac" vaccine, also known as the "Sputnik five" vaccine

- Health Canada is aware that the "Gam-COVID-Vac," also known as the "Sputnik five" vaccine, was granted marketing authorization by the Ministry of Health of the Russian Federation on August 11, 2020.
- Researchers and regulators around the world are waiting for more information on this vaccine to be released before it can be fully evaluated.
- According to information in the public domain, such as the clinicaltrials.gov registry, this vaccine appears to be in the early phases of clinical testing, and has not reached a Phase 3 clinical trial. A Phase 3 trial, where a vaccine is given to thousands of people to assess safety and effectiveness, is typically required before a new vaccine can be approved.

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- Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to ensure authorized vaccines are safe, of high quality and are effective at protecting against the diseases they target.
- Health Canada is working closely with other international regulators and the World Health Organisation to share information about potential COVID-19 vaccines. The Department will use all available data to make regulatory decisions about product approvals in Canada.

ANIMAL MODELS

- Our primary responsibility is the health and safety of Canadians—we cannot endanger human life with untested vaccines or medications.
- NML researchers are world leaders when it comes to developing animal models necessary for conducting pre-clinical research. It is important to test novel vaccines in an animal model before starting human clinical trials.
- Our scientists have developed animal models that can be used to study how viruses cause disease, as well as to evaluate vaccines and antiviral drugs that can be used to prevent and treat disease.
- Having an animal model that exhibits a similar course of illness that is seen in humans is one of the most valuable tools scientists use to test vaccines and antivirals before they are tested in humans.
- Our scientists have demonstrated that certain small animals, such as mice and hamsters can serve as reasonable, although not perfect models for many human diseases, including high consequence pathogens like SARS-CoV-2.
- Smaller animals, such as mice and hamsters are always used first to prove efficacy of any treatment or vaccine. However, research requirements at times necessitate the use of non-human primates prior to human clinical trials.
- Countless medical treatments and advancements have been made possible by animal testing. This includes insulin for diabetes, the polio vaccine, coronary surgery as well as a range of antibiotics.

COVID-19 Animal summary table

- The Public Health Agency of Canada (PHAC) continues to track and analyze research and case reports from around the world on COVID-19 and animals.
- The summary table, now posted on the canada.ca/coronavirus web page, provides a snapshot of the current research on animals and COVID-19 from sources outside the Government of Canada. It will be updated as more evidence becomes available, including studies currently underway at Government of Canada research facilities.
- It is important to remember that, while some animal species can become infected with COVID-19, this pandemic is being driven by human-to-human transmission.

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- Information is still limited with respect to animals and COVID-19; however, research in this area provides insights that are important for public health decision-making concerning livestock, wildlife and pets.
- Animal studies on COVID-19 provide us with important information on how the virus functions. Knowledge gained through animal models is a critical element for safely developing treatments and vaccines to protect Canadians from COVID-19.
- While there is evidence that some common pets, such as cats, dogs and hamsters, can become infected by COVID-19, generally any illness in these species is mild.
- To date, there is no evidence to show that common pets, such as cats, dogs and hamsters, have transmitted the virus that causes COVID-19 back to humans.
- PHAC's advice around pets remains unchanged. Unless you have symptoms of COVID-19 or have come into contact with somebody who does, you do not need to do anything differently in relation to your pets. If you do have COVID-19 symptoms or are self-isolating because of contact with a COVID-19 case, take the following precautions:
 - Avoid close contact with animals.
 - Practise good hygiene.
 - If possible, have another member of your household care for your animals.
 - Restrict your animal's contact with other people and animals outside the household.
- The data so far show that livestock, such as pigs, chickens and ducks, are not susceptible to COVID-19. The susceptibility of other livestock species is an area that continues to be studied by researchers, including the Canadian Food Inspection Agency. Results will be shared when available.

Research Study on Deer Mice Susceptibility to COVID-19

- New information on COVID-19 emerges every day. Researchers and scientists in Canada and around the world are working hard to better understand the virus, and its impacts on people and communities.
- Scientists from the Public Health Agency of Canada's National Microbiology Laboratory (NML) have conducted research and confirmed that deer mice are a suitable animal model for COVID-19. This is a very important discovery to help advance the development of COVID-19 vaccines and treatments and to help scientists study how the virus causes disease in animals and humans.
- NML scientists found that deer mice can become infected with SARS-CoV-2 and transmit the virus to other deer mice when they are housed together.
- Scientists also found that infected deer mice were either asymptomatic or developed mild illness. This seems to model human illness, where the majority of exposed humans do not develop severe symptoms with COVID-19.

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- This research took place in laboratory settings. More research is required to understand the susceptibility and impact of SARS-CoV-2 on wild deer mice populations.
- While more research on its exact origin is required, scientists believe the virus originated in bats. It is important for scientists to determine what other types of animals, including wild animals, are susceptible to SARS-CoV-2.
- The evidence gained through this research study will help scientists understand which animals may be susceptible to COVID-19.
- Understanding potential “natural reservoirs” where the virus may circulate is also a very important discovery so that scientists can monitor these populations for potential future spread.
- The scientific knowledge gained through this research project is evidence we are learning critical information about the virus that causes COVID-19.

Accusations of PHAC Retaliation at HESA

- The Public Health Agency of Canada is committed to working with partners and supports its scientists in conducting research and providing Canadians with the best scientific information possible.
- We welcome diverse perspectives and encourage respectful debate to challenge and improve scientific knowledge and understanding.
- PHAC scientists evaluate their contributions and role on research teams in light of their expertise and in alignment with PHAC priorities.
- PHAC is committed to the independence of this decision-making in the interest of optimizing scientific productivity.

If pressed...

- PHAC respects the role of external principal investigators in assembling their research teams.

In this instance, the decision to withdraw from the research team was made by the PHAC scientist. The Chief Public Health Officer and the PHAC President were not aware of and were not involved in any of the discussions related to the grant application.

COVID-19 wastewater surveillance research projects

- Detecting the COVID-19 virus by testing samples of wastewater can provide an early warning of the presence of this infection in communities.
- Infected individuals shed the virus through stool, and testing wastewater can alert a community to the presence of the virus that causes COVID-19 or provide early warning of a resurgence.



- Some studies suggest that early detection of the virus causing COVID-19 in wastewater may provide a 5-10-day warning before there are a large number of cases in the community, allowing for important intervention opportunities to try to stop further spread.
- A COVID-19 wastewater surveillance initiative is underway to collect and test sewage samples in First Nations, Northern and remote communities in addition to wastewater leaving hospitals and large cities.
- Scientists from the Public Health Agency of Canada, Environment and Climate Change Canada, Indigenous Services Canada, and Statistics Canada are working together to lay the foundation for community-wide surveillance program in various locations across the country.
- Evidence gained through the wastewater initiative will inform public health interventions for the ongoing management of COVID-19.

If pressed on specifics of the surveillance system:

- Participation in the initiative begins with the consent of municipalities who submit wastewater for testing and have ownership over the results.
- Work will be conducted in collaboration with and for the benefit of the communities/local health authorities to inform public health action.
- The initiative provides an alert to public health officials on a community-wide scale using large batches of collected samples to detect where COVID-19 may be spreading.
- Samples collected from sites across Canada will be sent to the Public Health Agency of Canada's (PHAC) National Microbiology Laboratory (NML) in Winnipeg for laboratory analysis and detection of the virus that causes COVID-19.
- Results will be shared with the local health authorities in the respective jurisdictions so appropriate public health measures can be taken if necessary.

If pressed on what communities are being targeted for the surveillance program:

- Negotiations are underway to determine which cities will be part of the wastewater initiative. Additional cities will be included as the program grows and expands.
- PHAC and ISC will be engaging with First Nations leadership to identify First Nation communities that may be willing and able to collaborate in the initiative.

If pressed on the metagenomics study:

- NML scientists are developing a metagenomics approach to detect the virus that causes COVID-19 in wastewater. Metagenomics is a cutting-edge approach used to study infectious diseases.
- This research will provide critical evidence to inform public health measures both in Canada and around the world in controlling COVID-19 and easing public health restrictions.

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- This COVID-19 metagenomics approach will not only identify the virus, it will also provide the genetic sequence so scientists can study how the virus is adapting and evolving. The sequences will be uploaded to the [GISAID database](#), allowing for rapid sharing of COVID-19 genetic information so scientists from around the world can track how the virus is genetically evolving.
- As part of this research effort, scientists will survey wastewater samples from treatment plants in Winnipeg, Guelph and Quebec City, as well as from hospitals in Quebec City.
- This is another example of NML scientists using emerging scientific approaches to study COVID-19.

Vaccination Schedules during COVID-19

- Vaccination is one of the most effective ways to prevent the spread of infectious diseases.
- Although public health is a shared responsibility in Canada, matters related to vaccination programs fall under provincial and territorial jurisdiction.
- Canadians should contact their health care provider or public health authority to see whether there have been any revisions to their or their family's recommended vaccination schedule as a result of the COVID-19 pandemic.
- Given the current pandemic, it is normal to feel concerned about visiting a doctor's office or clinic for routine appointments such as vaccinations.
- Canadians should consult with their health care provider or public health authority to:
 - find out whether there have been any revisions to their or their family's; recommended vaccination schedule as a result of the COVID-19 pandemic
 - determine when they should visit, and;
 - learn about the measures that have been put in place to safely deliver vaccination services during COVID-19.
- Health care providers have precautions in place to prevent the spread of infection during office visits. These precautions can include:
 - screening patients for symptoms or other risk factors before the appointment and upon arrival;
 - posting signage at the office;
 - encouraging patients to use alcohol-based or non-alcohol based hand sanitizer approved by Health Canada;
 - providing masks to patients upon arrival; and
 - staggering appointments to ensure physical distancing in the office.

Mandatory COVID-19 Vaccination



- Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to ensure vaccines are well supported by evidence to establish their safety and effectiveness in preventing the diseases they target. As well, there is a surveillance system in place to detect adverse events following immunization.
- The Government of Canada is committed to vaccination as a safe and effective public health measure that prevents disease and disability.
- Although vaccine recommendations are made at the federal level, the primary responsibility for matters related to the administration and delivery of vaccination programs falls within provincial/territorial jurisdiction.
- Some provinces and territories require mandatory reporting of vaccinations, where parents are required to submit their children's vaccination records to local public health units. This is to increase the ability of public health officials' to respond during an outbreak and to monitor the effectiveness of immunization programs.
- The National Advisory Committee on Immunization (NACI), an independent external advisory body to the Public Health Agency of Canada, makes recommendations for the use of vaccines currently or newly approved for use in humans in Canada, including the identification of groups at risk for vaccine-preventable diseases for whom vaccination should be targeted.
- NACI's recommendations will help inform the provinces and territories in making decisions around how to roll out a vaccine program once Canada has access to a safe and effective COVID-19 vaccine.

If pressed on mandatory vaccinations for school-aged children:

- None of Canada's provinces or territories currently have a policy of mandatory vaccination policies for any disease. In fact, mandatory vaccination has never been an approach used in Canada. However, some provinces (e.g. Ontario, British Columbia and New Brunswick) have legislation requiring showing proof of vaccination for children attending school or daycare with exemptions for medical, conscious and/or religious reasons.

Fluzone High Dose (HD) in Long-term Care Facilities during COVID-19

- Vaccination is one of the most effective ways to prevent the spread of infectious diseases, including influenza.
- The Government of Canada is preparing for the next flu season in the fall given the pressures on the health care system that are expected due to COVID-19.
- With the likelihood that we'll experience outbreaks of both COVID-19 and influenza in the fall, we want to put measures in place to protect seniors living in long-term care facilities. Outbreaks of COVID-19 in long-term care facilities have been devastating and we need to do everything we can to protect residents and staff.
- Fluzone High Dose is a special influenza vaccine for seniors aged 65 and older that stimulates the immune system more than some standard-dose vaccines.

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- Fluzone High Dose provides better protection and a stronger immune response than some standard dose vaccines for people in this age group, who are also among the people at greatest risk of complications and hospitalization from seasonal flu.
- For the 2020 flu season, the Government of Canada is purchasing Fluzone High Dose in sufficient quantity for **all** provincial and territorial **long term care residents aged 65 years and older**.

Public Health Ethics Framework: A Guide for Use in Response to the COVID-19 Epidemic in Canada

- Public health decision-makers are facing tough choices every day as they respond to the COVID-19 pandemic.
- Ethical considerations are a key factor in public health decision-making.
- That is why the Public Health Agency of Canada has developed an ethics framework to assist policy makers and public health professionals in making tough decisions in the context of COVID-19.
- The ethics framework includes a step-by-step process for guiding decisions that are:
 - grounded in evidence;
 - guided by core ethical values and principles; and
 - fair and equitable.
- The framework presents a series of questions that public health decision-makers should ask themselves as they weigh the pros and cons of any course of action, especially when competing values and interests have to be taken into account.
- The framework underscores the importance of treating people and groups equitably, which does not mean treating everybody the same. Ethical decision-making must take into account the harm that may be caused by any course of action, taking particular care not to increase existing inequalities.

Guidance

Public health management of cases and contacts associated with COVID-19

- The Public Health Agency of Canada (PHAC), in collaboration with provincial and territorial public health authorities, has updated its guidance to support the management and monitoring of cases and contacts of COVID-19 within jurisdictions.
- We recognize the impact that COVID-19 has on Canadians needing to isolate or self-isolate. These updates reflect psychosocial, economic and cultural considerations of isolation and self-isolation.

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- Additional criteria have been added for discontinuing home isolation for symptomatic and asymptomatic cases.
- As business and schools reopen thereby increasing the number of people we may come into contact with, cases will continue to be detected.
- This guidance emphasizes that jurisdictions need to take a strategic approach to lifting restrictive public health measures based on local circumstances and health system capacity.
- Provinces and territories need to quickly test, identify and isolate all cases, and trace and quarantine all contacts as soon as possible after exposure to decrease the likelihood of further spread
- To successfully implement public health measures, public health authorities should also consider the health, disability, economic, social, or other circumstances faced by some individuals and households that may limit their ability to follow the recommended measures.
- As there is currently no safe and effective vaccine or treatment for COVID-19 available at this time, both personal and community level public health measures remain essential to prevent the spread of infection.
- This guidance is informed by the latest available scientific evidence, epidemiology and expert opinion, and is subject to change as new information becomes available. This guidance should be read in conjunction with relevant provincial, territorial and local legislation, regulations and policies.

COVID-19 Antigen, Rapid Point-of-Care, Saliva and At-Home Test Kits, including Abbott

- The Government of Canada understands the importance of increasing testing capacity as early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada. This is why Health Canada has prioritized the review of all types of COVID-19 tests, including new, innovative testing options and technologies.
- Health Canada is taking all steps available to us as a regulator to give Canadians and our health system access to as many testing options as possible, as quickly as we can, without compromising safety.
- Health Canada is closely monitoring new technology, and when we hear of promising new tests that are not yet available in Canada, we proactively reach out to manufacturers to seek their interest in entering the Canadian market.
- Furthermore, the Government of Canada is providing \$4.28 billion to support provinces and territories with the costs of increasing their capacity to conduct testing, perform contact tracing, and share public health data that will help fight the pandemic. The goal is to ensure provinces and territories have the capacity to test up to 200,000 people per day, nationwide.

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- The health and safety of Canadians is the Government's utmost priority. Before any test is authorized for use in Canada, it is subject to a thorough assessment through Health Canada's regulatory process to ensure it is supported by sufficient evidence of safety, effectiveness and quality.
- Canada has one of the best regulatory systems in the world for medical devices. Health Canada takes steps to ensure that the applicable safety, effectiveness and quality requirements are met for medical devices prior to issuing an authorization.
- Health Canada is currently reviewing submissions for point-of-care rapid tests, and will prioritize new and innovative testing options such as other rapid tests and home tests.
- Health Canada is working as quickly as possible toward the approval of rapid, point-of-care diagnostic and monitoring tests based on nucleic acid and antigen technologies in order to meet Canadian testing needs without compromising Canadians' safety.
- The Government of Canada works proactively with companies that are developing innovative and new testing technologies in Canada and globally.
- You will find more information about testing here.

If asked about Abbott tests:

- The Abbott ID NOW COVID-19 test kit, which is the size of a toaster, can provide results within 13 minutes. Testing can take place in a variety of locations, such as medical clinics and nursing stations.
- Scientists at the NML are working closely with other federal, provincial and territorial partners to optimize point-of-care testing supplies and determine a national distribution strategy that will have the most benefit for Canadians.
- Once the devices are approved by Health Canada, the NML will provide training to support these testing devices. The NML will work with partners in the provinces and territories to verify the performance of the tests and provide best practice guidance on the use of these instruments.
- The NML offers ongoing support and technical advice for those using point-of-care devices in Canada. Part of this support is a robust quality assurance program to ensure that the devices are providing reliable results on a consistent basis.

If asked about other rapid test kits:

- On September 23, 2020, Health Canada authorized the *Hyris Global Diagnostics Kit* for point-of-care use.
- This point-of-care test should only be carried out by a trained health care professional.
- To date, Health Canada has authorized 36 COVID-19 testing devices for sale in Canada. A

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complete list of testing devices authorized by Health Canada is available at:
<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html>

If asked about point-of-care tests

- The Public Health Agency of Canada's (PHAC) National Microbiology Laboratory (NML) is working in collaboration with provincial and territorial public health laboratories to ensure high-quality diagnostic testing for COVID-19.
- Point-of-care diagnostic devices allow testing to occur in alternative healthcare settings and do not require shipping a specimen to a lab for analysis. This allows for quicker test results for patients.
- Quicker test results enable healthcare providers and patients to take appropriate actions, such as treating, contact tracing and isolating positive patients more rapidly to help reduce the spread of the disease.
- Point-of-care testing is essential for northern, remote and isolated communities, as well as specific high-risk settings where it is important to have test results quickly without having to send samples to a laboratory.
- Deploying diagnostic testing at the community level, especially in northern and isolated communities, will help address the testing gaps in underserved communities where laboratory testing is difficult to access.
- Health Canada authorizes point-of-care tests after completing a scientific review that is supported by evidence to ensure that the tests will provide accurate and reliable results. The NML and its provincial partners often contribute by assessing tests and sharing test results with Health Canada.
- A complete list of testing devices for use against COVID-19 is available on Health Canada's website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html>.

If asked about antigen tests:

- Antigen tests are used to diagnose COVID-19 by detecting specific proteins on the surface of the virus.
- On September 29, Health Canada published [information](#) for industry on the minimum sensitivity requirements that must be met when seeking authorization for COVID-19 antigen tests. Sensitivity is a measure of the diagnostic accuracy of a test.
- Health Canada is advising industry that they must provide evidence that clearly demonstrates that their antigen test meets a minimum standard of 80% sensitivity before it can be approved, so that the tests produce reliable results.

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- Health Canada welcomes new technology and will prioritize applications for all types of test kits. Only tests that are proven to perform accurately and reliably will be authorized.

If asked about the British Columbia’s “swish and spit” lab tests:

- “Swish and spit” is a new method of sample collection that has been developed by provincial health authorities and will be used in British Columbia as an alternative to the nasal swab, especially for collecting samples from children.
- Swish and spit samples are collected by rinsing a salt-water solution in your mouth and spitting the water mixed with your saliva into a cup.
- The “swish and spit” testing *process* is considered a lab-developed method, and is not subject to Health Canada oversight under the authority of the *Food and Drugs Act*.
- The sample *collection device* itself (i.e., the funnel in which the swish and spit sample is collected) is a Class I medical device that can be imported or sold under the authority of a Medical Device Establishment Licence, which is authorized by Health Canada.
- Health Canada and the Public Health Agency of Canada welcome all new technologies that will help in the fight against COVID-19 and reduce its impact on Canadians.

If asked about encouraging new device authorizations in Canada:

- Health Canada is actively engaging with manufacturers developing innovative and new testing technologies in Canada and abroad.
- Health Canada provides guidance on the regulatory process, and assists companies with their device submissions to help ensure that they submit the right information to be authorized promptly giving Canadians greater access to the tools they need in the fight of COVID-19.
- Health Canada also regularly contacts manufacturers who have obtained an authorization from another jurisdiction to encourage them to file a submission with Health Canada.

If asked about sharing information about new device authorizations:

- Health Canada continually updates and posts new information on its website. For example, the Department recently provided updated information on [home testing](#), and signalled that we welcome applications for all testing solutions.

Supplementary messages:

- We are committed to providing Canadians access to the tools they need to fight the spread of COVID-19 in Canada.
- Early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada.
- Health Canada is taking all steps available to us as a regulator to give Canadians and our health system access to as many testing options as possible, as quickly as we can, without compromising safety.

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- To date, Health Canada has authorized 36 COVID-19 testing devices for sale in Canada. A complete list of testing devices authorized by Health Canada is available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html>.
- Health Canada's consistent approach throughout the pandemic has ensured that the testing devices available for sale in Canada have been accurate and reliable, and we have avoided some of the challenges other countries have experienced with lower-quality tests.
- Health Canada is committed to ensuring that tests are safe and effective while working as quickly as possible to authorize testing technologies.
- The Minister of Health has provided authority that allows for faster access to tests for COVID-19 without compromising the quality, safety and efficacy of the device ([Interim order respecting the importation and sale of medical devices for use in relation to COVID-19](#)).

If asked about saliva tests:

- As of September 14, 2020, Health Canada has received two applications for saliva tests using saliva (spit) but not the "swish and spit" process which includes a saline rinse.
- Saliva test applications have been prioritized and are currently under review.

If pressed on the authorization of Spartan test kits:

- Health Canada continues to work with Spartan Bioscience Inc. in its efforts to produce the evidence that demonstrates its product functions appropriately.
- Health Canada has provided regulatory guidance to Spartan Bioscience Inc. relating to the completion of clinical trials on its testing device and will prioritize the review of its application for authorization when it is received.

If asked about the U.S. Food and Drug Administration's approval of at-home sample collection

- Health Canada has not yet received any applications for at-home test kits, or to collect samples at home and mail them in for evaluation.
- Health Canada is aware that the U.S. Food and Drug Administration (FDA) approved the COVID-19 RT-PCR Test for which the collection of a fluid sample is done at home.
- The swab is collected at home and then sent to a laboratory for testing. The swabs are subject to strict transportation requirements.
- Canada and the U.S. have different rules and approval processes. Each regulator reviews applications against different criteria or requirements that reflect the needs of their health care systems.



- Health Canada's consistent approach throughout the pandemic has ensured that the testing devices available for sale in Canada have been accurate and reliable, and we have avoided some of the challenges other countries have experienced with lower-quality tests.
- Other international regulators, including the U.S. FDA, have not approved complete at-home test kits for COVID-19.
- Health Canada is open to reviewing all innovative testing approaches as they become available.

If asked about the Health Canada's June 2020 notice on near-patient and point-of-care diagnostic tests:

- Health Canada posted guidance for industry to clarify its position on near-patient and point-of-care diagnostic tests in June 2020. At that time, the Department's position was in relation to the use of home tests for diagnostic purposes. In response to the evolution of the pandemic, Health Canada could now consider applications for self-collection and/or at-home test kits to enable individuals with or without symptoms who wish to assess and monitor their own infection status.
- Health Canada is open to reviewing all new testing solutions as they become available.

Specifics on the role of the NML

- NML is providing critical scientific leadership for Canada's response to COVID-19. This includes coordination with provincial and territorial governments and laboratories, as well as Indigenous Services Canada, to deploy point-of-care testing devices and supplies to rural and remote settings.
- NML scientists are exploring the best way to increase capacity of these devices through innovative testing approaches such as sample pooling.
- As of September 30, NML has conducted 40 remote and in-community training sessions for healthcare professionals who will be using the point-of-care devices.
- These training sessions provide valuable hands-on experience to those who will be operating the instruments.
- The NML offers ongoing support and technical advice for those using the devices. Part of this support is a robust quality assurance program to provide confirmation that the devices are providing reliable results on a consistent basis.
- NML has undertaken scientific studies of point-of-care diagnostic tests and supplies to support provincial laboratories in their decisions on adopting these tests for use in clinical settings. These studies are done in collaboration with provincial laboratories and clinical researchers to determine how well a test performs under actual clinical conditions. The test results are shared with Health Canada for consideration in the scientific review of applications for authorization under the Interim Order for Expedited Access to Medical Devices for COVID-19.

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- Results on the performance of diagnostic tests are shared with manufacturing companies, all provincial laboratories, and Health Canada to add to the evidence on the accuracy of diagnostic tests.
- NML's priorities continue to be accessing testing reagents, evaluating rapid point-of-care tests, and accessing authorized test kits to help ensure that provinces and territories are equipped to ramp up testing according to their requirements.

What is a point-of-care diagnostic test?

- Point-of-care diagnostic tests are done at the time and place of care, such as a hospital or a doctor's office, and do not require samples to be sent to another laboratory.
- Molecular point-of-care tests to detect active infections of COVID-19 are similar to the polymerase chain reaction (PCR) tests used in regular laboratories as they also use a swab to collect samples from the nose or throat.
- Samples are then loaded into an on-site point-of-care device—an automated diagnostic testing device that detects DNA sequences—such as a GeneXpert or Abbott ID NOW instruments. For GeneXpert, the test results are ready in 30-60 minutes. For Abbott ID NOW, the test results are ready in 13 minutes. A laboratory professional is not needed to perform the test.
- Point-of-care technologies provide an innovative approach to accessing diagnostic testing services for communities and populations that experience challenges with conventional laboratory methods.

On availability of COVID-19 point-of-care testing equipment and supplies

- Scientists at the NML are exploring the best way to optimize point-of-care testing supplies and determine a national distribution strategy to meet the needs of those most at risk.
- PHAC is committed to continuing to provide a supply of COVID-19 tests to provinces and territories on an ongoing basis. The current allotment of point-of-care test devices and reagents remains limited, as there is a global shortage of these supplies.
- Once PHAC receives an increase in devices and test cartridges and the necessary supplies become available, phased expansion of point-of-care testing can be considered.

On Sample Pooling

- Sample pooling is a diagnostic approach that involves grouping of samples in batches before running them through testing machines. If a negative result is received for the batch, laboratory professionals can rule out all the samples as having tested negative. If the batch tests positive, each sample is tested individually to determine the positive(s).
- Sample pooling is an approach used to increase throughput and conserve laboratory supplies. The challenge is to ensure that results are still accurate (i.e., specific and sensitive). Laboratory professionals must conduct research studies to confirm accurate results before sample pooling is implemented.

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- NML scientists have conducted research studies and have verified that pooling laboratory specimens for point-of-care devices used in remote and clinical settings provides accurate results. This is a very important discovery as there is a global shortage of laboratory supplies for these devices and pooling will help extend resources.

On specific deployment plans

- As of September 30, the NML has deployed 105 testing devices and over 34,000 COVID-19 tests for use across Northern, remote, and Indigenous communities.
- The devices are being deployed based on a needs analysis—in coordination with provinces and territories and Indigenous Services Canada—to get devices to communities that are at greatest risk if there were to be an outbreak of COVID-19.
- The risk is assessed based on remoteness, proximity to centralized laboratories, and logistical challenges with transporting samples due to weather and frequency of flights. Risk assessments are also based on the demographic of community members for those at greatest risk of COVID-19 complications.

On Devices in Northwest Territories

- As of June 8, PHAC has provided two GeneXpert Quad point-of-care testing devices and one 16-channel GeneXpert testing device to the Northwest Territories (NWT), along with a supply of test cartridges (160 tests) for COVID-19.
- PHAC is committed to continuing to provide a supply of COVID-19 tests to NWT on an ongoing basis. The current allotment from the company to PHAC remains limited, as there is a global shortage of point-of-care testing supplies. PHAC maintains a regular dialogue with NWT, and the other provinces and territories, regarding their testing needs and practices.

Guidance on Continuing Immunization Programs during COVID-19

- The COVID-19 pandemic reminds us of the crucial role that vaccines have in creating immunity—particularly for infants and toddlers. Vaccination is one of the most effective ways to prevent the spread of infectious diseases.
- The Public Health Agency of Canada (PHAC), in consultation with the National Advisory Committee on Immunization and the Canadian Immunization Committee, has released interim guidance on continuing immunization programs during COVID-19.
- Keeping our vaccinations up to date is an important way Canadians can help protect themselves and vulnerable people, as well as help reduce the burden on Canada's healthcare system during this unprecedented time.
- Delaying vaccines against serious diseases could leave your child, your family and people with weakened immune systems at risk of catching other serious diseases.
- We anticipate there could be a decrease in vaccination coverage due to vaccine providers responding to COVID-19 activities and the temporary closure of primary care offices to facilitate

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physical distancing.

- We know that keeping up to date with vaccines may not be possible for everyone given the current circumstances. However, we are asking Canadians to do their best to keep their vaccines up to date and to seek out open vaccination clinics.
- Canadians should consult with their healthcare provider to determine when they should visit, and learn about the measures that they have put in place to safely deliver vaccination services during COVID-19.
- Symptomatic individuals and those with suspected, probable or confirmed COVID-19, as well as people who are close contacts of a case, should not attend scheduled immunization appointments during their period of isolation.
- PHAC advises vaccine providers that if capacity is not sufficient to maintain all routine programs, emphasis should be put on the primary series and booster doses for children aged less than two years.
- A careful assessment of missed doses will be important to ensure that the pandemic does not leave a long-lasting immunization gap in any Canadian communities.
- PHAC's guidance on immunization programs during COVID-19 should be read in conjunction with current provincial and territorial policies on immunization during the pandemic.
- Given the current pandemic, it is normal to feel concerned about visiting a doctor's office or clinic for routine appointments such as vaccinations.
- Canadians should consult with their healthcare provider to:
 - find out whether there have been any revisions to their or their family's recommended vaccination schedule as a result of the COVID-19 pandemic;
 - determine when they should visit; and
 - learn about the measures that have been put in place to safely deliver vaccination services during COVID-19.
- As the COVID-19 pandemic progresses, vaccine providers should follow advice from their provincial and territorial governments and PHAC on when to relax physical distancing measures and other precautions in the context of the COVID-19 pandemic.

Additional guidance for people with disabilities in Canada

- We know some groups are significantly and disproportionately impacted by the COVID-19 epidemic, including persons with disabilities.
- The Public Health Agency of Canada (PHAC), in collaboration with the COVID-19 Disability Advisory Group, has identified considerations and accommodations that will be incorporated as part of the ongoing guidance for COVID-19 and people with disabilities and those who support and care for them.

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- This document complements other important guidance documents including the Infection Prevention and Control for COVID-19: Interim Guidance for Long Term Care Homes and the Infection Prevention and Control for COVID-19: Interim Guidance for Home Care Settings. These Infection Prevention and Control documents can be adapted to settings where people with disabilities reside.
- This document also contains considerations for health care providers and COVID-19 assessment centres, to adapt their approaches during the COVID-19 epidemic to support people with disabilities in accessing their services.

If pressed on the vulnerability of people with disabilities to COVID-19:

- Some people with disabilities might be at a higher risk of infection or severe illness because of their age, underlying medical conditions or their disability, which could put them at greater risk of being exposed and acquiring the infection.
- Some people with disabilities may face discrimination and barriers in accessing information, social services, and health care. The need for self-isolation and physical distancing may also create additional challenges.

Infection Prevention and Control Guidance for Acute Health Care Settings

- Protecting Canada's healthcare workers from COVID-19 infection is essential. These care providers are at the frontline of the pandemic and are looking after some of the most vulnerable Canadians.
- The Public Health Agency of Canada's (PHAC) infection prevention and control guidance complements provincial and territorial public health policies and procedures.
- PHAC's National Advisory Committee on Infection Prevention and Control, comprised of experts in this field and front-line care providers, worked with PHAC to develop this guidance.
- The F/P/T Special Advisory Committee on COVID-19 has endorsed the guidance and the technical brief.
- PHAC guidance is not mandatory. It should be read in conjunction with relevant provincial, territorial, and local legislation, regulations and policies.



Updated interim guidance on infection prevention and control in acute healthcare settings:

- This guidance was updated in line with our approach to keep guidance current and to ensure we provides comprehensive recommendations based on the best available evidence. The guidance emphasizes the need for environmental and administrative controls in facilities to protect healthcare workers and patients as well as the fundamental importance of training in the use of PPE.
- It indicates that droplet and contact precautions are appropriate for most patient care. Aerosol-generating medical procedures require N95 respirators along with other PPE.
- The guidance remains interim as it is subject to revision based on new scientific evidence.

Guidance for Infection Prevention and Control in outpatient and ambulatory care settings

- As a critical part of our health care system, outpatient and ambulatory care settings play a key role in preventing unnecessary hospital and long-term care admissions by supporting and caring for individuals in their facilities.
- The Public Health Agency of Canada is providing guidance to operators and staff of clinics, physician offices, community health centres and urgent care centres on how to prevent transmission of COVID-19.
- Infection prevention and control is an important part of the management of any outpatient and ambulatory care setting at all times, not just during COVID-19.
- The guidance reiterates the fundamentals of controlling the spread of infection, and emphasizes measures to be taken, in particular during the COVID-19 pandemic.
- This guidance is informed by the latest available scientific evidence and expert opinion, and is subject to change as new information becomes available.

Clinical Management of Patients with COVID-19 – 2nd Interim Guidance

- As a critical part of our health care system, doctors and healthcare providers play a key role in diagnosing, managing and treating COVID-19 infection among Canadians.
- The Public Health Agency of Canada (PHAC), in collaboration with the Association of Medical Microbiology and Infectious Disease and Canadian public health experts, has updated its guidance for health care professionals on the clinical management of patients with COVID-19.
- The updated guidance reflects the latest information and recommendations on the clinical care of patients with COVID-19.



- The updated guidance includes additional information on testing, the management of moderate COVID-19, and new information on potential COVID-19 treatments and clinical research.
- This guidance is informed by the latest available scientific evidence, epidemiology and expert opinion, and is subject to change as new information becomes available. This guidance should be read in conjunction with relevant provincial, territorial and local legislation, regulations and policies.
- Our understanding of the virus that causes COVID-19 continues to evolve. It is important that Canadians continue to help prevent the spread of COVID-19 by following public health guidance. Current guidance includes staying home if you are sick, physical distancing, wearing a non-medical mask or face covering when physical distancing is difficult, and regular hand washing.

Guidance for providers of services for people experiencing homelessness during the COVID-19 outbreak

- The Government of Canada recognizes the unique challenges that people experiencing homelessness can face during the COVID-19 outbreak in Canada.
- People experiencing homelessness may be at higher risk of contracting COVID-19 because their living conditions make it more difficult to practise physical distancing, effectively quarantine (self-isolate) and have access to facilities that would enable proper hand hygiene.
- People experiencing homelessness are also more likely to report pre-existing health conditions that make them more likely to experience health complications due to COVID-19.
- These realities and challenges need to be taken into account as we continue to respond to COVID-19. The Public Health Agency of Canada's updated guidance to service providers for people experiencing homelessness reflects the latest advice on preventing outbreaks. The updated guidance also acknowledges the challenges that are unique to implementing public health measures in this setting.
- The guidance has been updated to include the needs of marginalized and vulnerable populations within those experiencing homelessness, including people living with mental health conditions and substance use disorders, youth, Indigenous women and girls, and gender-diverse people.
- The guidance also contains additional recommendations for applying a trauma- and violence-informed approach when informing clients about public health recommendations, recognizing that many people experiencing homelessness have lived through trauma, which can be reactivated in uncertain or stressful situations.
- Staff and volunteers who work with people experiencing homelessness play a key role in preventing the spread of COVID-19 and protecting this vulnerable population.

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- It is necessary to ensure that the sector that serves people experiencing homelessness has the supports it needs to prepare for, and manage the impact of, COVID-19 on those experiencing homelessness.
- These guidelines aim to complement provincial, territorial and local public health guidance.

New technical brief guidance regarding masks and eye protection/ face shields, to be worn throughout shifts:

- PHAC recommends that all health care workers in acute care hospitals wear medical masks and eye protection/face shields for the full duration of a shift in acute healthcare settings.
- This recommendation is based on emerging evidence of asymptomatic and pre-symptomatic transmission of COVID-19 infection.
- Wearing a medical mask throughout the duration of a shift is an important measure to help reduce the risk of transmission from a health care worker to a patient.
- Wearing a medical mask and eye protection/face shield throughout the duration of a shift is an important measure to help reduce the risk of transmission from a patient to a healthcare worker.
- This recommendation applies to health care workers who are in direct contact with patients, as well as environmental services staff working in patient care areas.
- Another important measure to ensure COVID stays out of health care settings is the recommendation that any health care workers who have COVID-19-related symptoms should immediately go home and only return to work following the advice of their local public health units
- Health care workers should refer to their province or territory's guidance, as well as facility policies on the use of masks, eye protection, and other personal protective equipment (PPE), including any PPE conservation strategies that are in place.

Canada's supply of PPE and medical supplies:

- Health care workers need medical masks, including surgical masks, medical procedure masks, and respirators, such as N95 masks. It is extremely important to maintain the supply of medical masks where it is needed.
- The Government of Canada is working to ensure that health care workers have the PPE and medical supplies they need. We are doing this through collaborative bulk procurement with the provinces and territories, building domestic production capacity, and identifying potential alternatives and ways to extend product life.
- Canada is working to rapidly allocate PPE and medical supplies to the provinces and territories as per an approach agreed upon by federal, provincial and territorial Ministers of Health.

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Guidance and concerns from the Canadian Federation of Nurses Unions:

- We have engaged regularly with the Canadian Federation of Nurses Unions about their concerns with some aspects of the updated guidance.
- The Government of Canada has developed this guidance based on the best available evidence to protect the health and safety of health care workers.
- We will continue to reassess and update our guidance as the situation evolves and we learn more about COVID-19.

Point of Care Risk Assessment

- Before any patient interaction or procedure, all health care workers should assess the infectious risks posed to themselves, other patients and other workers. This is called Point of Care Risk Assessment, and is the basis for selecting the appropriate PPE.

Inclusion of cleaners or food providers who could be exposed to COVID-19:

- The advice in this guidance document covers anyone working in acute health care, including cleaners and food providers.

Use of surgical masks rather than N95 respirators:

- The choice of a surgical mask or N95 respirator should always be informed by a point of care risk assessment.

Re-use of PPE and guidance for health care facilities:

- N95 masks have historically been single-use products that are used by health care workers.
- Canada is exploring ways to extend the use of N95 respirators by decontaminating and reusing them. Decontamination of N95 respirators has been successful in other countries, including the United States.
- Canada is asking provinces and territories to set their used N95 respirators aside while a process for successful decontamination of the masks can be tested.
- Extending the use of PPE through decontamination is one way of helping to ensure that Canada has enough supply.

Infection Prevention and Control Guidance for Home Care Settings

- As a critical part of our health care system, home care organizations play a key role in preventing unnecessary hospital and long-term care admissions by supporting and caring for individuals in their homes.

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- People being cared for at home are often older and/or have underlying illnesses, which are risk factors for more serious COVID-19 infection. Preventing COVID-19 infection among this vulnerable population is a priority.
- The Public Health Agency of Canada's (PHAC) infection prevention and control guidance provides recommendations to home care organizations and providers to prevent the transmission of COVID-19 to frontline home care workers and to protect vulnerable clients in home care settings.
- PHAC's National Advisory Committee on Infection Prevention and Control, comprising infection prevention and control experts, and front-line care providers, worked with PHAC to develop this guidance, which is also endorsed by the Federal, Provincial and Territorial Special Advisory Committee on COVID-19.
- PHAC guidance is not mandatory. It should be read in conjunction with relevant provincial, territorial and local legislation, regulations and policies.
- To prevent transmission of COVID-19 to clients, home care providers are asked to monitor themselves for signs and symptoms of COVID-19, and to take their temperature daily. If home care providers show signs of infection, it is recommended that they be excluded from work until they are cleared to return by local public health.
- To protect home care clients from transmission of COVID-19 before symptoms are recognized, home care providers should wear masks for the full duration of home visits.
- To protect the frontline home care providers, they should contact their clients before visits to ask about whether they, or anyone in their household, has signs or symptoms of COVID-19. Home care organizations and providers can then determine whether the visit can be delayed or conducted in another way to ensure that home care providers and clients stay safe.
- To prevent possible transmission of COVID-19 to home care providers from unrecognized infection in clients, eye protection for home care providers should be strongly considered for the full duration of home visits.

Infection Prevention and Control Recommendations for Medical Evacuation by Aircraft of Patients with Suspected or Confirmed COVID-19 from Remote and Isolated Communities in Canada's North

- The Government of Canada recognizes the importance of preventing COVID-19 infection in northern, remote, and isolated communities in Canada that often experience obstacles in rapidly accessing conventional healthcare such as diagnostic testing services.
- Medical evacuation plays a critical role in the timely transfer of patients and providing en-route healthcare to patients from remote communities requiring urgent care.
- The Public Health Agency of Canada's (PHAC) infection prevention and control guidance provides recommendations to medical evacuation personnel and flight crew to help prevent the transmission of COVID-19.

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- This guidance was developed with the PHAC's National Advisory Committee on Infection Prevention and Control, in consultation with the provinces and territories via the Special Advisory Committee and with the Public Health Working Group on Remote and Isolated Indigenous Communities.
- PHAC guidance is not mandatory. It should be read in conjunction with relevant provincial, territorial, and local legislation, regulations and policies.
- Existing airline industry directives as well as organizational standard operation procedures may have additional recommendations and requirements.

Guidance Highlights

- To protect patients from transmission of COVID-19, all personnel on the aircraft should wear medical masks for the full duration of the flight even when the patient does not have symptoms.
- Medical evacuation personnel and flight crew require the patient, escort, and any ground personnel that may board the aircraft wear a mask and receive instruction on in-flight public health measures.
- To protect the aircraft personnel, medical evacuation personnel and flight crew should confirm that the patient's escort does not have COVID-19 symptoms prior to boarding the aircraft. If the escort has symptoms, they should not board the aircraft.
- Medical evacuation personnel should implement contact and droplet precautions, which include wearing a long sleeved cuffed gown, gloves, medical mask, and face or eye protection (e.g., face shield, mask with visor or goggles).
- To prevent transmission of COVID-19 to other individuals, cleaning and disinfection of the aircraft should be completed after the patient and escort have disembarked.

Canada's supply of personal protective equipment (PPE) and medical supplies:

- Personal protective equipment (PPE) is an important part of the infection prevention and control measures that can be used to protect home care workers and their clients from COVID-19 infection.
- Home care providers should refer to local, provincial or territorial guidance and facility policies on specific recommendations for use of masks, eye protection and other PPE, and PPE conservation strategies.
- The Government of Canada is working to ensure that health care workers, including those who provide home care services, have the PPE and medical supplies they need.
- We are doing this through collaborative bulk procurement with the provinces and territories, building domestic production capacity, and identifying potential alternatives and ways to extend product life.

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Shipments from China: Labelling of Personal Protective Equipment

- The Government of Canada's top priority in the procurement of personal protective equipment (PPE) and other medical supplies is the health and safety of frontline health care workers.
- The Public Health Agency of Canada (PHAC) verifies the quality of all PPE and medical supplies received by the Government of Canada, whether procured internationally or domestically, to confirm that they meet our technical specifications for health care settings for the COVID-19 response. The same process also applies to donations.
- To date, a large majority of the products received by the Government of Canada have met the technical specifications for health care settings for the COVID-19 response.
- Following a stringent review, PHAC determined that approximately 10 million KN95 respirators did not meet our technical specifications, and did not allocate them to provinces and territories.
- As the demand for PPE and other medical supplies remains high for frontline health care, we will continue to assess all shipments imported to Canada against the Government of Canada's technical specifications for health care settings.
- Because of China's certification and export controls for masks and other PPE, some products exported from China specify that the item is "not for medical use" in Simplified Chinese, even if it meets Canada's technical specifications for health care settings.
- PHAC will label products sourced from China that meet the Government of Canada's specifications on the outer shipping boxes once they are received, confirming quality and stating that they are suitable for use in health care settings.
- To maintain the integrity of the PPE packaging, PHAC will not be removing labels inserted inside each of the individual product boxes that communicate in Simplified Chinese that the product is "not for medical use." The process of removing these inserts would cause significant delays in the distribution.
- This is a labelling issue and is not reflective of PPE quality. As it will have ongoing implications for shipments received by the Government of Canada, PHAC will continue to work closely with the provinces and territories to clearly communicate that products distributed have been appropriately assessed, and are safe for use by frontline health care workers.
- If PHAC cannot account for the quality, the product will not be allocated to the provinces and territories, and will be subsequently assessed for potential use in non-health care settings.

Personal Protective Equipment and Plastic Waste

- PPE is a critical component of infection prevention and control for COVID-19. PPE and its sanitary packaging are frequently single-use products containing or made entirely of plastic. It is expected that demand for PPE will grow across all sectors as the economy continues to re-open and that demand for **non-medical masks or face coverings by the general public will grow as they** become a requirement to access services.

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- Increased PPE use creates more PPE waste, which is not recyclable or biodegradable. The Government of Canada is exploring options for reducing and managing PPE waste, and Canadians have a key role to play in minimizing the environmental impact of PPE for COVID-19.
- While single-use PPE is the current standard for medical settings, options are becoming increasingly available for reusable masks for non-medical purposes and the general public. These options are more cost-effective and environmentally friendly than single-use, disposable masks, particularly as more jurisdictions make mask-wearing mandatory in certain contexts.
- Since the beginning of the pandemic, a number of federal initiatives are investing in PPE technology advancements. These advancements, such as reusable masks or PPE sterilization techniques, will help reduce the amount of PPE waste in the environment.
- We encourage Canadians and businesses to follow their local health authority's advice on the use of PPE and non-medical masks, and to follow the advice of provincial and territorial environmental authorities and municipalities on their proper disposal.
- The Government of Canada maintains its commitment to reducing Canada's plastic waste, supporting innovation, and promoting the use of affordable and safe alternatives to single-use plastics.

Long-term Care Facilities

- We are calling on all Canadians to help protect older adults and medically vulnerable people, who are at greatest risk of severe health complications linked to COVID-19.
- We all need to do our part to help stop the spread of the virus among the residents of long-term care homes, as well as the workers who care for them.
- A "no visitor" policy should be strongly considered. If visitors are permitted, they should be strictly limited to those who are essential, meaning necessary to basic personal care medical or compassionate resident care. Essential visitors should be limited to one person at a time for each resident.
- Like all Canadians, residents and staff within long-term care homes should practise physical distancing to the greatest extent possible, including during meal times.
- Because they have direct contact with the most vulnerable in our society who are at highest risk of severe illness, health care workers should not go to work if they have symptoms.
- We understand that the efforts of Canadians to stop the spread of COVID-19 and to protect our most vulnerable involve difficult decisions and personal sacrifices.

Guidelines:

- The Public Health Agency of Canada (PHAC) develops evidence-informed infection prevention and control guidance to complement provincial and territorial public health efforts in monitoring, preventing and controlling healthcare-associated infections.
- The Government of Canada has released Infection Prevention and Control for COVID-19: Interim Guidance for Long-Term Care Homes to support the staff and residents in these facilities.



- This interim guidance is based on previous Canadian guidance developed for the coronavirus pandemic, lessons learned from the COVID-19 outbreak in China and other countries, and interim guidance from other Canadian and international bodies.

Public health guidance for long-term care homes:

- Long-term care homes should maintain a high level of vigilance to ensure that staff do not report to work with symptoms.
- Staff should be screened for symptoms of COVID-19 before every shift, and any staff member developing symptoms during a shift should be managed immediately.
- Wherever possible, employers should work with their staff to limit work to only a single facility, and to limit the number of locations in the facility in which the employees work.
- All staff and visitors should wear masks for the duration of their shifts or visits in order to prevent transmission of the virus, even before they are aware they are ill.
- If visitation is required, visitors should be screened for fever, cough or difficulty breathing, and prevented from entering if they have any COVID-related symptoms.
- Many facilities have already implemented measures, such as barring visitation or other non-essential on-site services.
- These facilities should also follow the recommendations for preventing transmission of infections, including COVID-19, in long-term care and assisted-living facilities developed by the relevant provincial or territorial health authority.

Alberta Long-Term Care Homes

- The Government of Canada is committed to protecting all Canadians, including vulnerable individuals.
- All levels of government are working in close collaboration so that public health measures to respond to the COVID-19 pandemic are in alignment.
- Public health authorities are closely monitoring for continued and stable slowing of the epidemic in Canada, while carefully considering approaches to ease public health restrictions when and where this may be possible.
- The epidemiology of COVID-19 is different in each jurisdiction. This means that approaches across Canada will not all be the same and will need to be tailored to the unique challenges and context of the disease in each province and territory.
- Each jurisdiction in Canada is looking at different kinds of community settings—such as long-term care homes—and developing risk-based approaches and assessments based on what is taking place within their jurisdiction.
- The Government of Canada is working with provincial, territorial and international partners to ensure that our response to the COVID-19 pandemic is based on the latest science and situational assessment.

On whether this approach is consistent with federal guidance:

- Care in long-term care facilities-based care is governed by provincial and territorial legislation.

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- The Public Health Agency of Canada (PHAC) develops evidence-informed infection prevention and control guidance to complement provincial and territorial public health efforts in monitoring, preventing and controlling healthcare-associated infections.
- Federal guidance recognizes that jurisdictions may choose to allow visitors limited access to long-term care facilities consistent with their legislation and policies.
- In these circumstances, we recommend that all staff and visitors, if allowed, should wear masks for the duration of their shifts or visits in order to prevent transmission of the virus, even if they have no symptoms of illness.
- If visitation is permitted, visitors should be screened for fever, cough or difficulty breathing, and prevented from entering if they have any COVID-related symptoms.
- Visitors, if allowed, should be reminded of the importance of hand hygiene and use alcohol-based hand rubs during their visits before putting on masks and before taking off masks.
- These facilities should also follow the recommendations of the relevant provincial or territorial health authority for preventing transmission of infections, including COVID-19, in long-term care and assisted-living facilities. Care in long-term care facilities is governed by provincial and territorial legislation.
- PHAC's infection prevention and control guidance for long-term care facilities should be read in conjunction with relevant provincial, territorial and local legislation, regulations, and policies.
- As we move into the next phase of this pandemic, jurisdictions will begin to ease restrictions while stressing extreme caution.

Guidance on Death Care Services and Mass Fatalities

- PHAC has developed guidance on the safe handling of human remains during the COVID-19 pandemic. All information provided in the guidance reflects the latest scientific evidence.
- We know that hearing about guidance like this can be difficult, especially for those who have lost a loved one, and we extend our sincere condolences to all who have lost a family member, friend or colleague to the disease.
- At the same time, the guidance on funeral care services and mass fatalities is an important part of pandemic planning and preparedness.
- Our understanding of the virus is continually evolving, and the risk of a transmission of COVID-19 from dead bodies is not yet known.
- We developed the guidance in collaboration with public health and infection prevention and control experts along with the Funeral Services Association of Canada to ensure the safe provision of services to families and to protect the health of those working to provide these services to the public.

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If pressed on the development of the guidance in response to recent outbreaks in long term care facilities:

- This guidance was developed to support the death care industry in proactive planning for potential scenarios during the pandemic.

If pressed on Indigenous/ethnic/religious/cultural body treatment or funeral practices:

- A number of religious, ethnic and cultural groups have specific directives about how bodies are managed after death. It is important to respect and accommodate these practices as much as possible while ensuring the health and safety of the community.
- We recommend that cultural and religious leaders be involved in planning for funeral services to help ensure that funeral arrangements continue to be culturally and religiously appropriate.
- Leaders may also be able to offer or facilitate cultural and religious support to those in mourning, including bereavement counselling.

If pressed on what happens if a Canadian dies of COVID-19 outside Canada:

- You can safely repatriate to Canada someone who has been identified as having died from COVID-19, providing certain conditions are met.
- In all cases, you must have appropriate documentation including a death certificate.
- Two options for repatriation of remains exist for people who were suspected or confirmed to have had COVID-19:
 - The body is cremated; or
 - The body is transported in a hermetically sealed container.
- We understand that this may pose some restrictions to families who are trying to return to Canada with the remains of a loved one. These restrictions are necessary to help protect their health and safety and the health and safety of individuals who will come into contact with the remains during the repatriation process.
- General information on what to do if someone dies while abroad is available through funeral providers in your community or on the Government of Canada website at <https://travel.gc.ca/assistance/emergency-info/death-abroad>.

If pressed on managing mass fatalities:

- Based on the experience of other countries, it is important to be prepared for an increase in the number of COVID-19-related deaths in Canada, which could overwhelm traditional capacity for funeral services.

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- PHAC has released guidance that aims to assist local and regional planners, community leaders, funeral service workers, medical examiners, and coroners in preparing to manage any surge in deaths relating to the pandemic.
- The guidance is based on the latest scientific evidence, and provides recommendations for the transportation of bodies, planning recommendations, storage capacity and other technical factors.

Guidance on Reopening of Dental Clinics

- The Canadian Dental Association is supporting provincial and territorial dental associations who are working with their government officials to help offices gradually reopen while complying with enhanced infection prevention and control guidelines.
- The provinces and territories regulate the field of dentistry and choose when to allow their private dental clinics to reopen.
- Dental clinics in some provinces and territories are gradually reopening following enhanced safety measures.
- The Public Health Agency of Canada's (PHAC) infection prevention and control guidance in acute healthcare settings, applicable in dental practices, complements provincial and territorial public health policies and procedures. PHAC guidance is not mandatory. It should be considered in conjunction with relevant provincial, territorial, and local legislation, regulations and policies.

If pressed on enhanced safety measures:

Each province and territory has the authority to decide which specific measures to adopt in their jurisdiction. These could include:

- Patients are screened for COVID-19 symptoms and have their temperatures taken.
- Booking fewer patients with staggered appointments.
- Minimizing aerosol-generating procedures and allowing 'settling time' before comprehensive cleaning and disinfection of treatment rooms.

PHAC guidance on infection prevention and control in acute healthcare settings:

- This guidance was updated to ensure it provides comprehensive recommendations based on the best available and current evidence.
- The guidance emphasizes the need for environmental and administrative controls in facilities to protect healthcare workers and patients as well as the fundamental importance of training in the use of personal protective equipment.



- Wearing a medical mask throughout the duration of a shift is an important measure to help reduce the risk of transmission from a healthcare worker to a patient.
- Wearing a medical mask and eye protection and face shield throughout the duration of a shift is an important measure to help reduce the risk of transmission from a patient to a healthcare worker.
- This recommendation applies to healthcare workers who are in direct contact with patients, as well as environmental services staff working in patient care areas.
- Any healthcare workers who have COVID-19-related symptoms should immediately go home and only return to work following the advice of their local public health unit.
- Healthcare workers should refer to their province or territory's guidance, as well as facility policies on the use of masks, eye protection, and other personal protective equipment (PPE, including any PPE conservation strategies that are in place.

Canada's supply of PPE and medical supplies:

- The Government of Canada is working to ensure that healthcare workers have the PPE and medical supplies they need. We are doing this through collaborative bulk procurement with the provinces and territories, building domestic production capacity, and identifying potential alternatives and ways to extend product life.
- Canada is working to rapidly allocate PPE and medical supplies to the provinces and territories as per an approach agreed upon by federal, provincial and territorial Ministers of Health.

Point of Care Risk Assessment:

- Before any patient interaction or procedure, all healthcare workers should assess the infectious risks posed to themselves, other patients and other workers. This is called Point of Care Risk Assessment, and is the basis for selecting the appropriate PPE.

Use of medical masks rather than N95 respirators:

- The choice of a medical mask or N95 respirator should always be informed by a point of care risk assessment.

Guidance for a Strategic Approach to Lifting Restrictive Public Health Measures in Canada

- Nationally, we are seeing the impact of public health measures on slowing down the growth of new cases of COVID-19, although there are some regional differences across the country.
- All levels of government are working in close collaboration so that the approaches to lifting restrictive public health measures to respond to the COVID-19 pandemic are aligned.



- Public health authorities are closely monitoring the agreed-upon set of criteria and indicators to assess readiness to lift restrictive public health measures in Canada. The level of COVID-19 transmission in any given region is central to the decision to gradually lift restrictive public health measures.
- The epidemiology of COVID-19 is different in each jurisdiction. This means that adjustments to public health measures across Canada will not all be the same and will need to be tailored to the unique challenges and context in each province and territory, and the regions therein.
- The Public Health Agency of Canada, in coordination with the provinces and territories, has developed guidance to public health authorities for transition planning that is underway across Canada as well as a strategic approach to lifting restrictive public health measures that can be tailored to jurisdictions. It builds on the Federal Provincial Territorial (FPT) Special Advisory Committee on COVID-19's Recommendations on Foundations for Living with COVID-19 in Canada.
- The guidance contains criteria and indicators that provide an evidence base for jurisdictions to determine their readiness to gradually lift or adjust restrictive measures, as well as progressive steps for a phased approach to safely re-start economies and regular activities.
- The aim of the strategic approach to lifting restrictive public health measures is to carefully balance the risks associated with the spread of COVID-19 with the unintended social and economic consequences of prolonged restrictive public health measures.
- The guidance is based on the latest science and will be implemented regionally and provincially, based on local circumstances.
- We recognize that we will continue to see the transmission of COVID-19 in the community as things start opening up again. That is why we need to move slowly and cautiously, as we live through the next phases of this pandemic, until we have a vaccine.
- It is critical that Canadians continue to practice the proven measures to limit transmission: stay home and away from others if you are sick, wash your hands often, cover your cough with a tissue or your sleeve, practise physical distancing, clean and disinfect surfaces and objects, and protect those most at risk.
- In addition, where the local epidemiology warrants it, non-medical masks or cloth face coverings are recommended in settings where physical distancing is not possible or unpredictable, such as public transit, stores and shopping areas.
- If you suspect you have symptoms of COVID-19, get tested. This will help us identify any outbreaks in the community and put in place measures to prevent further spread.
- Public health officials in your area will make recommendations based on a number of factors, including the rates of infection and/or transmission in the community. Recommendations may vary from location to location based on local epidemiology.

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Community-Based Measures to Mitigate the Spread of Coronavirus Disease (COVID-19) in Canada

- The Public Health Agency of Canada, in collaboration with federal, provincial and territorial public health authorities, and with the Canadian Pandemic Influenza Preparedness Task Group, has released updated guidance on the use of community-based measures to mitigate the transmission of COVID-19 as jurisdictions begin to gradually lift some restrictions.
- We recognize that we will continue to see the transmission of COVID-19 in the community as things start opening up again.
- As no therapies or vaccines are available at this time, both personal and community level public health measures remain essential to prevent the spread of infection.
- Public health measures are effective actions people can take themselves, such as physical distancing, and the actions that communities can require, such as prohibiting large gatherings, to reduce community spread of COVID-19.
- The public health measures outlined in this guidance include personal practices that individuals can take to protect themselves and others, as well as the community-based measures that protect groups and the community.
- This guidance is based on current scientific evidence. The guidance may change as new evidence emerges, as we learn from the experiences of other jurisdictions as they lift restrictions, or as treatment options or vaccines become available.

If pressed about the guidance itself:

- The guidance identifies strategies for implementing core public health measures in specific settings where the public gathers such as congregate living settings, businesses and workplaces, child and youth settings, community gathering spaces, outdoor spaces, public transportation and interpersonal gatherings.
- The core personal public health measures are to be maintained for the duration of the pandemic, including as restrictions are lifted, and include:
 - staying home and away from others if you are ill;
 - washing your hands frequently;
 - covering your cough with tissues or your sleeve;
 - practising physical distancing;
 - cleaning and disinfecting surfaces and objects; and
 - protecting those most at risk from the virus.
- In addition, where the local epidemiology warrants it, non-medical masks or cloth face coverings are recommended in settings where physical distancing is not possible or unpredictable, such as public transit, stores and shopping areas.



COVID-19 Risk Factors

- The Public Health Agency of Canada (PHAC) has updated its information on COVID-19 risk factors to reflect the evolving COVID-19 knowledge base.
- The updated risk factors identify two groups of people:
 - those who are more likely to be exposed to COVID-19 because of their occupation or social, economic and life circumstances; and,
 - those who are at risk of more severe disease or outcomes, including hospitalization or death, due to their age or other medical conditions.
- PHAC has updated the risk factors to better reflect current understanding of who may be at greater risk of exposure or severe outcomes.
- Knowing which factors increase the risks of COVID-19 can help Canadians make informed decisions to keep themselves, their families and their communities safe.
- PHAC remains committed to updating Canadians as the COVID-19 situation evolves and new evidence emerges.
- The updated information is available on the Government of Canada [website](#), Canada.ca/coronavirus, and included in guidance documents for professionals.

Risk mitigation tool for child and youth settings operating during the COVID-19 pandemic

- The Public Health Agency of Canada, in collaboration with federal, provincial and territorial public health authorities, has released a risk mitigation tool for child and youth settings operating during the COVID-19 pandemic.
- This risk mitigation tool for child and youth settings is based on concepts outlined in the updated guidance developed for community-based measures to mitigate the transmission of COVID-19 as jurisdictions begin to gradually lift some restrictions.
- As no specific therapies or vaccines are available to treat or prevent COVID-19 at this time, both personal and community level public health measures remain essential to preventing the spread of infection.
- This tool should be used alongside and in support of guidance from [provincial/territorial health authorities](#), ministries of education and Indigenous community governance structures.
- We recommend using a layered approach of multiple mitigation measures to reduce the risk of COVID-19 spread, including decreasing the number of interactions with others and increasing the safety of interactions.
- This tool highlights the importance of promoting and providing [mental health support services](#) to children and youth, as well as staff and volunteers, who may experience increased stress

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associated with COVID-19. The tool identifies additional resources for parents and children as well as youth and students.

- Mental health and wellness supports may contribute to the resiliency of children and youth and the staff responsible for them in child and youth settings.
- The public health measures outlined in this risk mitigation tool for child and youth settings include personal practices that individuals can take to protect themselves and others, as well as the community-based measures that protect groups and the community.
- This risk mitigation tool for child and youth settings is based on current scientific evidence. The recommendations may change as new evidence emerges, as we learn from the experiences of other jurisdictions as they lift restrictions, or as treatment options or vaccines become available.

If pressed about the tool itself:

- This tool helps those responsible for child and youth settings to better understand the risk factors of transmitting COVID-19 and helps them implement public health measures to mitigate the risks.
- Child and youth settings include early learning and daycare centres, schools (K-12), day programs, summer camps, and other settings where children and youth represent the majority of the population accessing the setting.
- The core personal public health measures are to be maintained for the duration of the pandemic, including as restrictions are lifted, and include:
 - staying home and away from others if you are ill;
 - washing your hands frequently;
 - covering your cough with tissues or your sleeve;
 - practising physical distancing;
 - cleaning and disinfecting surfaces and objects; and
 - protecting those most at risk from the virus.
- Non-medical masks or cloth face coverings for children and youth settings where physical distancing is difficult should be considered based on a risk assessment, but may not always be appropriate.
- Non-medical masks or cloth face coverings should not be placed on young children under the age of 2 or on anyone who has trouble breathing or is unconscious, incapacitated or otherwise unable to remove the mask without assistance.
- Advice regarding the wearing of masks in child and youth settings may vary from jurisdiction to jurisdiction. Childcare providers and schools should always consult with their relevant Occupational Health and Safety team and [local public health](#) when considering mask-wearing policies.



Risk mitigation tool for outdoor recreation spaces and activities operating during the COVID-19 pandemic

- The Public Health Agency of Canada, in collaboration with federal, provincial and territorial public health authorities, has released a risk mitigation tool for recreation spaces and activities operating during the COVID-19 pandemic.
- This tool is based on concepts outlined in the updated guidance developed for the use of community-based measures to mitigate the transmission of COVID-19 as jurisdictions begin to gradually lift some restrictions.
- This tool is a resource and should be used alongside and in support of guidance from provincial and territorial health authorities, other relevant government departments and Indigenous community governance structures.
- We know that we will continue to see the transmission of COVID-19 in the community as businesses and other settings begin to reopen.
- As no specific therapies or vaccines are available at this time, both personal and community-level public health measures remain essential to prevent the spread of infection.
- The public health measures outlined in this risk mitigation tool include actions that individuals can take to protect themselves and others, as well as the community-based measures that protect groups and the community.
- We recommend using a “layered” approach of multiple mitigation measures (e.g., hand hygiene, respiratory etiquette, staying home when ill) to reduce the risk of COVID-19 spread, including decreasing the number of interactions with others and increasing the safety of interactions. Layering of multiple mitigation measures strengthens risk mitigation overall.
- This risk mitigation tool for outdoor recreation spaces and activities is based on current scientific evidence. The recommendations may change as new evidence emerges, as we learn from the experiences of other jurisdictions as they lift restrictions, or as treatment options or vaccines become available.

If pressed about the tool itself:

- This tool helps those responsible for parks and outdoor recreational places and programming understand the risk factors of transmitting COVID-19, and it helps them implement public health measures to mitigate the risks.
- Outdoor recreation spaces include municipal or public parks, community gardens, hiking paths and trails, dog parks, playgrounds, skate parks, outdoor pools, splash pads, beaches, piers and campgrounds. Outdoor recreational activities include team sports (e.g., baseball, soccer, lacrosse, street hockey), individual sports (e.g., skateboarding, golf, tennis), as well as activities such as tai chi, cycling, fishing, boating and hunting.
- The core **personal** public health measures are to be maintained for the duration of the pandemic, including as restrictions are lifted, and include:

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- staying home and away from others if you are ill;
 - washing your hands frequently;
 - covering your cough with tissues or your sleeve;
 - practising physical distancing;
 - cleaning and disinfecting surfaces and objects; and
 - protecting those most at risk from the virus.
- In addition, where the local epidemiology warrants it, non-medical masks or cloth face coverings are recommended in settings where physical distancing is not possible.
 - In some outdoor activities, wearing a non-medical mask may not be practical or tolerable. When playing active sports, for example, there might be a risk of poor oxygenation, the mask could be easily soiled or moistened because of sweating or heavy breathing, or there could be a risk of injury if the mask is caught on equipment.
 - Not everyone is able to wear a non-medical mask or face covering. They should not be placed on young children under age 2, anyone who has trouble breathing or who is unconscious, incapacitated or otherwise unable to remove the mask without assistance.
 - For sports where one is permitted (e.g., hockey), a face shield may be considered.

Risk mitigation tool for gatherings and events operating during the COVID-19 pandemic

- The Public Health Agency of Canada, in collaboration with federal, provincial and territorial public health authorities, has released a risk mitigation tool to help people responsible for gatherings or events understand the risk factors associated with the spread of COVID-19.
- It also provides information to help implement public health measures to mitigate the risks of transmission of COVID-19 as jurisdictions begin to gradually lift some restrictions.
- You should review the guidance alongside guidance from provincial, territorial and local health authorities, relevant ministries and Indigenous community governance structures.
- As no specific therapies or vaccines are available at this time, personal and community-level public health measures are essential to prevent the spread of COVID-19.
- We recommend using a “layered” approach of multiple mitigation measures to reduce the risk of COVID-19 spread, including decreasing the number of interactions with others and increasing the safety of interactions. Layering of multiple mitigation measures reduces overall risk.
- The public health measures outlined in this risk mitigation tool for gatherings and events include personal practices that individuals can take to protect themselves and others, as well as the community-based measures that protect groups and the community.



- This risk mitigation tool for gatherings and events is based on current scientific evidence. The recommendations may change as new evidence emerges, as we learn from the experiences of other jurisdictions as they lift restrictions, or as treatment options or vaccines become available.

If pressed about the tool itself:

- All planners, organizers and operators of gatherings or events, regardless of their purpose and size, have a responsibility to assess the risks associated with their gatherings/events and their ability to reduce these risks. This tool provides practical advice on ensuring that gatherings and events operate in the safest way possible, thus preventing and limiting COVID-19 spread.
- This tool is applicable to a wide range of gatherings, from gatherings of family and friends (e.g., weddings, funerals, parties), to community gatherings (e.g., places of worship, libraries, recreational centres, cultural centres), to larger gatherings or events, including mass gatherings (e.g., sporting events, conferences, cultural or religious events, festivals) and more.
- Canadians seeking public health advice on small gatherings or events of family and friends can refer to the Public Health Agency of Canada's awareness resources to find information on personal preventive practices such as physical distancing, hand hygiene and environmental cleaning, as these practices will be essential in preventing and reducing the spread of COVID-19. They should also consult the guidance of their local public health authority.
- The core **personal** preventive practices to be maintained for the duration of the pandemic, including as restrictions are lifted, include:
 - staying home and away from others if you are ill;
 - washing your hands frequently;
 - covering your cough with tissues or your sleeve;
 - practising physical distancing;
 - wearing a mask when physical distancing is difficult; and
 - cleaning and disinfecting surfaces and objects.
- Not everyone is able to wear a non-medical mask or face covering. They should not be placed on young children under the age of 2 or on anyone who has trouble breathing or who is unconscious, incapacitated or otherwise unable to remove the mask without assistance.

If pressed on additional resources on specific settings:

- *Planners, organizers and operators of indoor public community gathering spaces that operate continuously (e.g., recreation facilities such as gyms, libraries, museums, theatres, cinemas) can also refer to the Risk mitigation tool for workplaces/businesses operating during the COVID-19 pandemic for guidance on risk factors and risk mitigation measures specific to employers, employees and clients.*
- *Planners and organizers of gatherings and events catering primarily to children and youth can also refer to the Risk mitigation tool for child and youth settings operating during the COVID-19 pandemic for guidance and considerations specific that population.*

Guidance for Essential Retailers during COVID-19 pandemic



- The Government of Canada recognizes that essential retailers provide critical services in our communities. Everyday, they are ensuring safe and reliable access to food, supplies and other provisions to Canadians.
- The updated guidance provides recommendations to retailers on how to prevent and reduce the spread of COVID-19 among workers and customers by implementing appropriate public health measures (e.g., discouraging entry of ill people, promoting hand hygiene, supporting physical distancing), and adjusting their operations with enhanced environmental cleaning.
- The guidance recommends practices for workers to follow to prevent and limit virus transmission in the workplace.
- The guidance also provides advice on how to support the mental health and workplace wellness of essential workers in retail establishments.
- The COVID-19 pandemic continues to evolve in Canada. As new evidence emerges, advice for specific sectors will also continue to evolve.
- It is important to assess which specific public health measures are appropriate according to the needs of individual settings.
- This guidance should be reviewed in conjunction with the advice or recommendations from local or regional public health authority.

Guidance for schools: Kindergarten to grade 12 (K-12) during COVID-19

- The Public Health Agency of Canada (PHAC), in collaboration with Canadian public health experts and education stakeholders, has developed guidance for administrators of schools from kindergarten to grade 12 (K-12) and local public health authorities to support the safer resumption of in-school educational programming during the COVID-19 outbreak.
- This guidance document should be used alongside guidance from provincial and territorial health authorities, ministries of education and Indigenous community governance structures.
- This guidance is based on current scientific evidence. Recommendations may change as new evidence emerges, as we learn from the experiences of other jurisdictions as they lift restrictions, or as treatment options or vaccines become available.

If pressed on potential health risks to children congregating in school settings:

- Emerging evidence currently suggests that the virus can spread efficiently in all age groups. Children over 10 years old may be as likely as adults to transmit the virus to others.



- Children, especially those below 10 years of age, appear to experience less severe symptoms due to COVID-19 and they form a very small proportion of reported cases to date. Children under 10 years can also transmit the virus, but are less likely to do so than adults.
- As no specific therapies or vaccines are available to treat or prevent COVID-19 at this time, both personal and community level public health measures remain essential to preventing the spread of infection.
- Schools provide the education and social environment that helps to prepare children for adulthood. For most K-12 students, long-term online education is not a substitute for in-person learning and socialization in a school setting.
- We recommend using a layered approach of multiple mitigation measures to reduce the risk of COVID-19 spread, including decreasing the number of interactions with others and increasing the safety of interactions.

If pressed about the guidance itself:

- This guidance provides strategies to help administrators (K-12) and local public health authorities understand, assess, and mitigate the risk of COVID-19 transmission in classrooms and other school settings.
- PHAC recommends that schools work with their local public health authorities and implement multiple concurrent mitigation measures to help protect students and staff. This layered approach helps minimize the risk of transmission in case one measure, such as physical distancing is not possible.
- The guidance provides age-appropriate examples of how schools can implement risk mitigation measures such as:
 - physical distancing in the classroom
 - separating people from each other through physical barriers
 - maintaining good hand and respiratory hygiene
 - environmental cleaning
 - maintaining a social bubble
 - wearing non-medical masks according to age and setting.
- Educational institutions (K-12) should work closely with their local public health authorities in advance of, and during the academic year, to ensure:
 - appropriate mitigation strategies are in place to help protect their faculty, staff, students and visitors; and
 - appropriate planning, policies and protocols are in place for case management and outbreak response efforts on school grounds.

Background:

- Public Health Measures (PHM) consulted the following Canadian public health experts and stakeholders for the K-12 guidance:
 - The Canadian Pandemic Influenza Preparedness task group (CPIP);

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- Special Advisory Committee (SAC);
- Technical Advisory Committee (TAC);
- Public Health Working Group on Remote and Isolated Communities;
- Indigenous Services Canada;
- Immigration, Refugees and Citizenship Canada & Global Affairs Canada (they were consulted but no comments were provided);
- Employment and Social Development Canada (specifically mobility, office of persons with disabilities, early childhood/child-care, and learning program);
- Canadian Accredited Independent School (CAIS);
- Canadian Pediatric Society; and
- Outdoor Council of Canada.

CPHO – Issue Lines Back to School

- Throughout the COVID-19 outbreak, Canadian families have made many sacrifices to maintain the well-being of their families. Parents, guardians, students and teachers alike have been awaiting the “back to school” plans for this year.
- Provinces across Canada have unveiled re-opening plans for primary and secondary schools.
- The Public Health Agency of Canada (PHAC), in collaboration with Canadian public health experts and stakeholders, has developed guidance for administrators of schools from kindergarten to grade 12 (K-12) and local public health authorities to support the safer resumption of in-school educational programming during the COVID-19 outbreak.
- Education is a provincial jurisdiction. Each province and territory will make plans according to their local realities. Local public health and each school’s advice should be taken into consideration when making back-to-school decisions.
- For parents and guardians across the country back-to-school planning can be stressful. It is important that families consider a number of complex personal factors, such as:
 - The risk of severe illness from COVID-19. It is vitally important to support families and community members who are most at risk. If your child or a member of your family has an underlying health condition, you should consider that specific risk in the context of back-to school planning;
 - Your child’s educational and developmental needs;
 - Mental health considerations and the emotional and psychological needs of your child, yourself and anyone else in your household;
 - The economic well-being of the family, including the work situation of parents and guardians; and
 - The unique challenges your household may have, which affect considerations like internet access.

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- Parents can help prepare kids for going back to school by:
 - Reviewing how and when to wash hands;
 - Providing hand sanitizer, for times when soap and water aren't available;
 - Demonstrating physical distancing (and giving kids a reference of what 2 metres is);
 - Practicing putting on, wearing, and removing non-medical masks; and
 - Modelling these behaviours for their kids inside and outside of the home.
- It is also normal to have many questions for school administrators. You have the right to ask questions to help inform your decision-making, including classroom layout, sanitation practices, social distancing, mask rules, transportation and online alternatives.
- Wearing masks in schools, where appropriate, should also be considered as an important *additional* layer of protection. Wearing a mask should be done in addition to public health measures taken by school boards and local health authorities.
- When making your own back-to-school plans, please also remember that each parent or guardian is also making plans that best suits the unique needs of their family unit. There is no one-size-fits-all solution.
- Support your community of parents, students, teachers and administrators as schools work to re-open this academic year. By working together, not only can we help students of all ages thrive in what will certainly be a non-conventional school year, but we will also be able to protect those members of our community most at risk of serious illness.

If Pressed – Masks in Schools

- On wearing masks in schools, it is important to note that health and education are provincial jurisdictions. Provincial and territorial governments are best suited to address the health and educational needs in their regions.
- When we consider the risks of schools, the most important thing is the level of community spread—and whether it is low. Local public health authorities are, again, best suited to respond to local realities and to adjust their policies based on the level of community spread.
- Our general guidance, in collaboration with provinces and territories, is that non-medical masks can reduce transmission, in a school environment.
- Masks can play a role, but it is not a panacea. You have to have layers of protection. Masks must be used alongside multiple layers of public health measures, such as hand-washing and physical distancing.

If Pressed - transmission from kids above and under the age of ten

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- The current scientific data suggest that children over the age of 10, transmit the disease the same way as adults. As such, we recommend non-medical masks for all children age 10 years or over.
- Children under ten can still be infected and spread COVID-19 to other children and adults, even if they transmit it at a lower likelihood when compared to adults. Masks can thus still play a role if worn by younger children.

Students in Canada-US Border Communities Crossing the Border to Attend School

- The Government of Canada remains committed to protecting the health and safety of Canadians and reducing the spread of COVID-19 in Canada.
- Most Canadians, persons with status under the Indian Act and permanent residents entering Canada—no matter their mode of entry—must isolate themselves for 14 days if they have symptoms of COVID-19 or quarantine themselves for 14 days if they do not have symptoms. Limited exceptions are granted to essential workers who can confirm their regular employment status.
- A broad interpretation of certain provisions of the Mandatory Isolation Order was made last spring to allow students to complete their school year. However, as schools reopen, given the current rate of COVID-19 infection in the U.S., the Public Health Agency of Canada has clarified that students crossing the border to attend school on a daily basis are not exempt from the 14-day quarantine period on return to Canada.

If pressed on initially exempting cross-border students from the quarantine requirements

- Canada's public health experts are concerned that importation of COVID-19 infections could spark community transmission and therefore are taking a cautious approach to avoid risk.
- While there are no specific provisions in the current *Mandatory Isolation Order* that exempt Canadian students who cross the border on a daily basis to attend in-person classes from having to quarantine for 14 days, a broad interpretation of section 6(m) related to integrated border communities was taken in the early days of the pandemic that allowed cross border travel to attend school on a daily basis.
- Given concerns about a possible resurgence of infection and illness this fall, the Government of Canada has clarified the application of the Order to these students. This approach will be the same for all students (Kindergarten to grade 12 and post-secondary) who attend school across the border in other border communities, with rare exceptions such as needing to cross into the US to get to back to Canada (e.g., Campobello Island) or the formally integrated trans-border community of Akwesasne.

- **Information point for user:**



Akwesasne is the only formal “trans-boundary” Indigenous community. This community has shared territory on both sides of the border and as such, residents are exempt from quarantine. While there are other communities on both sides on the border that are reliant on each other (e.g. Windsor-Detroit), these are not fully integrated communities like Akwesasne.

- Another exception is for those living in communities with geographical constraints, such as Campobello Island, where ferry service provides connection to Canada in summer months, but where residents must travel over land via Maine in the winter to obtain goods and services and return to their Canadian residence.

If pressed on US residents who travel to Canada to attend school

- Foreign nationals are prohibited from entry into Canada under OIC 2020-0538 under subsection 4(1), whereby “*a foreign national is prohibited from entering Canada from the United States if, based on the purpose of entry and the length of their stay, the requirement to quarantine under the Minimizing the Risk of Exposure to COVID-19 in Canada Order (Mandatory Isolation), cannot be complied with*”.
- In the circumstance where the foreign national planned to quarantine for 14 days in Canada prior to attending school, their entry may not be prohibited. However, each time they sought entry, they would be subject to the 14 day requirement.

Foreign nationals are generally prohibited from entering if they are symptomatic.

Guidance for post-secondary institutions during the coronavirus (COVID-19)

- The Public Health Agency of Canada (PHAC), in collaboration with Canadian public health experts and stakeholders, has developed guidance for post-secondary institution administrators and local public health authorities for operating in the context of the coronavirus outbreak.
- This guidance document should be used alongside relevant federal, provincial/territorial and local legislation, regulations and policies.
- This guidance is based on current scientific evidence. Recommendations may change as new evidence emerges, as we learn from the experiences of other jurisdictions as they lift restrictions, or as treatment options or vaccines become available.
- As no specific therapies or vaccines are available to treat or prevent COVID-19 at this time, both personal and community level public health measures remain essential to preventing the spread of infection.
- We recommend using a layered approach of multiple mitigation measures to reduce the risk of COVID-19 spread, including decreasing the number of interactions with others and increasing the safety of interactions.

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If pressed about the tool itself:

- This guidance helps those responsible for administering activities in post-secondary institutions to better understand the risk factors for COVID-19 transmission and implement public health measures to mitigate the risks in a variety of settings common to post-secondary institutions. It includes examples of mitigation strategies that may be adopted in different settings.
- Post-secondary institutions include public and private colleges, universities, vocational and technical schools, and CEGEPs. Post-secondary settings addressed in the guidance include learning and research activities, on-campus housing, supports and services, community gatherings and student life.
- Post-secondary institutions should work closely with their local public health authorities in advance of, and during the academic year, to ensure:
 - appropriate mitigation strategies are in place to help protect their faculty, staff, students, and visitors; and
 - appropriate planning, policies and protocols are in place for case management and outbreak response efforts on-campus.
- The core personal preventive practices are to be maintained for the duration of the outbreak, including as restrictions are lifted, and include:
 - staying home and away from others if you are ill;
 - washing your hands frequently;
 - covering your cough with tissues or your sleeve;
 - practising physical distancing;
 - considering wearing a non-medical mask or homemade face covering, when physical distancing cannot be maintained;
 - cleaning and disinfecting surfaces and objects; and
 - protecting those most at risk from the virus.

This guidance also highlights public health considerations and requirements for individuals arriving at a post-secondary institution from outside the local community via domestic or international travel. For operational plans regarding international students, Immigration, Refugees and Citizenship Canada has further guidance, including Guidelines for Institutions on the Arrival of International Students

Publishing and promoting the toolkit on substance use and safer supply during COVID-19

- In parallel with the COVID-19 pandemic, many regions of the country continue to struggle with historic rates of drug overdose and harms. Tragically, in many communities, the pandemic is compounding a deadly and ongoing public health crisis of opioid overdose and death.
- The Government of Canada is committed to ensuring that provinces and territories have the tools they need to manage the compounding effects of the opioid overdose crisis and the COVID-19 pandemic.
- To respond to a need from stakeholders for information on accessing medications for people who use drugs or are in recovery during the pandemic, Health Canada has published a toolkit

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with guidance on providing medication as a treatment for substance use disorder or as a pharmaceutical-grade alternative to toxic street drugs (this is also known as safer supply).

- Providing flexible treatment options for substance use disorder, such as those in the toolkit, can support people who use drugs and those who are in recovery to stabilize and improve their health, and reduce the risk of overdose, infection and withdrawal as they practise physical distancing or self-isolate.
- This information assists healthcare practitioners in providing medications to support different models of care, including treating substance use disorder, preventing withdrawal symptoms, and providing access to pharmaceutical-grade medications, such as hydromorphone, as a safer alternative to street drugs. For example, the toolkit informs health practitioners of recent changes by Health Canada to temporarily allow prescribers to issue verbal prescriptions for narcotics.
- The toolkit also provides people who use drugs and those who are in recovery with information on services they may be able to access through a health care provider during the pandemic.
- The toolkit contains:
 - Practical answers to questions about the legislative and regulatory requirements for substance use disorder treatment and safer supply;
 - Information on public drug plan coverage of medications used for treatment and safer supply in each province and territory; and
 - Resources on prescribing and delivering substance use treatment, safer supply models, harm reduction options and chronic pain treatment in the context of COVID-19.
- The Government of Canada is working with provinces and territories to help patients and practitioners maintain access to critical medicine and harm reduction services, treatment, housing and other services for people who use drugs, while respecting public health advice on physical distancing.

COVID-19 Signs, Symptoms and Severity of Disease – A Clinician Guide

- Our understanding of the virus that causes COVID-19 continues to evolve. It is important that Canadians continue to help prevent the spread of COVID-19 by following public health guidance. Current guidance includes staying home if you are sick, physical distancing, wearing a non-medical mask or face covering when physical distancing is difficult, and regular hand washing.
- COVID-19 can be present with a variety of symptoms. Some people will have more severe symptoms than others. The most commonly reported COVID-19 symptoms, such as fever, cough, fatigue, loss of appetite, and shortness of breath, are not specific to COVID-19.
- The main way COVID-19 spreads is from person-to-person contact by respiratory droplets. An example of this type of transmission would be coughing or sneezing without covering the mouth. The time period in which an individual with COVID-19 is infectious is uncertain. A Canadian study found that the virus that causes COVID-19 has the highest likelihood of being infectious

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for the first 8 days following symptom onset. Infectivity of patients with symptoms lasting equal to 8 days or longer is likely very low. The duration of viral shedding in severely ill patients, such as those in intensive care units or with immune suppression, is unknown but may be more prolonged. For these reasons, it is critically important that Canadians continue to follow safety guidance and best practices related to COVID-19.

- To reduce the risk of spreading COVID-19, we recommend using a “layered” approach to public health measures, including decreasing the number of interactions with others and increasing the safety of interactions. Layering of multiple measures reduces overall risk.

Right now, we do not know if a person can be re-infected.

Isolation, Quarantine (Self-Isolation) and Physical Distancing

- There is a difference between advice to quarantine (self-isolate) and advice to isolate. It is important to note these measures are in place to protect the health and safety of Canadians.

Isolation

- Isolation means staying at home when you have a symptom of COVID-19 and it is possible that you have been exposed to the virus. By avoiding contact with other people, you help prevent the spread of disease to others in your home and your community.

You must:

- **go directly home and/or stay at home** if you have:
 - been diagnosed with COVID-19, or are waiting to hear the results of a lab test for COVID-19
 - any symptom of COVID-19, even if mild, and have
 - been in contact with a suspected, probable or confirmed case of COVID-19
 - been told by public health (directly, through public communications or through a self-assessment tool) that you may have been exposed to COVID-19
 - returned from travel outside Canada with symptoms of COVID-19 (mandatory)
- monitor your symptoms as directed by your healthcare provider or Public Health Authority until they advise you that you are no longer at risk of spreading the virus to others
- immediately contact your healthcare provider or Public Health Authority and follow their instructions if your symptoms get worse.
- **Limit contact with others**
 - Do not leave home unless it's to seek medical care.
 - Do not use public transportation (e.g., buses, taxis).
 - Arrange to have groceries and supplies dropped off at your door to minimize contact.
 - Stay in a separate room and use a separate bathroom from others in your home, if possible.

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- If you have to be in contact with others, practise physical distancing and keep at least 2 metres between yourself and the other person.
 - Avoid contact with individuals with chronic conditions, compromised immune systems and older adults.
 - Keep any interactions brief and wear a medical mask if available, or if not available, a non-medical mask or face covering (i.e. constructed to completely cover the nose and mouth without gaping, and secured to the head by ties or ear loops) when coughing, sneezing or if you need to be in the same room with others in the home.
 - Follow instructions online for the safe use and disposal or laundering of face masks, or as provided by your Public Health Authority.
 - Avoid contact with animals, as there have been several reports of people transmitting COVID-19 to their pets.
- **Keep your hands clean**
 - Wash your hands **often** with soap and water for at least 20 seconds, and dry with disposable paper towels or dry reusable towel, replacing it when it becomes wet.
 - You can also remove dirt with a wet wipe and then use an alcohol-based or non alcohol based hand sanitizer approved by Health Canada.
 - Avoid touching your eyes, nose and mouth.
 - Cough or sneeze into the bend of your arm or into a tissue.
 - Avoid contaminating common items and surfaces
 - At least once daily, clean and disinfect surfaces that you touch often, like toilets, bedside tables, doorknobs, phones and television remotes.
 - Do not share personal items with others, such as toothbrushes, towels, bed linen, utensils or electronic devices.
 - To disinfect, use only approved hard-surface disinfectants that have a Drug Identification Number (DIN). A DIN is an 8-digit number given by Health Canada that confirms the disinfectant product is approved and safe for use in Canada.
 - Place contaminated items that cannot be cleaned in a lined container, secure the contents and dispose of them with other household waste.
 - Put the lid of the toilet down before flushing.
 - Wearing a face mask, including a non-medical mask or facial covering, may trap respiratory droplets and stop them from contaminating surfaces around you - but wearing a mask does not reduce the need for cleaning.
 - **Care for yourself**
 - Monitor your symptoms as directed by your health care provider or public health authority.
 - If your symptoms get worse, immediately contact your health care provider or public health authority and follow their instructions.
 - Get some rest, eat a balanced diet and stay in touch with others through communication devices.
 - **Supplies to have at home when isolating**
 - Medical masks if available for the case and the caregiver. If not available, non-medical mask or face covering (i.e. constructed to completely cover the nose and mouth without gaping, and secured to the head by ties or ear loops)
 - Eye protection (face shield or goggles) for use by caregiver
 - Disposable gloves (do not re-use) for use by caregiver

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- Disposable paper towels
- Tissues
- Waste container with plastic liner
- Thermometer
- Over the counter medication to reduce fever (e.g., ibuprofen or acetaminophen)
- Running water
- Hand soap
- Alcohol-based sanitizer containing at least 60% alcohol
- Dish soap
- Regular laundry soap
- Regular household cleaning products
- Hard-surface disinfectant, or if not available, concentrated (5%) liquid bleach and a separate container for dilution
- Alcohol prep wipes or appropriate cleaning products for high-touch electronics

Self-Isolation (Quarantine)

- Quarantine for 14 days if you have **no symptoms** and **any** of the following apply:
 - you are returning from travel **outside of Canada** (mandatory quarantine)
 - you had close contact with someone who has or is suspected to have COVID-19
 - you have been told by the public health authority that you may have been exposed and need to quarantine
- Quarantine means that for 14 days you need to:
 - **stay at home** and monitor yourself for symptoms, even if mild
 - avoid contact with others to help prevent transmission of the virus at the earliest stage of illness
 - practise physical (social) distancing in your home and community
- If you develop symptoms, even if mild, stay home and isolate yourself from others. Immediately call a health care professional or your public health authority.

Physical distancing

- We are advising Canadians to stay home, if possible. If you must leave your home, practise physical distancing.
- Physical distancing is proven to be one of the most effective ways to reduce the spread of illness during an outbreak.
- Everyone needs to practice physical distancing, even if you have:
 - NO symptoms of COVID-19
 - NO known risk of exposure
 - not travelled outside of Canada within the last 14 days.
- You can practise physical distancing by making changes in your everyday routines to minimize close contact with others. For example:
 - avoiding crowded places and gatherings
 - avoiding common greetings, such as handshakes
 - limiting contact with people at higher risk (e.g. older adults and those in poor health)
 - keeping a distance of at least 2 arms lengths (approximately 2 metres) from others, as much as possible
- To stay healthy and prevent the spread of respiratory and other illnesses is to:

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- wash your hands often with soap and water for at least 20 seconds;
 - cough and sneeze into your sleeve and not your hands;
 - avoid touching your eyes, nose or mouth, especially with unwashed hands;
 - avoid close contact with people who are sick; and
 - stay home if you are sick to avoid spreading illness to others.
- While keeping a physical distance of 2 metres from others, you can:
 - greet with a wave instead of a handshake, a kiss or a hug
 - use food delivery services or online shopping
 - ask family, a neighbor or friend to help with essential errands
 - exercise at home
 - go outside for some fresh air, a run, a bike ride, or to walk the dog
 - host online dinners and games with family and friends
 - use technology, such as video calls, to keep in touch with family and friends
 - work from home
 - get creative by drawing chalk art or running back yard obstacle courses and games

Physical Distancing Recommendations

- The Public Health Agency of Canada recommends that Canadians maintain a two-metre distance from others to reduce the risk of exposure to COVID-19 through respiratory droplets generated by coughing, sneezing, laughing, singing or talking.
- A distance of two metres is the generally accepted “risk zone” for respiratory droplet transmission for other viruses (e.g., influenza).
- As we learn more about COVID-19, our recommendation could change but, right now, maintaining a two-metre distance from others is a reasonable and cautious threshold for droplet transmission.
- To stay healthy and to protect ourselves and others, we must be mindful of the ever-present risk of exposure to the virus. Some settings and situations increase the risk, such as being in:
 - **closed spaces** with poor ventilation;
 - **crowded places** with large numbers of people gathered; and
 - **close contact** where you cannot keep two metres apart from others.
- It is critical that Canadians continue to practise the proven measures to reduce the risk of spreading COVID-19. This means:
 - stay home and away from others if you are sick,
 - wash your hands often with soap and water for at least 20 seconds,
 - avoid touching your face,
 - cover your sneeze and cough with a tissue or your sleeve,
 - maintain a physical distance of two metres from others,
 - wear a non-medical mask or face covering in settings where maintaining a two-metre physical distance is not possible or unpredictable, such as public transit, stores and shopping areas,

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- clean and disinfect surfaces and objects, and
- protect those most at risk.
- Since those who are infected with COVID-19 may have little to no symptoms, and recognizing that physical distancing in some settings may not be possible, using a "layered" approach with multiple public health measures will help to reduce the risk of spreading COVID-19.
- The Government of Canada has developed these recommendations based on the best available evidence to protect the health and safety of Canadians. We will continue to reassess and update our recommendations as we learn more about COVID-19.

Prime Minister Trudeau and some of his ministers attended the anti-racism protest

- Canadians have the legal right to protest.
- The right to protest peacefully is an important part of Canadian democracy, and it is up to each person to decide how and when to exercise that right.
- During this ongoing pandemic, expressing one's right to protest should be done as safely as possible by following local public health advice.
- The Public Health Agency of Canada continues to recommend that Canadians consider the risk to themselves and others, especially people at higher risk of severe illness, and that Canadians consider a virtual means of expression.
- If you do attend large gatherings, it is important to follow public health measures. This includes wearing a non-medical mask or face covering, practising physical distancing from others, using hand sanitizer frequently, and minimizing shouting to prevent the spread of transmission via respiratory droplets.
- People who participated in protests last week should self-monitor for symptoms for the next 14 days, and follow the advice of their provincial or territorial public health authority on when to seek testing.
- Anti-black racism, racism against Indigenous people and racism against other minorities negatively affects their health and safety.

If pressed

- The Prime Minister was following public health advice as he wore a non-medical mask, brought hand sanitizer and took the necessary precautions to limit his exposure to COVID-19.

Be Prepared

- There are simple, practical things you can do to prepare in case you or someone in your household becomes ill or if COVID-19 becomes common in your community.
- Make a plan that includes:
 - Have essential supplies (a few weeks' worth) on hand so you will not need to leave your home if you become ill.

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- Avoid panic buying. Add a few extra items to your cart every time you shop. This places less of a burden on suppliers, and can help ease financial burden on you as well.
- Renew and refill your prescription medications.
- Alternative arrangements in case you become ill or if you need to care for a sick family member. For example:
 - Have backup childcare in case you or your usual care provider become ill.
 - If you care for dependents, have a backup caregiver in place.
 - Talk to your employer about working from home if possible.
- We are aware that the novel coronavirus can cause a range of mild to severe symptoms. It is possible that individuals will not recognize when they first develop symptoms, because they can be similar to a cold or flu.
- If you have symptoms (fever, cough or difficulty breathing) and suspect you may have COVID-19, contact a health professional before arriving in person so that the appropriate measures can be taken when you arrive.
- Do not go to a health care provider without calling ahead so that appropriate measures can be taken when you arrive.

Stay informed

- Go to credible sources for up-to-date information and advice:
 - the [Canada.ca/coronavirus](https://www.canada.ca/coronavirus) web page;
 - the national toll-free phone number (1-833-784-4397) for COVID-19;
 - Government of Canada Twitter, Facebook and LinkedIn social media accounts; and
 - provincial, territorial and municipal government websites and social media accounts.

Science Disinformation

- Misinformation and disinformation remain an ever-growing threat to trust in democratic institutions. It leads to conflicting messages, public confusion and mistrust of science and science-informed policies.
- Throughout the COVID-19 pandemic, there have been false or misleading claims surrounding COVID-19, for example on the origin of the virus, transmission, diagnosis, prevention, treatment and even the underlying science.
- Over the past few months, we have been learning more and more about the coronavirus that causes COVID-19. The Government of Canada has been working around the clock to ensure a steady flow of timely, evidence-based information to Canadians about the coronavirus and COVID-19, based on the latest scientific data.
- This effort includes almost daily press briefings, in which Dr. Theresa Tam, Canada's Chief Public Health Officer, provides the latest updates on COVID-19 in Canada. Our goal is to ensure that Canadians always have the most up-to-date information and offer practical advice on how Canadians can stay healthy and protect others.
- The Government of Canada has also implemented a comprehensive national public education campaign for COVID-19. The campaign includes television, digital, radio and print advertising; social marketing using platforms such as YouTube, Instagram and Spotify; an information mail-

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out to households across Canada; the establishment of partnerships; and targeted outreach to at-risk populations.

- Canada.ca/coronavirus is updated daily with the latest information. Updates and tailored responses are provided to Canadians on a daily basis through Facebook, Twitter, Instagram and YouTube. Responses are also developed and used to help support social media responses to address misinformation.
- Health Canada and the Public Health Agency of Canada have regularly published social media posts addressing misinformation, using hashtags such as #COVID19Question, #thinkbeforeyoushare and #misinformation, with messages:
 - encouraging followers to consult trustworthy sources,
 - addressing specific misinformation,
 - promoting advisories that address the misinformation, and
 - reminding followers that there is no cure for COVID-19.
- The Canada COVID-19 mobile application, launched in April, provides Canadians with easy access to the information they need about COVID-19. The app is a central resource to be used for accessing trusted, evidence-based information about the COVID-19 pandemic across Canada.
- In addition, scientists at Health Canada and the Public Health Agency of Canada provide leading-edge, world-renowned research and expertise that helps save and improve lives in Canada and around the world. They publish their findings in peer-reviewed scientific journals to ensure that evidence-based information is available to inform public policy. Their work is translated into plain language to share these discoveries with Canadians and media through many sources, including science blogs.
- The Government of Canada, through the Canadian Institutes of Health Research, is funding several research projects that are investigating how to identify and respond to misinformation and disinformation, and how to cope with the “infodemic” of content on COVID-19 being distributed through websites, news media and social media. This research will help public health agencies develop public information campaigns and help Canadians assess the credibility of information sources.
- On March 27, Health Canada issued a public advisory to warn Canadians about the risks associated with products making false and misleading claims related to COVID-19. Canadians are encouraged to report any information on potential false and misleading advertising or the sale of products that have not been approved by Health Canada to the Department using Health Canada’s online complaint form.
- The Government of Canada has been tackling this complex issue of misinformation and disinformation for several years, and is using lessons learned about vaccine hesitancy and from the 2019 measles outbreak to continue to examine and mitigate the impacts of misinformation and disinformation related to COVID-19 and for future pandemics.

Enforcing Isolation and Quarantine (Self-Isolation)

- For questions regarding whether Canada would ever consider fining or arresting individuals who are not following the advice to self-isolate:

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- We are asking Canadians to **do the right thing** and to continue to stay home, if possible, and to practice physical distancing if they leave their home.
- Canadians need to understand the role that they play personally and the potential risk that they may have been exposed to the virus during any travel outside the country and the risk that they in turn may pose to other Canadians including the most vulnerable.
- Canadians need to also respect any guidance given to them by local public health and, if they are sick, they need to stay home.
- The failure to comply is a real concern. Individuals who are asked to self-isolate should take this seriously and stay home. If there is a need to leave home for food and/or medication, efforts should be made to ask a friend or family member to help out.
- For Canadians not self-isolating, there will continue to be the need to leave their homes for essential items like food and medication. As long as individuals do not have COVID-19 symptoms, people can also continue to get fresh air and exercise outdoors while practicing physical distancing.
- This will help protect older adults and medically vulnerable people who are at greatest risk of severe COVID-19 disease. We need to help as many Canadians as possible to stay healthy.

If pressed:

- There are some very powerful measures under the Quarantine Acts within every level of government, to help enforce measures to protect the health and safety of Canadians. A number of provinces and territories have put in place mandatory self-isolation orders.
- Such extreme action could take place, but we are not at that point and we continue to expect Canadians to help their neighbours, friends and family by continuing to stay at home as much as possible, wash their hands often and avoid close contact with people who are sick.

Criteria for individuals to discontinue home isolation after COVID-19 symptoms

- Based on the latest science and in consultation with provincial and territorial experts, we have updated the guidance on when individuals can end a period of home isolation following the presence of COVID-19 symptoms.
- The new guidance recommends that an individual in home isolation, who had symptoms consistent with COVID-19, can end home isolation a minimum of 10 days after the onset of their first symptoms, provided they are feeling better and do not have a fever.
- The 10 day minimum is based on when these people are no longer expected to be able to spread the virus to others. Some people can have a persistent cough after an illness like COVID-19 and we do not want to keep them isolated longer than necessary.
- This new guidance means that an individual on home isolation no longer needs to have two negative COVID-19 tests 24 hours apart once they no longer exhibit symptoms consistent with COVID-19.

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- This change does not apply to hospitalized patients.
- Provinces and territories may impose a longer period of isolation. Individuals who work in health care settings may need to meet additional requirements, as set out by their employer or provincial/territorial jurisdiction, before they are able to return to their workplace.
- Everyone has to contribute to reducing the spread of COVID-19 in Canada and flattening the curve. Using tried and true measures such as continuing to practise physical distancing once home isolation has ended will help our overall public health efforts and protect Canada's most vulnerable people.

If pressed on why the criteria are being changed

- Across Canada, we need to strategically use laboratory testing resources.
- This change to the approach for laboratory testing will help ensure the best use of limited health and laboratory resources.
- Not all persons on home isolation with symptoms consistent with COVID-19 require a laboratory test to confirm or rule out infection, provided they adhere to strict home isolation guidance.
- The updated criteria will allow the provinces and territories to recommend a period of home isolation for individuals with symptoms consistent with COVID-19 without requiring multiple laboratory tests.

If pressed on how the time period was decided upon

- The research and data on COVID-19 continues to grow and evolve.
- One unpublished study found that when scientists tried to find live virus in specimens from people who had COVID-19, no live virus could be found by the eighth day after onset of illness/symptoms. When these same people were tested using a different test (polymerase chain reaction (PCR)) several of them still came up as positive because that test can detect both live and dead virus.
- This means some people can test positive even though they are no longer at risk of spreading the virus to others.
- In the absence of a large amount of conclusive data, a minimum of 10 days of home isolation is an appropriate recommendation at this time.

If pressed on whether the new criteria are more or less stringent than previous criteria:

- The new guidance replaces the current, more stringent and resource intensive, requirement for individuals to receive two negative tests before being allowed to end home isolation.

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Announcement of funding to support voluntary isolation program for COVID-19

- The Government of Canada is taking action to prevent the spread of COVID-19 in our communities and across the country.
- The Public Health Agency of Canada is investing \$13.9 million in funding over 12 months for Toronto Public Health to operate a voluntary self-isolation centre.
- When presenting with symptoms of COVID-19, self-isolation is one of the most effective ways to reduce the risk of spreading the virus. However, for some Canadians, crowded housing conditions and restrictive costs can make it unsafe or impossible to effectively self-isolate at home.
- Preliminary socio-economic data from Toronto Public Health and Public Health Ontario have revealed that lower-income neighbourhoods have been disproportionately affected by COVID-19, including its most severe outcomes. Individuals from these neighbourhoods may have more difficulty properly isolating themselves.
- This voluntary self-isolation site will assist individuals who live in crowded housing, or have insufficient space to allow for proper distance from household contacts, to self-isolate, thereby reducing the risk of spreading the virus to household contacts.
- Through its case and contact management process, Toronto Public Health will identify individuals to be offered transfer to the isolation site on a voluntary basis, based on eligibility criteria recommended by the Ontario Medical Officer of Health.
- While at the site, individuals will be provided with lodging, including bedding and other necessities, daily meals and incidentals, and daily check-ins by phone from a Toronto Public Health Communicable Disease Investigator.

Work environments/for employers

- Some situations may call for the use of a medical mask, for example, medical masks may be a more appropriate choice for some service providers, depending on their environment and their clientele.
- There may be some non-healthcare work settings for which medical masks may be more appropriate than non-medical masks. Masks may not be suitable for all types of occupations. Employers should consult with their Occupational Health and Safety team and local public health before introducing mask-wearing policies to the workplace.

WHO Guidance on Masks

- The World Health Organization (WHO) continues to update and modify its recommendations to public health decision makers based on emerging evidence and data. Their work enables Canada to continue doing risk-based analysis and making evidence-informed decisions.
- The Public Health Agency of Canada (PHAC), along with provincial and territorial counterparts and dedicated experts, is reviewing the WHO's recommendations to consider how they can

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further support us in providing the best and latest evidenced-informed advice to Canadians so that they can protect themselves and each other.

- The current Canadian recommendations continue to align with the key recommendations of the WHO:
 - Continue to practice the behaviours that are known to limit transmission, stay home and away from others if you are sick, wash your hands often, cover your cough with a tissue or your sleeve, practise physical distancing, and clean and disinfect surfaces and objects.
 - If worn correctly, a non-medical mask is an additional measure people can take to protect others around them.
 - A non-medical mask or cloth face covering **is recommended** in certain circumstances, particularly in crowded settings when it is not possible to keep the recommended physical distance from others.
- The WHO has now provided further information on the construction and use of cloth masks. PHAC is reviewing this information and will adjust its current information as required.
- Any adjustments to our current guidance will consider the benefits of specific construction materials or methods, as well as the potential challenges these may pose to access and availability of cloth masks.
- The WHO guidelines are only one of many resources that inform Canada's guidance on non-medical masks. We are also closely following the emerging scientific literature and the experiences of other jurisdictions.

With regard to the WHO guidance related to the use of medical-grade masks for use by people 60 years or older and those with underlying co-morbidities:

- The health of all Canadians is PHAC's highest priority.
- People with chronic disease, older adults and anyone at higher risk of serious illness should maintain a high-level of vigilance.
- The WHO emphasizes that it is important that medical-grade masks are reserved for health workers first.
- PHAC encourages those with underlying medical conditions to stay home as much as possible, to continue to avoid crowded settings and, if they must be in crowded community settings, to wear a mask or cloth face covering.
- PHAC is reviewing the updated WHO recommendations alongside other factors critical to consider in a risk-based analysis—such as setting, availability, feasibility—to determine whether and how those recommendations might apply in the Canadian context. At present, Canada does not have specific standards for non-medical masks.
- If people are wearing a non-medical mask or cloth face covering when in public spaces, it does not mean people can stop practising other public health measures. **A non-medical mask or face covering does not replace physical distancing and frequent hand hygiene, use of respiratory etiquette, and cleaning and disinfecting surfaces and objects.**

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- Please visit Canada.ca/coronavirus for information on the appropriate use of non-medical masks or face coverings. The website may be updated once new evidence is reviewed and assessed.
- Canadians should also follow the advice of their provincial or territorial public health authority.

If pressed on WHO guidance that refers to physical distancing of “at-least one-metre” apart vs. Canadian advice of two metres:

- Based on what is known about the transmission of COVID-19, as well as the Canadian context, PHAC continues to recommend that people keep a distance of at least two metres from each other to reduce the risk of spreading COVID-19 in public settings and places where people from outside your household are present.

How wearing non-medical masks can help protect others

- Wearing a non-medical mask is another way of covering your mouth and nose to prevent your respiratory droplets from contaminating others.
- A cloth mask or face covering can reduce the chance that others are coming into contact with your respiratory droplets, in the same way that our recommendation to cover your cough with tissues or your sleeve can reduce that chance.

Considerations when wearing non-medical masks

- Canadians need to understand exactly what wearing a mask will achieve, and that if they choose to wear non-medical masks they need to be used safely:
 - Avoid moving the mask around or adjusting it often
 - Masks should not be shared with others
 - If you choose to use a non-medical mask, it should be well-fitted (non-gaping)
- If wearing a non-medical mask makes you feel safer and stops you from touching your nose and mouth, that is good. Remember not to touch or rub your eyes as that is another route of infection.
- It is important to ensure you put on and take off your non-medical mask with clean hands, and wash your hands or use a Health Canada approved hand sanitizer if you do touch your face.
- Non-medical masks should be changed as soon as they get damp or soiled, and should be washed in hot water and dried thoroughly before re-using.
- People should also be aware that masks can become contaminated on the outside or when touched by hands.
- Non-medical masks or facial coverings should not be placed on young children under age 2, anyone who has trouble breathing, or is unconscious, incapacitated or otherwise unable to remove the mask without assistance.

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Please remember that non-medical masks will not prevent COVID-19 spread without consistent and strict adherence to good hygiene and public health measures, including frequent handwashing and physical distancing. The website Canada.ca/coronavirus is updated with information on the measures you should take, such as hand washing, when putting a mask on or taking it off. There is also information on how to wash cloth masks or safely dispose of other non-medical masks (such as dust masks).

Modelling and Surveillance:

Surveillance for COVID-19

- Canada's health system has been on high alert to detect possible COVID-19 cases for many weeks.
- Canada remains focussed on containment efforts to delay and slow the spread of COVID-19. We do this by rapidly identifying cases, meticulously finding close contacts and using proven public health measures such as isolation and recommending that Canadians practise physical distancing.
- Canada has a highly integrated federal, provincial and territorial approach to surveillance, involving front-line healthcare settings and laboratories across the country that have effectively equipped us to detect respiratory illnesses, including COVID-19.
- Public health laboratories across Canada are also working together to report COVID-19 test results weekly. These reports will allow us to monitor where COVID-19 is occurring, which can provide us with an early signal of potential clusters that can indicate community spread.
- Hospital surveillance is another important area for detection of COVID-19. These sites allow us to monitor for people with respiratory symptoms, including those with pneumonia or severe infections, even if they have not travelled to an affected country. This is another means of broadening the scope of our surveillance to identify signals of potential community spread so that public health authorities can take appropriate action.
- Finally, Canada has established networks of paediatricians and family doctors that are essential to surveillance. These networks include providers at the front line of primary care, who are often the first to detect new or unexpected patterns of illness that may be a first alert to an emerging health concern.
- It is by bringing data together from all these sources that we can detect signals and investigate transmission patterns to closely monitor the emergence and spread of COVID-19 in communities across Canada.

Modelling Data Update Update #8 (October 9, 2020)

- The Government of Canada continues to work with provincial, territorial and international partners to base our response to the COVID-19 epidemic on the latest science and situational assessment.

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- Recent trends show that epidemic growth in Canada is accelerating. Several regions are reporting consistent increases in cases and some others—in particular Ontario and Quebec—are seeing steeper increases.
- Our modelling forecasts the epidemic will resurge in the coming months if we do not lower our current rate of contacts.
- The collective actions of Canadians, public health authorities and government at all levels are needed to limit any potential resurgence while also allowing essential services, businesses and educational facilities to remain open.
- This will require ongoing effort and commitment from Canadians to adhere to physical distancing, practise protective measures and keep their number of close contacts low, and from public health authorities to rapidly test and isolate cases and trace and quarantine controls.
- Individual Canadians can contribute to controlling resurgence by:
 - maintaining physical distancing;
 - wearing masks or cloth face coverings when physical distancing is difficult and according to local public health instructions;
 - staying home if experiencing any symptoms, even if mild;
 - maintaining good hand and respiratory hygiene;
 - limiting time spent in closed indoor spaces, crowded places and close contact situations where there are inadequate measures, protocols and policies in place to reduce the risk of exposure; and
 - downloading the COVID Alert app, which helps notify users if they may have been exposed to someone who has tested positive for COVID-19.
- Controlling the spread of COVID-19 this fall and winter is possible, if we all continue to follow personal and community-based public health measures.

Supplemental Messages

- PHAC works collaboratively with the provinces and territories to gather epidemiological data so that Canada's public health response to COVID-19 is based on the most accurate information and best evidence available.
- We are also collaborating with federal, provincial and territorial governments and universities to model and explore the possible future spread of COVID-19 in Canada and the impacts of public health measures.
- Modelling helps us to evaluate and, if need be, adjust public health measures to control the spread of COVID-19.
- Models cannot predict what will happen. But they can help us understand what *might* happen in certain scenarios, which can help us plan and take actions to achieve the best possible outcome.

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- Modelling for COVID-19 requires that we make assumptions based on incomplete data and evolving science. These assumptions change as we get new information about the virus and more data about the epidemic in Canada.
- Just as case rates are different across the country, so too are projections about the impacts in various provinces and territories.
- We are continually improving the models to provide the best available information to Canadians about possible outcomes.

Government of Canada's support to La Loche, SK

- The Government of Canada is collaborating with provincial and territorial health authorities to help prevent the spread of COVID-19 in Canada, including in remote communities.
- The Public Health Agency of Canada has provided point-of-care testing devices authorized by Health Canada to La Loche, Saskatchewan, to assist with the outbreak of COVID-19 in the community.
- Indigenous Services Canada has also offered surge capacity support to First Nations on reserves impacted by COVID-19.

Support to Saskatchewan

- The National Microbiology Laboratory has provided the La Loche community with GeneXpert XpertXpress SARS-CoV-2 point-of-care testing devices and 46 test kits (each test kit contains 10 tests).
- The NML has also provided GeneXpert XpertXpress SARS-CoV-2 point-of-care testing devices and test kits to other remote communities in Saskatchewan:
 - All Nations Healing Hospital in Fort Qu'Appelle has received point-of-care testing devices and 8 test kits.
 - Île-à-la-Crosse has received point-of-care testing devices and 3 test kits.
 - La Ronge has received point-of-care testing devices and 3 test kits.
 - Hatchet Lake has received point-of-care testing devices and 2 test kits.
 - Stony Rapids in the Athabasca Region has received 10 test kits.
- The NML is prepared to ship at least an additional 70 test kits to Saskatchewan once the province has confirmed where these tests would have the greatest impact.

If pressed

- The Public Health Agency of Canada (PHAC) is working rapidly to allocate personal protective equipment (PPE) and medical supplies to the provinces and territories, as per an approach agreed upon by federal, provincial and territorial Ministers of Health.
- Provinces and territories can also request assistance from the National Emergency Strategic Stockpile (NESS) for critical needs. To date, in response to COVID-19, the NESS has responded to more than 40 requests for assistance.



- Provinces and territories provide PPE to Indigenous communities according to the allocation and guidelines in place in their jurisdiction.
- PHAC does not comment on the overall amounts of PPE an individual province or territory has received from the Government of Canada.

Virus epidemiology

- In Canada, and around the world, researchers are actively investigating all aspects of the novel coronavirus outbreak to further understand this disease and how the outbreak may progress.
- Canada is following the guidance of the WHO, which recommends a quarantine period of two weeks (14 days).
- The WHO noted on February 10, 2020, that it is not considering changing its recommended quarantine time.
- The World Health Organization (WHO) has cautioned that a 24-day incubation period could be an outlier or an unrecognized second exposure. An unrecognized second exposure is a situation where an individual already recognized as having been exposed to the virus is exposed to the virus again but this second exposure is not recognized. If they develop illness due to the second exposure it may mistakenly appear like the incubation period is longer than 14 days because the “clock” was not “re-set” at the time of the second exposure.
- To date, there has been no verified data to suggest the incubation period extends beyond 14 days.
- PHAC is an active participant in a number of expert groups that are examining how the disease is transmitted, developing models to predict how it may spread, and developing guidance for infection prevention and control based on the most recent information.
- The Public Health Agency of Canada (PHAC) continues to liaise with international partners, including the World Health Organization (WHO), to better understand the epidemiology of this disease.

COVID-19 Actual Transmission Rate

- The Government of Canada uses indicators to understand how effective our measures are at controlling the epidemic, such as illness rates, COVID-19-related deaths, testing rates and the actual transmission rate of the virus, called R_t .
- The actual transmission rate of a virus, called R_t (or the effective reproduction number at time t), refers to the average number of people one infected person is likely to infect at a particular time (t) during the epidemic.

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- R_t tells us how the virus is spreading in a particular population in close to real-time. This helps us adjust public health measures to keep transmission under control. The aim is to keep R_t under one.
- The actual transmission rate is based on COVID-19 rates and reflects transmission events that occurred 1-2 weeks earlier by the time it is calculated and reported.
- In addition, R_t can vary with different methods of calculation and with short-term variations in the number of reported COVID-19 cases.
- To understand of how public health measures are helping to flatten the curve, the actual transmission rate should be interpreted and used in conjunction with other measures of the status of an epidemic, such as trends in illness, hospitalizations, testing patterns and rates of contact tracing.

Pediatric multi-system inflammatory syndrome

- We continue to learn about COVID-19 and the ways that it can present. Some of the manifestations are very rare.
- A better understanding of pediatric multi-system inflammatory syndrome is needed. This syndrome appears to have occurred at higher rates in areas that have had a high number of COVID-19 cases.
- So far, there have been fewer cases of COVID-19 among children than in adults. However, children can have serious outcomes, so it is important that everyone take precautions to prevent infection.
- Parents and caregivers are advised to contact their health care provider if their child shows symptoms such as fever, lethargy, gastrointestinal illness and rash.
- The Public Health Agency of Canada is working with Canada's pediatricians to closely monitor the situation.
- Health care providers in Canada are aware of this potential syndrome and are on alert to identify cases.

Monitoring

- PHAC continues monitoring, intelligence gathering and international engagement to inform Canadian public health action.
- PHAC has multiple systems in place to monitor community spread and severe outcomes related to COVID-19 in pediatric populations.
- As part of PHAC's monitoring of COVID-19, the syndrome is being monitored through:
 1. a national reporting system where all cases are reported to provinces and territories, then to PHAC;
 2. a network of pediatric emergency department physicians in children's hospitals who report on COVID-19 cases; and

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3. the Canadian Paediatric Surveillance Program (CPSP), a collaboration between PHAC and the Canadian Paediatric Society.

- To increase the available data concerning this emerging condition, the CPSP COVID-19 monitoring protocol is being modified to capture cases of multi-system inflammatory syndrome even in the absence of a positive test for COVID-19.

Rates of COVID-19 in Children

- Our understanding of the virus continues to evolve. At this time, there is still much we do not know about how easily children are infected, and the extent to which they spread the virus.
- There is an overall downward trend in newly reported cases in all age groups. The proportion of new reported cases during the week of June 11 to 17, 2020, was slightly higher for younger Canadians, but the overall numbers are still declining.
- These changes in age range may be related to the gradual reopening of activities across the country, and outbreaks in non-health-related workplace settings.
- So far, there have been fewer cases of COVID-19 among children than in adults. Nevertheless, children can also have serious outcomes, so it is important that everyone take precautions to prevent infection.
- The Public Health Agency of Canada (PHAC), in collaboration with provincial and territorial public health authorities, has released a risk mitigation tool for child and youth settings operating during the COVID-19 pandemic.
- The risk mitigation tool will help those responsible for child and youth settings to better understand the COVID-19 risks in those settings, and what measures can be implemented to mitigate the risks. This tool should be used alongside and in support of guidance from provincial and territorial health authorities, ministries of education and Indigenous community governance structures.
- Canada's public health advice will continue to be based on science and will be updated as it evolves.

Supplemental Messages:

- PHAC has multiple systems in place to monitor community spread and severe outcomes related to COVID-19 in pediatric populations.
- As part of PHAC's monitoring of COVID-19, we are working through:
 - a national reporting system where all cases are reported to provinces and territories, then to PHAC;



- a network of pediatric emergency department physicians in children's hospitals who report on COVID-19 cases; and
- the Canadian Paediatric Surveillance Program (CPSP)—a collaboration between PHAC and the Canadian Paediatric Society.

Canadian Paediatric Surveillance Program Commentary on Hospitalizations from COVID-19 Among Children in Canada

- The Canadian Paediatric Surveillance Program (CPSP), a joint program of the Canadian Paediatric Society and the Public Health Agency of Canada (PHAC), launched a COVID-19 surveillance study this past spring.
- PHAC worked closely with paediatricians across Canada to capture information about the impact of COVID-19 on high-risk children, such as those hospitalized with acute COVID-19, and those who, though not hospitalized, may be at greater risk of complications due to underlying medical conditions.
- So far, the findings suggest that severe complications in children due to COVID-19 have been rare. These findings are consistent with the data being reported by the provinces and territories.
- To date, there have been fewer cases of COVID-19 among children than in adults. Nevertheless, children can also have serious outcomes, so it is important that everyone take precautions to prevent infection.
- PHAC has multiple systems in place to monitor community spread and severe outcomes related to COVID-19 in paediatric populations.
- As schools and daycares are reopening in Canada, PHAC will continue to closely monitor the impact of COVID-19 on children and youth.
- PHAC's public health advice will continue to be based on latest science and will be updated as it evolves.

Supplementary on Guidance:

- In June, PHAC, in collaboration with federal, provincial and territorial public health authorities, released a new tool to help organizers evaluate and mitigate risks for #COVID19 in outdoor recreation spaces and activities.
- The tool is helping those responsible for child and youth settings to better understand the COVID-19 risks in those settings, and what measures can be implemented to mitigate the risks. This tool should be used alongside and in support of guidance from provincial and territorial health authorities, ministries of education and Indigenous community governance structures.
- In August, PHAC, in collaboration with Canadian public health experts and education stakeholders, has developed guidance for administrators of schools from kindergarten to grade 12 and local public health authorities to support the safer resumption of in-school educational programming during the COVID-19 outbreak.

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- The school guidance document should be used alongside guidance from provincial and territorial health authorities, ministries of education and Indigenous community governance structures.
- This guidance is based on current scientific evidence. Recommendations may change as new evidence emerges, as we learn from the experiences of other jurisdictions as they lift restrictions, or as treatment options or vaccines become available.

If pressed on potential health risks to children congregating in school settings:

- Emerging evidence currently suggests that the virus can spread in all age groups. Children over 10 years old may be as likely as adults to transmit the virus to others. Children under 10 years may also transmit the virus, but appear to be less likely to do so than adults.
- Children, especially those below 10 years of age, appear to experience less severe symptoms due to COVID-19 and they form a small proportion of reported cases to date.
- As no vaccines are available to prevent COVID-19 at this time, both personal and community level public health measures remain essential to preventing the spread of infection.

We recommend using a layered approach of multiple mitigation measures to reduce the risk of COVID-19 spread, including decreasing the number of interactions with others and increasing the safety of interactions.

COVID-19 Becoming an Endemic Virus

- COVID-19 is a new virus. While we are accelerating efforts to make future treatments and vaccines available, accessible, and affordable to all, it is going to take time.
- The COVID-19 pandemic has resulted in a global review of therapies that may be used to treat or prevent the disease. However, like many other viral respiratory infections, COVID-19 may be here to stay and a vaccine will be needed to help protect against this virus in the long term.
- Scientists in Canada and around the world are working hard to develop a vaccine to help prevent people from getting COVID-19, in addition to working on treatments for people who become sick, including early supportive therapy, management of symptoms and prevention of complications.
- Once a vaccine does become available, it is expected that it will provide protection similar to other vaccines that exist today.
- An example of Canada's participation in global efforts to advance treatment of COVID-19 for individuals who have the disease includes the SOLIDARITY trial—a multinational trial coordinated by the World Health Organization that is testing multiple potential drugs for the fight against COVID-19.
- This unprecedented multinational trial to test potential treatments for COVID-19 is a new model for global collaboration, with the goal of being able to quickly identify treatments that could reduce the toll of COVID-19. The Canadian arm of this study has already begun enrolling patients, which will see up to 20 sites recruited across Canada.

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- At the same time, we are moving quickly to develop a vaccine to prevent the spread of COVID-19 and people becoming ill in the first place. Through the Canadian Institutes of Health Research (CIHR) Rapid Research Response program, the Government of Canada has invested a total of \$54.2 million to support 99 research teams across the country.
- These teams are focusing on developing and implementing measures to rapidly detect, manage and reduce the transmission of COVID-19. This includes research into a vaccine, as well as the development of strategies to combat stigma, misinformation and fear.
- While we wait for a vaccine and continue to advance efforts to treat COVID-19, it is important that people do everything under their control to prevent the spread of the virus such as:
 - staying home and away from others if you are ill
 - washing your hands frequently
 - covering your cough with a tissue or your sleeve
 - practising physical distancing
 - cleaning and disinfecting surfaces and objects

If pressed:

May 15, 2020, Health Canada approved a clinical trial application from CanSino Biologics for a COVID-19 vaccine. This is the first clinical trial application in Canada for a vaccine specifically designed to prevent COVID-19

COVID-19 – Airborne and Aerosol

- Aerosol transmission of COVID-19 in ventilated and unventilated environments continues to be studied.
- What we know from the current body of evidence is that the virus that causes COVID-19 is mainly transmitted by droplets produced by an infected person coughing, sneezing, talking, shouting or singing.
- There have been situations where aerosol transmission in closed settings has occurred.
- Respiratory virus transmission occurs on a spectrum—from large droplets transmitted in close contact with others, to smaller droplets called aerosols. It is these smaller droplets or aerosols that have the potential to be suspended and infect others nearby.
- Aerosol transmission refers to when the very small droplets containing the virus that are released when an infected person coughs, speaks, talks, shouts or sings, are suspended in the air for a period of time and breathed in by another person. How often this occurs, and under what conditions is not known.
- This virus does not appear to be airborne, meaning it does not spread or circulate from one room to another through air ducts, for example.
- Fresh air disperses the virus so that it is diluted and inactivated. That is why outside is better than inside and why it is good to ventilate indoor spaces with air drawn from the outside. Whenever possible, increase fresh air coming from the outside by opening windows. Always use multiple layers of public health measures for protection.

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- Our advice remains the same: to reduce your risk of infection, limit time spent in closed places, crowded places and close contact situations where there are no controls, protocols, or policies in place to reduce the risk of COVID-19 like good ventilation. Maintain physical distancing, practice frequent handwashing, and wear a non-medical mask or face covering when you can't keep two metres distance from others. Using multiple layers of protection is safest.

If pressed on if PHAC is going to change its guidance to Canadians

- Evidence reviews are underway. Based on the science, we are always prepared to change our guidance on the risks of transmission and what additional steps Canadians can take to prevent the spread and to protect themselves.

If pressed on how easily the virus spreads

- Information suggests that COVID-19 is spreading more efficiently than influenza, but not as efficiently as measles, which is highly contagious. In general, the more closely a person interacts with others and the longer that interaction, the higher the risk of COVID-19 spread.

If pressed on aerosol transmission

- The amount of exposure and circumstances under which infection can occur with aerosols is unknown, though inadequate ventilation is known to play a role.
- Validating effective aerosol transmission in real world settings is very complex, thus making it difficult to rigorously assess COVID-19 infection risk from aerosol transmission.
- By studying some of the outbreaks that have occurred, we have learned that the ability of COVID-19 to transmit doesn't appear to be uniform. In some cases, very few contacts become infected despite prolonged contact, but in some other situations many people can get infected at one event.
- Most scientific evidence indicates that transmission of COVID-19 is predominantly among close contacts however, there is some evidence that suggests aerosol transmission has occurred.

If pressed on the CDC posting then retracting information about aerosol transmission

- We cannot comment on the actions of the CDC.

COVID-19 – Swimming and risk of transmission

- The Public Health Agency of Canada continues to evaluate new evidence as scientific information on COVID-19 becomes available.
- There is no evidence that COVID-19 can spread through the water. However, it can spread from person to person through close contact and contaminated surfaces in and around public swimming areas.



- To reduce the risk of spreading COVID-19, it is important to practice physical distancing and limit close contact with others while on pool decks or swimming in crowded areas such as public beaches and pools.

Testing for COVID-19 in Canada

- We continue to **test at a very high rate** in Canada—one of the highest rates in the world.
- Our focus to date has been to **test people who present with symptoms** and those in **high-risk situations**.
- This includes people working in **healthcare settings, long-term care facilities, correctional facilities** and situations where a positive case is connected to a **high-risk setting** that could lead to an outbreak.
- As we move into the next phase of lifting some public health measures and re-opening some parts of the economy, cases of **COVID-19 will still occur** until the population has enough immunity or a vaccine is available to prevent the disease.
- COVID-19 will be part of our lives, and **testing will remain an important tool** to detect and isolate new cases, follow up with close contacts, stop spread of the virus and prevent outbreaks in the community.
- High-risk settings, such as long-term care facilities, continue to report cases and outbreaks at a worrisome rate. In this next phase, **testing will be critical for groups that are more vulnerable to complications from COVID-19**. This testing will be an early warning for our healthcare system.
- **More testing doesn't mean a faster return to regular activities**, or to everyday life as it was before COVID-19. **Testing is not a replacement for public health measures**.
- There is no specific number of daily tests that would allow us to ease public health measures equally and at the same time across Canada. **The epidemic varies across** provinces and territories and even within jurisdictions.
- We also need to **test smartly**. People can be infectious before they have symptoms, while they have symptoms and even without having any symptoms at all. It doesn't make sense to use all our resources and testing supplies when or where there are a low number of cases and no signs of community transmission.
- **The timing of testing is critical**. A negative test does not indicate whether someone has been exposed, which can leave individuals with a false sense of security. Individuals can still become infectious in the days following the test. It is best to test someone five or more days after a potential exposure.
- As of June 16, we are averaging 37,287 **tests daily** in Canada. This number continues to grow.

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- Canada has been maintaining a 4% to 7% positivity rate, which is within the range needed to **accurately detect** where the disease is circulating.
- If Canada were to drop below a 3% positivity rate—for example, to 1%—it would mean that we were **casting our net too widely** by testing a lot of people who might not otherwise need testing, such as:
 - people who are not in an area of Canada where the disease is circulating; or
 - people who are being tested too early.
- The amount of testing and the positivity rate show that we currently have a **highly sensitive testing system**. We continue to increase our laboratory capacity to keep things that way.
- Health Canada has been working with manufacturers to enable market access for commercial diagnostic devices in order to **increase Canada's COVID-19 diagnostic capacity**.
- The Minister of Health signed an Interim Order, as an emergency public health measure, to allow expedited access to COVID-19-related medical devices. With the Interim Order, **new diagnostic tests are being made available in Canada**. They are listed on Health Canada's [website](#).
- New diagnostic tests will permit **faster and more convenient testing** of patients in Canada.
- **We have to stay the course and stick with the measures we know are working**. No matter the level of testing where you live, to prevent the spread of COVID-19, every Canadian needs to:
 - **Stay home and away from others when sick;**
 - **Wash their hands frequently;**
 - **Clean common surfaces with an appropriate disinfectant;**
 - **Protect vulnerable people; and**
 - **Practise physical distancing.**
- The wearing of a non-medical mask or face covering is also **recommended in crowded public settings and for periods of time when it is not possible to consistently maintain a 2 metre physical distance** from others.

Reagents and Testing for COVID-19

- There are several Health Canada-approved commercial reagents that can be used for testing for COVID-19 infection. There is a global shortage of many of these reagents, and this affects laboratory capacity. We need made-in-Canada solutions to tackle this problem.
- Shortage of reagents required for COVID-19 testing is affecting Canada's testing capacity. The Public Health Agency's National Microbiology Laboratory has developed a reagent to help address this shortage. This reagent is being mass-produced by Luminultra Technologies Ltd., a New Brunswick-based company.
- PHAC has also signed a temporary licence agreement with bioMérieux Canada, to receive the rights and formulation for its reagent that is used in COVID-19 diagnostics.

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- The Government of Canada's testing priorities are accessing testing reagents, evaluating commercial testing technologies, and accessing authorized test kits in order to equip provinces and territories to expand their testing.

On Luminutra

- Scientists from Canada's National Microbiology Laboratory (NML) have replicated and validated a commercial COVID-19 reagent using open source information. This reagent is comparable to those used in diagnostic laboratories across the country.
- Luminutra Technologies Ltd. is purchasing the raw ingredients needed to develop the NML-formulated batches of reagent, and is coordinating the shipment of the reagent to public health laboratories across the country.
- Luminutra shipped its first batch of reagent on April 10, 2020.
- At full capacity, Luminutra will be able to manufacture reagent for up to 500,000 tests a week.
- It is expected that, as its production capacity scales up, Luminutra will be able to produce enough reagent to help meet national demand.

On the bioMérieux agreement:

- bioMérieux is a French company that produces reagents used in COVID-19 diagnostic testing. The company is facing challenges obtaining certain ingredients needed to manufacture and meet global demand of its product.
- In an innovative public-private partnership, the Public Health Agency of Canada has signed a temporary licence agreement with bioMérieux Canada at no cost, to receive the rights and formulation for their reagents that are used in COVID-19 diagnostics. The production systems to produce these reagents are in various stages of development and testing, with the goal of alleviating some of the shortages of reagents in the near future.

What are reagents?

- A reagent is a chemical formulation used to process specimens for laboratory testing.
- The specific reagents being produced for COVID-19 testing are extraction reagents.
- They extract the virus from a specimen so that the genetic material can be detected, and determine whether a patient is positive or negative for COVID-19 infection.

Point-of-care testing devices to detect COVID-19

- The Public Health Agency of Canada's (PHAC) National Microbiology Laboratory (NML) is working in collaboration with provincial and territorial public health laboratories to ensure high-quality diagnostic testing for COVID-19.



- Point-of-care diagnostic devices allow testing to occur in alternative healthcare settings and do not require shipping a specimen to a lab for analysis. This allows for quicker test results for patients.
- Quicker test results enable healthcare providers and patients to take appropriate actions, such as treating, contact tracing and isolating positive patients more rapidly to help reduce the spread of the disease.
- Point-of-care testing is essential for northern, remote and isolated communities, as well as specific high-risk settings where it is important to have test results quickly without having to send samples to a laboratory.
- Deploying diagnostic testing at the community level, especially in northern and isolated communities, will help address the testing gaps in underserved communities where laboratory testing is difficult to access.
- Health Canada authorized point-of-care tests after completing a scientific review that is supported by evidence to ensure that the tests will provide accurate and reliable results. The NML and its provincial partners often contribute by assessing tests and sharing test results with Health Canada.
- A complete list of testing devices for use against COVID-19 is available on Health Canada's website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html>.

Specifics on the role of the NML

- The NML is providing critical scientific leadership for Canada's response to COVID-19. This includes coordination with provincial and territorial governments and laboratories, as well as Indigenous Services Canada, to deploy point-of-care testing devices and supplies to rural and remote settings.
- NML scientists are exploring the best way to increase capacity of these devices through innovative testing approaches such as sample pooling.
- The NML has conducted 10 remote and in-community training sessions for healthcare professionals who will be using the point-of-care devices.
- These training sessions provide valuable hands-on experience to those who will be operating the instruments.
- The NML offers ongoing support and technical advice for those using the devices. Part of this support is a robust quality assurance program to provide confirmation that the devices are providing reliable results on a consistent basis.
- The NML has undertaken scientific studies of point-of-care diagnostic tests and supplies to support provincial laboratories in their decisions on adopting these tests for use in clinical settings. These studies are done in collaboration with provincial laboratories and clinical

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researchers to determine how well a test performs under actual clinical conditions. The test results are shared with Health Canada for consideration in the scientific review of applications for authorization under the Interim Order for Expedited Access to Medical Devices for COVID-19.

- Results on the performance of diagnostic tests are shared with manufacturing companies, all provincial laboratories, and Health Canada to add to the evidence on the accuracy of diagnostic tests.
- The NML's priorities continue to be accessing testing reagents, evaluating rapid point-of-care tests, and accessing authorized test kits to help ensure that provinces and territories are equipped to ramp up testing according to their requirements.

What is a point-of-care diagnostic test?

- Point-of-care diagnostic tests are done at the time and place of care, such as a hospital or a doctor's office, and do not require samples to be sent to another laboratory.
- Molecular point-of-care tests to detect active infections of COVID-19 are similar to the polymerase chain reaction (PCR) tests used in regular laboratories as they also use a swab to collect samples from the nose or throat.
- Samples are then loaded into an on-site point-of-care device—an automated diagnostic testing device that detects DNA sequences—such as a GeneXpert instrument. The test results are ready in 30-60 minutes. A laboratory professional is not needed to perform the test.
- Point-of-care technologies provide an innovative approach to accessing diagnostic testing services for communities and populations that experience challenges with conventional laboratory methods.

On availability of COVID-19 point-of-care testing equipment and supplies

- There is a global shortage of supplies for COVID-19 point-of-care testing.

Health Canada has approved one point-of-care device for COVID-19 diagnosis for commercial distribution: the Xpert Xpress SARS-CoV-2 test by Cepheid

- There is one application for a promising point-of-care test that is currently under review; and the Department is anticipating another application before the end of June.
- Scientists at the NML are exploring the best way to optimize point-of-care testing supplies and determine a national distribution strategy to meet the needs of those most at risk.
- PHAC is committed to continuing to provide a supply of COVID-19 tests to provinces and territories on an ongoing basis. The current allotment of Xpert Xpress SARS-CoV-2 test devices and reagents remains limited, as there is a global shortage of point-of-care testing supplies.
- Once PHAC receives an increase in devices and test cartridges and the necessary supplies become available, phased expansion of Xpert Xpress SARS-CoV-2 testing can be considered.

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On Sample Pooling

- Sample pooling is a diagnostic approach that involves grouping of samples in batches before running them through testing machines. If a negative result is received for the batch, laboratory professionals can rule out all the samples as having tested negative. If the batch tests positive, each sample is tested individually to determine the positive(s).
- Sample pooling is an approach used to increase throughput and conserve laboratory supplies. The challenge is to ensure that results are still accurate (i.e., specific and sensitive). Laboratory professionals must conduct research studies to confirm accurate results before sample pooling is implemented.
- NML scientists have conducted research studies and have verified that pooling laboratory specimens for point-of-care devices used in remote and clinical settings provides accurate results. This is a very important discovery as there is a global shortage of laboratory supplies for these devices and pooling will help extend resources.

On specific deployment plans

- As of June 9, NML has deployed 28 testing devices across remote communities:
 - 1 to British Columbia
 - 5 to Saskatchewan
 - 5 to Northern Manitoba
 - 3 to Northwestern Ontario
 - 2 to Nunavut
 - 3 to Northwest Territories
 - 3 to Yukon
 - 3 to Quebec
 - 3 to Newfoundland and Labrador
- The devices are being deployed based on a needs analysis—in coordination with provinces and territories and Indigenous Services Canada—to get devices to communities that are at greatest risk if there were to be an outbreak of COVID-19.
- The risk is assessed based on remoteness, proximity to centralized laboratories, and logistical challenges with transporting samples due to weather and frequency of flights. Risk assessments are also based on the demographic of community members for those at greatest risk of COVID-19 complications.

On Devices in Northwest Territories

- As of June 8, PHAC has provided two GeneXpert Quad point-of-care testing devices and one 16-channel GeneXpert testing device to the Northwest Territories (NWT), along with a supply of test cartridges (160 tests) for COVID-19.
- PHAC is committed to continuing to provide a supply of COVID-19 tests to NWT on an ongoing basis. The current allotment from the company to PHAC remains limited, as there is a global shortage of point-of-care testing supplies. PHAC maintains a regular dialogue with NWT, and the other provinces and territories, regarding their testing needs and practices.

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Testing individuals

- Testing for the novel coronavirus in symptomatic individuals has clear clinical and public health value, but the same is not true for testing asymptomatic persons.
- Canada has and will continue to test all symptomatic individuals, as part of our evidence-based approach, while considering the evolving science on other testing scenarios. As the science evolves, our approach will keep pace, and policies and protocols will be updated accordingly.
- One thing that is clear in our approach is that we test all symptomatic individuals and our threshold for that has been very low.
- It is important to understand that this is not a simple or straightforward issue, and the science is not clear.

National Approach to Laboratory Testing for COVID-19

- In Canada, although there are regional differences across the country, there are signs that our collective efforts are helping to slow down the COVID-19 epidemic.
- COVID-19 will continue be part of our lives, and **testing will remain an important tool** to detect and isolate new cases, to support follow up with close contacts and to prevent outbreaks in the community. Access to testing is an essential aspect of monitoring for a resurgence of cases as time goes on and people start to resume daily activities, so that early interventions to prevent further spread can be taken.
- Testing also plays an important role in **informing the public health actions** we take. Changes to the number of cases help inform these actions. For example, a decrease in positive test results can assist with decisions on lifting public health measures while an increase in the number of positive test results in a specific community, may lead to prolonging or reintroducing measures to prevent further spread of infection in that community. .
- The Public Health Agency of Canada (PHAC) has developed guidance, to support a **national approach to testing in Canada** and to optimize the use of local resources in protecting the health of Canadians across the country. This guidance has been approved by the Federal, Provincial and Territorial (FPT) Special Advisory Committee on COVID-19.
- Regional differences in the epidemiology of COVID-19, and the public health response will determine how individual provinces and territories implement this guidance, taking the local context into account.
- When it comes to testing for COVID-19, there are **different types of tests** that are used for different purposes.

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- **Molecular tests** detect the presence of the SARS-COV-2 virus and are used to diagnose COVID-19 infection. Samples are taken from the nose or throat with swabs and sent to a laboratory for analysis. Many samples can be tested together in a laboratory with the appropriate equipment, with results ready in 1 to 3 days. This diagnostic technology is considered the most effective and efficient way to test a large number of submitted samples. This allows public health authorities to take action to stop further transmission.
- The guidance recommends **prioritizing people with symptoms of COVID-19, even mild ones**, for molecular testing to diagnose the illness in individuals.
- Testing people **who have symptoms** allows us to:
 - identify, isolate and provide care for individuals with COVID-19;
 - identify contacts of the case; and
 - implement public health measures to stop further transmission.
- As the incidence of new infections decrease, testing all symptomatic individuals will also help to determine if community transmission is still occurring or if there are new sources of community transmission.
- Testing people who have symptoms is also **the best strategy** because the tests provide more accurate results when symptoms are present.
- The ability of molecular tests to correctly identify those who truly are infected with the virus that causes COVID-19 is linked to the amount of virus or viral load within the person being tested.
- When a person who has been infected has a low viral load, which can occur in the very early stage of the disease or during the recovery phase, a test could give a **false negative** result. In other words, the virus could be present in the individual, but not be detected through testing during some stages of the illness.
- Test results are used to guide individual patient management, as well as population based public health measures. Therefore, false negative test results could, at the individual level, lead to patients not being managed appropriately or feeling a false sense of security and not following public health measures (e.g., hand/cough hygiene, physical distancing, etc.) and unknowingly spreading the virus to others. At the population level, such false negative test results could lead to public health measures possibly being lifted too soon.

For a Technical/Clinical Audience:

There are important limitations to molecular testing:

- *Sensitivity varies throughout the disease course: the accuracy of the PCR test is directly related to the presence of viral genomic material. Some studies suggest that the peak viral load occurs just before onset of symptoms or on the first day of symptoms, while other studies demonstrate some patients with a climbing viral load that peaks on day two or three of illness. Testing too early or later on, during the recovery phase, may affect the sensitivity of the test.*

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- *Performance in asymptomatic individuals is unknown: since, by definition, it is not possible to define what day of illness it is for someone with no symptoms, it is difficult to study the performance of PCR testing in this population. Once serology is more reliable, it may be possible to determine PCR performance in this group of individuals by comparing PCR result with ultimate serological status.*
- *Specificity is high but false positives can still occur: While it is very unusual to get a “true” false positive (defined as a RNA sequence from a different virus being similar enough to react to the SARS-CoV-2 test), the nature of PCR testing can give non-specific results at the tail-end of the testing parameters. These non-specific results can be hard to distinguish from a patient with a low viral load and therefore can result in a false-positive.*
- Broad-based testing of individuals without symptoms is not generally recommended. There are, however, risk settings that can identify individuals and groups that might benefit from testing in the absence of symptoms in certain scenarios. For example, testing an asymptomatic person may be beneficial in local settings or circumstances such as contact tracing and management of an outbreak among a vulnerable group in a high-risk setting (e.g., long-term care facilities).
- **In some specific instances**, testing an asymptomatic person may be beneficial in some local settings or circumstances, such as contact tracing and management of an outbreak among a vulnerable group in a high-risk setting (e.g., long-term care facilities).
- The overall effectiveness of using testing to identify COVID-19 infection depends on **testing the right people, at the right time, in the right place**. This approach is dependent, in large part, on individuals who have symptoms that are consistent with COVID-19 being able to come forward to request and successfully access testing.
- The percentage of tests that come back positive is a helpful indicator of whether we are testing the right people, or casting the net too wide. Canada’s overall test positivity rate has stayed roughly between 3 – 7%, which is within a good range for accurate detection. The guidance also outlines that based on local epidemiology there may be situations where testing of asymptomatic individuals may be undertaken through a pilot study or surveillance activities to generate knowledge to make evidence-informed decisions.
- As of mid-May, the volume of daily testing in Canada has doubled, compared to the previous month, as laboratories have increased their testing capacity.
- The volume of testing increases or decreases in different jurisdictions based on the amount of respiratory disease circulating in the population. That is why it is so important to continue to increase and maintain strong testing capacity—we need to be able to do enough testing in the event of a resurgence of COVID-19 and/or when influenza season brings increased respiratory illnesses, so that we can distinguish between COVID-19 and other respiratory infectious diseases.

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- To help provincial, territorial and local public health authorities **consider testing strategies** within their jurisdictions, the guidance provides considerations and objectives for testing specific groups of individuals, including:
 - children and youth;
 - health care workers and staff in health care facilities;
 - residents and staff in long-term care facilities, prisons, shelters and work camps;
 - hospitalized patients;
 - members of remote, isolated, rural and/or Indigenous communities; and
 - symptomatic travellers identified at Canadian points of entry.
- To test individuals in **rural, remote, isolated and/or Indigenous communities**, samples must ordinarily be shipped to laboratories, which increases the time it takes to get results and subsequently take appropriate action. In addition, there are specific high-risk settings in which it is critical to have testing that can yield results without having to send samples to a laboratory (e.g., long-term care facilities).
- In these circumstances, the guidance recommends the use, if available, of **point-of-care molecular testing** for people with symptoms of COVID-19. With point-of-care testing, nose or throat swabs are taken and tested at the point of care, such as a lab in a hospital or doctor's office, without having to be sent to an off-site laboratory. Results can be ready in 30 to 60 minutes.
- Point-of-care testing technology can only test a limited number of samples in a single specialized machine and its use should, therefore, be prioritized for settings where they have the most impact, such as rural, remote, isolated and/or Indigenous communities.
- A third type of test, recently authorized in Canada, is **serological testing**, which is a blood test that detects the presence of virus-specific antibodies in blood samples and tells us whether a person has been previously exposed to the virus that causes COVID-19.
- This type of test can also be used to more accurately determine how widely the virus has spread in Canada, estimate the risk of further waves of infection, and study potential immunity in previously infected individuals.
- The Government of Canada has established the COVID-19 Immunity Task Force. The task force will catalyse, support and harmonize the design and rapid implementation of population-based studies or surveys that will generate reliable first estimates of SARS-CoV-2 immunity, overall and in priority populations across Canada.
- The Public Health Agency of Canada's National Microbiology Laboratory will support the task force and will provide testing standardization, support procurement of commercial test kits to enable the efficient and standardized operations of the task force.



- Rapid and representative national surveys provide a snapshot of where we stand now, and what to expect in a possible second wave of infection. They can also shed light on the potential exposure status of vulnerable populations such as Indigenous communities, and residents of nursing homes and long-term care facilities.
- Serological surveys can also help guide important public health decisions once a vaccine becomes available.

Testing and contact tracing

- The Government of Canada is working with provinces and territories on a testing and contact tracing strategy to assist in managing the different pandemic experiences across the country.
- The strategy is designed to flexibly respond to the highly varied pandemic experience across the country and relies on collaboration to ensure that the necessary resources, technology and supplies are in place to expand testing and contact tracing.
- The strategy will help ensure that provinces and territories have the capacity required to rapidly detect cases, trace contacts, and isolate and quarantine infected individuals in order to support economic restart and living with COVID-19.
- There are ongoing discussions between the federal government and provincial and territorial governments to facilitate rapid access to data across the country, create data standards, and assess a potential new national data management platform.
- The Government of Canada continues to work with provincial and territorial governments to support a robust contact tracing process, which is necessary not only to support current efforts in outbreak containment, but also to enable economic recovery. We will do so while ensuring privacy and security for Canadians.

Federal Employees to Help with Contact Tracing

- Once a person has tested positive for COVID-19, rapidly identifying the people they have been in contact with is key to Canada's strategy for preventing further spread of the disease.
- Contact tracing activities are led by the provinces and territories; however, as the federal government has access to a significant number of experienced and fully equipped human resources able to do this work, it has extended an offer of support to the provinces and territories, if needed, to help meet increased demands due to COVID-19.
- To date, Ontario has asked for support, and in April the federal government mobilized more than 260 volunteers, fully operational employees from Health Canada, the Public Health Agency of Canada and the Department of National Defence, to provide surge capacity for contact tracing for the province. (Note: 28 employees from DND and approximately 240 employees from HC and PHAC.)

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- Statistics Canada has also identified up to 1,700 field survey interviewers who could be available for contact tracing support. These interviewers have bilingual capacity and proficiency in more than 35 languages, and could do an estimated 600,000 contact tracing calls per month.
- The Government of Canada will continue to work with provincial and territorial governments to support a robust contact tracing process, which is necessary not only to support current efforts in outbreak containment, but also to enable economic recovery. We will do so while ensuring privacy and security for Canadians.

Supplementary Messages

- All federal employees engaged in contact tracing have received training from Public Health Ontario.
- All data collected by federal employees meet rigorous privacy requirements. Data collection is done on behalf of the provinces and territories and, as such, remains under their authority.

COVID-19 testing at private clinics

- Testing is a key pillar of Canada's response to the COVID-19 pandemic, enabling the detection, prevention and public health management of the virus.
- According to the [guidelines and criteria](#) on testing developed by our public health officials, testing should be available for free to all Canadians who meet the guidelines and criteria on testing developed by our public health officials.
- Federal, provincial and territorial governments remain committed to working together to ensure that access to COVID-19 testing is based on the advice of public health leaders.

Why asymptomatic people are not being tested for COVID-19:

- It is important to focus on testing the right people at the right time.
- Testing in Canada is focused on people who present with symptoms consistent with COVID-19.
- Testing people who are asymptomatic is not considered an effective approach to detecting and preventing the spread of this virus and may give a false sense of reassurance.
- Testing asymptomatic individuals offers a false sense of reassurance, because it does not mean that an individual will not go on to become symptomatic and develop disease within the incubation period. The timing of testing matters. This is why we took the precaution to quarantine individuals again in Canada. There is a real assurance in monitoring for the 14-day incubation period and that means more for preventing spread than a potentially false negative test result.
- In addition, if an asymptomatic individual was tested and the test was positive, it is not clear what the significance and implications are. A positive test could mean presence of virus genetic material was detected, but that does not mean the person is necessarily infectious to others.

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Unusable Testing Kit Swabs

- ESBE Scientific shipped swabs between March 28 and June 25, 2020, which were sent to various locations in Canada.
- On April 11, 2020, and again on June 25, 2020, the company issued an urgent recall notice because of a problem with swab kit contamination. In both instances, the company voluntarily recalled the product and committed to taking corrective action and replacing the product.
- The provincial and territorial public health laboratories were immediately informed of the recalls. All public health laboratories that received the affected swabs were advised of the issue on June 25. Recipients were asked to return the unused swabs to the distributor.
- Health Canada worked with the company to ensure that the recalls ran smoothly and posted all health product recalls in its [Recalls and Safety Alerts database](#).
- Health Canada will continue to work with the manufacturer to ensure that required corrective action is taken and follows the appropriate protocols.
- The Government of Canada has awarded contracts for over 23 million swabs from a variety of suppliers and is providing or producing other items required for laboratory tests to support the provinces and territories. It is currently looking into ways of ensuring a steady, safe supply of sterile swabs, including options for producing and sterilizing swabs in Canada.
- The Public Health Agency of Canada is continuing to work with the provinces and territories to determine their medical supply needs to place bulk orders.
- Public Services and Procurement Canada is continuing to identify suppliers capable of meeting Canada's needs.
- Health Canada is working to ensure that swabs with a novel design or swabs manufactured through retooling meet standards of safety and effectiveness.
- ESBE Scientific holds a valid medical device establishment licence (company number 103659).

If pressed

- The swabs are sterile and do not pose a risk to patients as the concern is with the transfer medium gel used to store the sample and not with the swab itself.
- As of July 9, 2020, Health Canada has received only one mandatory incident report for the recalled devices. This report was related to a swab breaking because of an error made by the user.

Amendments to the Authorization of the Spartan Test Kit

- Canadians rely on accurate diagnostic test results to help limit the spread of COVID-19 in Canada.



- After Health Canada authorizes test kits for use in Canada, it continues to monitor them for safety and effectiveness. If concerns arise, Health Canada takes appropriate action to protect the health and safety of Canadians.
- Health Canada has placed conditions on the authorization of the Spartan test kit to restrict its sale for only research, until we receive adequate evidence of clinical performance.
- On June 23, 2020, Health Canada authorized Spartan's clinical trial to "evaluate the efficacy of various sample collection methods for use with the Spartan COVID-19 System."
- Spartan is to submit a final study report when the clinical trial is complete.
- Spartan will need to complete a second clinical trial to demonstrate clinical efficacy of the new swab design identified during the first clinical trial.
- Health Canada continues to work with Spartan to address the regulatory requirements to enable use of the device as a point-of-care test kit.

If pressed:

- Spartan has not yet provided the clinical information required to remove the conditions on the device's authorization.
- As of July 13, 2020, Health Canada has not received an application for a second clinical trial.
- Health Canada has not cancelled the authorization, given evidence that the device performs well in laboratory settings. The Spartan product can continue to be sold for research purposes.

Supplementary Key Messages on Authorization:

- On March 26, 2020, Health Canada issued an authorization with terms and conditions to Spartan Bioscience Inc. for its Spartan Cube.
- This authorization was made under the [Interim Order](#) for medical devices in the context of COVID-19, which enables Health Canada to authorize devices under an expedited scientific review process.
- On May 1, 2020, the National Microbiology Lab provided Health Canada with a final report of clinical testing performed using Spartan swabs to collect specimens directly from patients under clinical conditions.
- The report showed that, while the Spartan Cube performed well in a laboratory setting, there were performance issues in the clinical trial. These issues may be related to the proprietary swab, which may not collect enough mucosal material for testing.
- Health Canada placed conditions on the authorization of the Spartan test kit to restrict its sale for only research, until adequate evidence of clinical performance is provided.

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If pressed on how many tests were distributed following authorization of the test kits:

- Spartan Bioscience Inc. shared its distribution record with Health Canada on May 2, 2020, and confirmed it had distributed 5,500 test kits to four public health organizations for research in a clinical setting:
 - Alberta Health Services;
 - CHU de Québec-Université Laval;
 - Ontario Agency for Health Protection and Promotion; and
 - Public Health Agency of Canada.
- These organizations are aware of the new Health Canada conditions on Spartan's authorization.
- At Health Canada's request, the company issued a partial voluntary recall to prevent its use in diagnostic settings.
- Health Canada has restricted the sale of the test kits to research use until the company provides adequate evidence of the device's clinical performance.

If pressed on the Public Health Agency of Canada's National Microbiology Laboratory's (NML) review of the test kit:

- As part of its research efforts, the Public Health Agency of Canada's NML performs scientific reviews of new medical devices.
- In response to the urgent nature of COVID-19, the NML is being asked by companies to perform scientific reviews and to assess the performance of diagnostic supplies such as COVID-19 testing kits.
- The NML reviews these COVID-19 laboratory supplies for clinical diagnostic to ensure they meet the gold standard used in public health laboratories and can be used to obtain reliable and accurate results when diagnosing COVID-19.
- This test verification function is part of scientific research and is independent of Health Canada's regulatory approval process. While this assessment is separate from Health Canada's authorization process, the NML works closely in collaboration with Health Canada to share knowledge gained through the review process.

If pressed on the Government's procurement of the Spartan test:

- The Government of Canada has a procurement contract with Spartan to secure supply of these devices. The contract is conditional on the Spartan test kit being authorized for sale by Health Canada.

Authorizations for 3D-printed swabs under the Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19

- In response to the COVID-19 pandemic, Health Canada continues to authorize medical devices under an expedited regulatory review process.
- On June 23, 2020, Health Canada authorized the CANSWAB 3D-printed nasopharyngeal swab. This is the first 3D-printed swab authorized by Health Canada.

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- The CANSWAB will be used by healthcare professionals to collect samples from patients for COVID-19 diagnosis. The swab is a clear, flexible and slender rod with a texturized bristled tip for specimen collection.
- The swab was authorized under the [Interim Order](#) for COVID-19 medical devices, which enables Health Canada to authorize devices under an expedited scientific review process. The swab has not been authorized in any other country to date.
- 3D-printed devices must meet the same criteria for safety, quality and effectiveness as devices manufactured through other means. Health Canada determined that the CANSWAB met these requirements under the Interim Order process.
- A list of devices authorized through this Interim Order is available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/other.html>
- Health Canada continues to monitor the safety, quality, and effectiveness of all medical devices for use in the diagnosis, treatment, mitigation and prevention of COVID-19 once they are on the market. As with all medical devices, manufacturers must follow strict post-market safety requirements, such as mandatory problem reporting, recall procedures and complaint handling.

If pressed on ISED's role

- Innovation, Science and Economic Development Canada and Public Services and Procurement Canada continue to actively support Canadian industries to increase domestic manufacturing capacity, including re-tooling facilities to produce equipment and supplies including ventilators, surgical masks and testing kits.
- Through these efforts, the Government of Canada continues to sign new procurement agreements with Canadian companies that can provide urgently needed equipment.
- Throughout this process, the Public Health Agency of Canada, Health Canada and the National Research Council of Canada are playing critical roles, conducting technical reviews to verify that the products meet the Government of Canada technical specifications for COVID-19 as available on the Public Services and Procurement Canada's [buy and sell website](#).

If pressed on the company

- The swabs are manufactured by Precision ADM, an engineering and manufacturing company headquartered in Winnipeg, Manitoba.
- This is Precision ADM's first Interim Order Authorization in Canada.

If pressed on the role of the National Research Council

- In May 2020, the National Microbiology Laboratory (NML) transferred verification testing of swabs to the National Research Council.

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- Assessment criteria are based on existing guidelines from Health Canada and the United States Centers for Disease Control and Prevention.
- The testing process includes:
 - assessing the swab for comfort and mechanics (i.e., is it suitable to insert in someone's nose without harming them);
 - determining whether the swab can collect and release sufficient quantity of virus compared to the gold standard NML Laboratory swab; and
 - providing feedback to companies in real time.

COVID-19 home test kits

- Early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada.
- Health Canada is open to reviewing all testing solutions. This includes approaches that use self-collection and/or at-home test kits, in particular for screening purposes.
- The health and safety of Canadians is a priority. Before any product is authorized for use in Canada, it is subject to a thorough assessment through Health Canada's regulatory process to ensure products are supported by sufficient evidence of safety, effectiveness and quality.
- Government of Canada is currently working with companies that are developing innovative and new testing technologies in Canada and globally.
- The Minister of Health has also signed an Interim order respecting the importation and sale of medical devices for use in relation to COVID-19 that allows for faster access to COVID-19-related tests in Canada, some of which Health Canada have already authorized.
- Health Canada has authorized a number of accurate and reliable COVID-19 tests devices for use with various samples other than the nasopharyngeal swab, including oropharyngeal swabs, nasal swabs, and sputum, among others. The samples types that are authorized are based on the evidence provided to the Department by the manufacturer of the device.
- A complete list of testing devices authorized by Health Canada is available at: <https://www.canada.ca/protecting-the-health-and-safety-of-Canadians/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html>.
- The health and safety of Canadians is our top priority. We are committed to getting Canadians access to the tools they need to fight the spread of COVID-19 in Canada.

If asked about the U.S. FDA approval of at-home test

- We are aware that the U.S. FDA approved the COVID-19 RT-PCR Test for which the collection of a fluid sample is done at home.

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- The swab is collected at home then needs to be sent to a laboratory for testing. These are subject to strict transportation requirements.
- Other international regulators, including the United States Food and Drug Administration (U.S. FDA), have not approved complete at-home test kits for COVID-19.
- Health Canada is open to reviewing all innovative testing approaches as they become available.

If asked about the Health Canada's June 2020 notice:

- Health Canada posted guidance for industry to clarify its position on near-patient and point-of-care diagnostic tests in June 2020. At that time, the Department's position was in relation to the use of home tests for diagnostic purposes. In response to the evolution of the pandemic, Health Canada could now consider applications for home testing devices for screening purposes.
- The designation "near patient" could include devices intended for home testing or testing in alternative health care settings, such as a doctor's office, pharmacy, health centre or bedside in hospital.
- Health Canada is open to reviewing all new testing solutions as they become available.

Journal Article on COVID-19 Saliva Testing Study

- Early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada.
- This study looked at the performance of the oral self collection tool for saliva samples compared to standard swab testing for the detection of the virus that causes COVID-19.
- Nine researchers, including three scientists from the Public Health Agency of Canada's National Microbiology Laboratory analyzed the COVID-19 testing data from 1,939 individuals, at a testing centre in Ottawa, who were categorized either as:
 - individuals with mild symptoms; or
 - asymptomatic high-risk individuals.
- All patients in the study had a standard nasal or throat swab collected by a healthcare professional in addition to an oral self-collected saliva sample.
- This study showed that COVID-19 was detected less frequently with the OMNIgeneORAI self-collection tool for saliva than with a traditional nasopharyngeal swab. This result is in contrast with earlier reports that showed similar performance in hospitalized patients. The difference in these results is likely due to the patient population being tested, with those with mild symptoms having less virus than generally sicker hospitalized patients.
- Despite the decreased sensitivity, saliva testing presents many advantages:
 - It does not require specialized medical staff or personal protective equipment.
 - It is not painful.
 - It can be performed outside of testing centres (which benefits remote and vulnerable populations).

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- It may be better tolerated in challenging or pediatric populations.
- Viral material collected through saliva testing can be kept at room temperature for transport and analysis, whereas refrigeration is recommended for nasopharyngeal swabs.
- The self-collection tool for saliva used in this study is called OMNIgene®-ORAL, OM-505 by DNA Genotek Inc. Saliva is not a specimen type currently authorized by Health Canada for COVID-19 testing.
- Further study is needed to determine when saliva testing might be best used, balancing the ease of collection against the decreased sensitivity.

If pressed on the current testing process for COVID-19 in Canada:

- Current guidelines for COVID-19 testing require the use of a nasopharyngeal swab. Throat and nasal swab samples are not currently approved.
- Health Canada does not currently support home testing for COVID-19 (which may include saliva testing), because no home test kits have been reviewed by Health Canada and authorized, therefore they can provide inaccurate results.
- They also make it hard for the health care system to collect timely and accurate data on the spread of infection, which are key for managing an outbreak.
- Health Canada will consider the evidence provided by manufacturers in deciding whether to authorize a test that uses saliva samples. Manufacturers would have to demonstrate that the virus or antibodies to the virus can be reliably and accurately detected in the saliva sample. At this time, Health Canada has not authorized the use of saliva samples with any authorized testing device.
- Health Canada has been working with manufacturers to enable market access for commercial diagnostic devices in order to increase Canada's COVID-19 diagnostic capacity.
- New diagnostic tests will permit faster and more convenient testing of patients in Canada. To date, Health Canada has not authorized the sale of any saliva-based COVID-19 tests. The Department has received one application for the Quantivirus Sars-Cov-2 Multiplex Test Kit. Health Canada reviews all COVID-19-related applications as quickly as possible without compromising patient safety. For more information, please consult our [list of testing device applications under evaluation](#).
- The Minister of Health signed an Interim Order, as an emergency public health measure, to allow expedited access to COVID-19-related medical devices. With the Interim Order, new diagnostic tests are being made available in Canada. They are listed on Health Canada's [website](#).

COVID-19 Antigen Tests

- On October 5, 2020, Health Canada authorized the Abbott Panbio antigen test kit for COVID-19 diagnosis. It is the first antigen test kit authorized by Health Canada.

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- Antigen testing is one of several emerging technologies that can be used to determine if a person is infected with the COVID-19 virus. The test works by detecting specific proteins associated with the virus.
- Samples for this test need to be collected using a nasopharyngeal swab and the test should only be carried out by a health care professional. The test is designed to provide results within 20 minutes. The test is intended for use only in people who have symptoms (symptomatic).
- Although easier and quicker to use, antigen tests may be less sensitive than *polymerase chain reaction* (PCR) tests for COVID-19 detection, so they may be less accurate.
- To date, Health Canada has authorized 38 COVID-19 testing devices for sale in Canada. A complete list of testing devices authorized by Health Canada is available at <https://www.canada.ca/protecting-the-health-and-safety-of-Canadians/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html>.
- The health and safety of Canadians is the Government's utmost priority. Before any test is authorized for use in Canada, it is subject to a thorough assessment through Health Canada's regulatory process to ensure it is supported by sufficient evidence of safety, effectiveness and quality.

If pressed on procurement of antigen tests

- On October 6, the Government of Canada announced an agreement with Abbott Rapid Diagnostics to purchase 20.5 million Panbio COVID-19 Antigen rapid tests.
- PHAC will deploy these tests to provinces and territories to support them in ramping up COVID-19 testing.

Supplementary Messages

- The Government of Canada understands the importance of increasing testing capacity as early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada. This is why Health Canada has prioritized the review of all types of COVID-19 tests, including new, innovative testing options and technologies.
- Health Canada is taking all steps available to us as a regulator to give Canadians and our health system access to as many testing options as possible, as quickly as we can, without compromising safety.
- On September 29, Health Canada published [information](#) for industry to advise that they must clearly demonstrate that their antigen test meets a minimum standard of 80% sensitivity before their application can be approved, so that the tests produce reliable results.
- Health Canada is closely monitoring new technology, and when we hear of promising new tests that are not yet available in Canada, we proactively reach out to manufacturers to seek their interest in entering the Canadian market.

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- Furthermore, the Government of Canada is providing \$4.28 billion to support provinces and territories with the costs of increasing their capacity to conduct testing, perform contact tracing, and share public health data that will help fight the pandemic. The goal is to ensure provinces and territories have the capacity to test up to 200,000 people per day, nationwide.
- Canada has one of the best regulatory systems in the world for medical devices. Health Canada takes steps to ensure that the applicable safety, effectiveness and quality requirements are met for medical devices prior to issuing an authorization.
- Health Canada is currently reviewing submissions for other point-of-care rapid tests, and will prioritize new and innovative testing options such as other rapid tests and home tests.
- Health Canada welcomes new technology and will prioritize applications for all types of test kits. Only tests that are proven to perform accurately and reliably will be authorized.
- You will find more information about testing here.

Specifics on the role of NML and NML Antigen Guidance

- The Public Health Agency of Canada's NML is providing critical scientific leadership for Canada's response to COVID-19. This includes coordination with provincial and territorial governments and laboratories, as well as Indigenous Services Canada, to deploy point-of-care testing devices and supplies across Canada.
- NML and Public Services and Procurement Canada are actively exploring the procurement of antigen-testing supplies to provide to provinces and territories.
- Rapid tests are only one aspect of the Government of Canada's testing strategy.
- Since March, we have been working hard to secure the necessary equipment and supplies, including tests, to support the COVID-19 response.
- The Government of Canada continues to work with federal, provincial and territorial governments to assess ongoing needs for medical equipment and supplies. We will be working with provinces and territories to ensure that device allocation is able to have the most impact based on existing and future COVID-19 hotspots in Canada.
- As part of its research efforts, the Public Health Agency of Canada's NML performs a verification of new medical devices.
- This test verification function is part of scientific research and is independent of Health Canada's regulatory approval process. While this assessment is separate from Health Canada's authorization process, NML works in collaboration with Health Canada to share knowledge gained through the verification process.



- Results on the performance of diagnostic tests are shared with manufacturing companies, provincial and territorial laboratories, and Health Canada to add to the evidence on the accuracy of diagnostic tests.

On Interim Guidance

- To respond to a growing need for a variety of tests, the Government of Canada along with territorial and provincial partners finalized Interim Guidance on the Use of Rapid Antigen Detection Tests for the Identification of SARS-CoV-2 Infection.
- This guidance provides information on the use of rapid antigen detection tests (RADT) for SARS-CoV-2 in the context of the public health system.
- This is a rapidly evolving field as new tests and technologies come to market and data on performance and utility increase.

The interim guidance should be finalized in the coming days (TBD) and will be periodically updated as the science evolves.

Serology and Immunity Passports

- Canada's Chief Medical Officers of Health do not support immunity passport programs. We do not yet know enough about the immune response to infection with SARS-CoV-2, the virus that causes COVID-19.
- Research is underway to find out whether people who have recovered from COVID-19 have protective immunity, and how long that immunity may last.
- Health Canada authorized (on May 12, 2020) the first COVID-19 serological test for use in Canada, followed by a second test on May 14. The tests are not authorized for use in the diagnosis of COVID-19. For an up-to-date list of authorized tests, check [Health Canada's website](#).
- Serological tests are blood tests that detect the presence of antibodies to the virus that causes COVID-19. They indicate whether a person has been previously infected with the virus.
- As scientists are working to understand COVID-19 immunity, we are focusing on the public health measures that we know are effective.
- We are continuing to advise Canadians to stay home when ill, practice good hand hygiene, and if you have to leave your home, practise physical distancing. These are tried and true public health measures that we know work.

If asked about concerns about Immunity Passports:

- The World Health Organization recently warned that there is currently not enough evidence about the effectiveness of antibody-mediated immunity to guarantee the accuracy of an

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immunity passport and that the use of such passports may increase the risks of continued transmission.

- A false-positive result might lead an individual to change their behaviour, potentially becoming infected or unknowingly infecting others.
- Ethical and legal considerations of sharing information on individual serological test results need to be addressed to ensure privacy of personal health data, to prevent stigmatizing lower-income Canadians and/or those with unstable employment. Immunity passport programs may increase the risk of discrimination against employees who may not have COVID-19 antibodies. Pressures to return to work could drive people to willfully expose themselves or their families to infection if immunity passports were a tool used to confirm a return to work.
- The creation of a registry of people with immunity passports may lead to privacy/data security considerations that would need to be addressed.

General Key Messages for Serological Testing

- Serological tests are authorized to detect antibodies specific to the virus. Serological tests provide evidence of a previous exposure to the virus that causes COVID-19 by testing for the presence of antibodies.
- Serological tests will play an important role in tracking how widely the virus has spread.
 - Serology testing will contribute to a better understanding of the immune status of those who have been infected.
 - Using validated and effective serological tests for COVID-19 will be an important step in Canada's public health response.
- Information made available through the results of serological testing could also prove valuable in estimating potential immunity and vulnerabilities in our population.
- Serological surveys can also help guide important public health decisions once a vaccine becomes available.

Key Messages for Health Canada's Serological Test Approval:

- Following scientific review, Health Canada has now authorized the sale of five serological tests:
 - DiaSorin LIAISON® test (authorized May 12)
 - Abbott ARCHITECT SARS-CoV-2 IgG Assay (authorized May 14)
 - Roche Elecsys Anti-SARS-CoV-2 (authorized June 5)
 - Ortho Clinical Diagnostics VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack (authorized June 8)
 - Abbott Laboratories Diagnostics Division SARS-CoV-2 IgG (authorized June 11)
- Serological tests are authorized to detect antibodies specific to the virus. Serological tests provide evidence of a previous exposure to the virus that causes COVID-19 by testing for the presence of antibodies.

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- Health Canada authorized the tests after completing scientific reviews that were supported by evidence to ensure that the tests will provide accurate and reliable results.
- A complete list of testing devices for COVID-19 is available on Health Canada's [website](#).
- Health Canada will continue to focus on the health and safety of Canadians while expediting the supply of safe and effective health products related to COVID-19.
- The Government of Canada has finalized a contract with Abbott Laboratories for 140,000 serological test kits.
- These kits can detect the presence of previous exposure to COVID-19 and will be used for research studies that are being coordinated by the [Immunity Task Force](#).

Supplemental messages:

- These tests must be carried out in a laboratory setting.
- Serology-based tests are essential to understanding the immune response to virus infection and will play a key role in determining the extent of exposure to the virus through sero-surveillance studies.
- Further research is required to fully comprehend the relationship between positive antibody tests and protection against re-infection.
- In accordance with Health Canada's [Guidance on serological tests](#), a condition is applied to the authorization issued to serology-based tests in order to monitor the ability of the test to perform as intended once in use by the Canadian health care system.
- Serology-based tests should be used in conjunction with the testing strategy outlined by municipal, provincial or territorial public health authorities.
- Nucleic acid-based tests are the only authorized testing devices in Canada to diagnose an active infection with COVID-19.

If pressed on Canada's approach to authorizing COVID-19 testing devices

- As an emergency public health measure, the Minister of Health signed an Interim Order to allow expedited access to COVID-19-related medical devices, including testing devices.
- Only testing devices authorized by Health Canada can be imported or sold in Canada. Unauthorized tests may not produce accurate results.
- Health Canada has confirmed that authorized COVID-19 tests are well supported by evidence that they will provide accurate and reliable results. More than 20 COVID-19 testing devices are now accessible in Canada. The list of authorized testing devices is posted on [Health Canada's website](#).



- Canada has maintained a science-informed approach to managing the pandemic, including maintaining requirements for pre-market authorization of testing technologies.
- Providing the Canadian population and individuals with accurate information about infection status is a pillar of the country's response to the pandemic.
- Health Canada's position on the use of serological assays is in line with the World Health Organization's view that serological assays will play an important role in research and surveillance.
- The Public Health Agency of Canada's National Microbiology Laboratory (NML) and its partners are working on assessing a variety of commercial serological tests for the SARS-CoV-2 virus. This pan-Canadian collaboration includes members of the Canadian Public Health Laboratory Network, clinical researchers from front-line health care settings, and Canadian Blood Services, all of whom are working to establish the materials needed for both the evaluation and implementation of serologic testing across Canada.
- Health Canada continues to review other serological technologies in accordance with its Guidance on serological tests. Health Canada will authorize other serological tests that show high sensitivity and specificity. For additional information, please consult the serological testing devices for use against COVID-19.

If pressed on the Public Health Agency of Canada's National Microbiology Laboratory's (NML) review:

- As part of its research efforts, the Public Health Agency of Canada's NML performs scientific reviews of new medical devices.
- In response to the urgent nature of COVID-19, the NML is being asked by companies to perform scientific review and assess the performance of medical supplies, such as COVID-19 test kits.
- NML reviews these COVID-19 medical supplies to ensure they meet the gold standard used in public health laboratories and can be used to obtain reliable and accurate results.
- This test verification function is part of scientific research and is independent of Health Canada's regulatory approval process. While this assessment is separate from Health Canada's authorization process, the NML works closely in collaboration with Health Canada to share knowledge gained through the review process.

Final Results of the Sero Survey

- On September 8, 2020, the Canadian Blood Services and Canada's COVID-19 Immunity Task Force (CITF) released results of the entire blood donor samples from nine provinces assessed for SARS-CoV-2 antibodies.
- This analysis revealed that, over the period May 9 through June 18, 2020, less than 1% of the 37,373 samples from blood donors tested positive for antibodies to the novel coronavirus.

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- These results suggest that only 0.7 per cent of healthy Canadians have been exposed to SARS-CoV-2. The results are consistent with preliminary analyses done in British Columbia and Ontario.
- Antibodies indicate past infection with SARS-CoV-2, and population studies like this one tell us how many people have likely been exposed to the virus.
- While these first results reflect widespread adherence with public health measures, they also mean most Canadians remain susceptible to infection.
- With the increasing number of COVID-19 cases that we are seeing in some parts of the country, these findings also point to the need for continued vigilance and adherence to the best public health practices.
- Health Canada approved serological tests are being used to detect antibodies specific to the virus. Serological tests provide evidence of a previous exposure to the virus that causes COVID-19 by testing for the presence of antibodies.
- The use of validated and effective serological tests for COVID-19 is an important step in Canada's public health response.
- Serological surveys of the general population and at-risk subgroups can also help guide important public health decisions once a vaccine becomes available.

Immunity Task Force

- On April 23, 2020, the Government of Canada launched the COVID-19 Immunity Task Force to lead a Canada-wide unified effort to test blood samples for signs of COVID-19 infections.
- The task force catalyzes, supports and harmonizes the design and rapid implementation of population-based studies that generate reliable first estimates of SARS-CoV-2 antibody positivity overall and in priority populations across Canada.
- Rapid and representative national surveys provide a snapshot of where we stand now, and what to expect in a possible second wave of infection. They can also shed light on the potential immunity status of vulnerable populations such as Indigenous communities, and residents of nursing homes and long-term care facilities.
- Conducting large serological (blood test) surveys of the Canadian population will measure the scope and scale of COVID-19 infections across the country.
- This effort needs to be well coordinated and well executed to achieve the best results to inform policy decisions.
- The Government established a task force of organizations that work together under the direction of a Governing Board charged with setting priorities and recommending projects for funding to the Government of Canada. The leadership team comprises three individuals who are renowned for

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their contributions to research, academia and innovation in both public health and healthcare in Canada and internationally.

- The Governing Board is co-chaired by:
 - Dr. David Naylor, well known for his scientific and academic leadership and successful management of large and complex organizations;
 - Dr. Catherine Hankins, who brings domestic and international experience in leading large and complex research endeavours and in creating partnerships to advance public health priorities;
 - Dr. Timothy Evans, Director, School of Population and Global Health at McGill University, who leads the Secretariat responsible for the efficient execution of this complex endeavour.
- The Immunity Task Force is working with an Indigenous Advisory Circle with representatives from Indigenous communities across the country to promote immunity testing in Indigenous communities.

Strengthening Pre-clinical and Medical Countermeasures at the National Microbiology Laboratory

- Protecting Canadians from established and emerging infectious diseases is a priority for the Government of Canada.
- COVID-19 is a reminder that emerging infections can dramatically reshape society in a matter of weeks.
- That is why we are investing in science and research to control the spread of COVID-19 and to prepare for infectious disease threats of the future.
- The Government of Canada is investing \$264 million over the next two years, and \$52 million on an ongoing basis, to expand Canada's National Microbiology Laboratory (NML). Part of the funding will be used to acquire and retrofit an existing surplus Crown asset in Winnipeg, Manitoba.
- The new NML research facility will focus on developing and testing pre-clinical treatments and vaccines for novel diseases such as COVID-19. This testing will enable Canadian industry to move treatments and vaccines through the early stages of development through to clinical trials in humans.
- The new NML research facility will enhance Canada's capacity to detect, diagnose and respond to infectious diseases.
- It will also be home to a biobank to store important clinical specimens for research purposes, including blood collected through COVID-19 sero-surveys.
- The new facility will increase the Government of Canada's capacity to develop vaccines from start to finish by funding vaccine research, validating vaccines in animal models and facilitating vaccine clinical trials.

On the level of labs in the new facility:

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- The new research facility will have both containment level 2 (CL2) and containment level 3 (CL3) laboratories.

On biobanking:

- A biobank is a storage facility for biological materials that collects, processes, stores and distributes specimens to support future scientific investigations.

On pre-clinical testing:

- Pre-clinical testing is required to help support current and future response efforts against novel emerging infections.

On the retrofit completion date:

- The NML will be using the facility to support COVID-19 surge activities while the retrofit is progressing since it is already a functional containment level 2 laboratory.
- It is anticipated that the retrofitting will take approximately two years to complete.

If pressed on Manitoba Métis Federation's bid to purchase the building from the National Research Council of Canada

- The Government of Canada is committed to advancing long-term reconciliation with Indigenous peoples, including Métis, through renewed nation-to-nation, government-to-government relationships based on recognition of rights, respect, co-operation and partnership.
- We acknowledge that the facility in question is on Treaty 1 territory and the homeland of the Métis Nation.
- We are aware of the bid request from the Manitoba Métis Federation to purchase the existing laboratory space.
- There is an urgent need to develop this type of facility for COVID-19 response. Retrofitting an existing laboratory space is the quickest and most cost-effective option to creating new laboratory space.
- For more information, please contact the National Research Council.

If pressed on the use of animals for medical research (previously approved):

- The Public Health Agency of Canada (PHAC) and Health Canada are committed to the humane and ethical treatment of all animals used in research.
- The decision to work with any animal is never taken lightly. The majority of research conducted in PHAC laboratories is done without any animal testing and whenever possible, other options are used. However, for certain research, there is no alternative to using animals.
- Our primary responsibility is the health and safety of Canadians—we cannot endanger human life with untested vaccines or medications.



- Countless medical treatments and advancements have been made possible by animal testing. This includes insulin for diabetes, the polio vaccine, coronary surgery as well as a range of antibiotics.
- Every consideration is given to the mental and physical well-being of animals in our care. They are under the care of a veterinarian and are closely monitored at all times.
- Our animal facilities are inspected and certified on a regular basis by the Canadian Council on Animal Care (CCAC).
 - The CCAC is the national organization responsible for setting and maintaining standards for the care and use of animals in science in Canada. Inspections of the facilities are carried out at least every three years.
- The facility's Animal Care Committee includes a member nominated by the Humane Society, a knowledgeable local citizen, scientists from the facility that are not associated with the project and veterinary professionals. The Committee reviews research submissions to ensure there are no alternatives to animal use and that appropriate plans for animal care are in place; they also take into consideration the value of the research.

On why non-human primates must be used rather than other animals in research:

- In the majority of animal research projects conducted at PHAC, lower order animals such as mice and ferrets are used but research requirements at times necessitate the use of non-human primates.
- Non-human primates are our closest relatives among members of the animal kingdom, therefore play an important role as an animal model when:
 - conducting advanced research into pathogenesis (origin of the disease),
 - determining vaccine or therapeutic efficacy, and
 - characterizing mechanisms by which infectious agents are transmitted.
- Not using non-human primates could endanger the health and safety of Canadians. Using other animal models (such as mice or ferrets) may not as accurately reflect a response to a vaccine, or the study and diagnosis of an infectious disease agent.
- We need to be sure that novel vaccines and medications used to combat a range of diseases are as safe as possible—this is a regulatory requirement.

On what animal testing is used for at PHAC:

- Countless medical treatments and advancements have been made possible by animal testing. This includes insulin for diabetes, the polio vaccine, coronary surgery as well as a range of antibiotics.
- The use of animals (including non-human primates) was essential during the H1N1 pandemic as well as during the SARS outbreak. Working with animals provided PHAC researchers with invaluable information about the mechanisms and significance of the diseases. Their use greatly helped the Government respond to these serious events.



- Animals (including non-human primates) are being used at PHAC to make advances in vaccines that can treat the most deadly and devastating of infectious diseases in the world, such as Ebola and Marburg haemorrhagic fever.

On the use of animals in other institutions:

- The use of animals is common throughout academia, government institutions (both in Canada and abroad) as well as private research and medical facilities. Their use is essential in ensuring the health and safety of Canadians and of populations around the world.
- Notable institutions that use animals to further research include the Centre for Disease Control and Prevention in Atlanta, the U.S. National Institute of Allergy and Infectious Diseases, the U.S. Army Medical Research Institute of Infectious Diseases and the Defence Science and Technology Laboratory in Porton Down, England.

Independent review of the Global Public Health Intelligence Network, or GPHIN

- The Global Public Health Intelligence Network (GPHIN) is an early-warning and situational awareness system for potential chemical, biological, radiological and nuclear public health threats worldwide. This includes monitoring of infectious disease outbreaks.
- GPHIN was established in 1997. Since that time, a significant number of non-governmental entities now conduct open source surveillance and alerting alongside governmental systems. These global shifts have impacted the role that GPHIN plays in Canada and on the world stage.
- In the coming weeks, the Minister of Health will launch an independent review of Canada's global public health surveillance system and capabilities.
- This independent review will provide opportunity to identify:
 - capabilities of the existing system;
 - its role in detecting and informing the Agency's response to COVID-19;
 - opportunities for system enhancements; and
 - opportunities to improve how the Agency synthesizes, shares and leverages key information sources for early detection.
- The results of this review will help inform future policy decisions around Canada's global public health surveillance system to position the Government of Canada well for future public health events.

Canada's Pandemic Preparedness – GPHIN

- The Global Public Health Intelligence Network (GPHIN) is an early-warning and situational awareness system for potential chemical, biological, radiological and nuclear public health threats worldwide. This includes monitoring of infectious disease outbreaks.
- GPHIN was established to support the timely sharing of information amongst public health professionals, with alerts providing a mechanism to highlight issues potentially meriting closer attention.



- GPHIN's comprehensive Situational Awareness Daily Report provides timely reporting to Canadian public health authorities at the federal, provincial, and territorial levels.
- GPHIN users include non-governmental agencies and organizations, as well as government authorities who conduct public health surveillance.
- GPHIN is a significant contributor to the World Health Organization's (WHO) Epidemic Intelligence from Open Sources.
- GPHIN analysts also develop special reports to address needs identified by organizations such as the WHO. GPHIN system consists of two critical components:
 - An Information Management Tool (IMT) that uses machine learning and natural language processing to facilitate the work of the analysts; and
 - A multidisciplinary team of life science analysts, reviewing IMT and additional information in nine languages and conducting rapid assessments to detect public health threats.

If pressed on Canada's/GPHIN's early response to COVID-19

- What would become COVID-19 was first detected by GPHIN on the evening of December 30, 2019. Subscribers to GPHIN's Daily Reports would have seen first reporting the morning of December 31.
- The first report of cases of pneumonia of unknown cause in China, which would later be known as COVID-19, was in *Agence France-Presse* on the evening of December 30, 2019.
- This information was disseminated quickly to public health authorities through multiple mechanisms, including:
 - The December 31, 2019, GPHIN Situational Awareness Daily Report distributed to Canadian public health practitioners at the federal, provincial and territorial levels;
 - A posting on the widely subscribed Program for Monitoring Emerging Diseases (ProMED); and
 - An official reporting from the Wuhan Municipal Health Commission.
- This enabled a rapid response both domestically and globally. Enhanced surveillance and reporting began immediately on December 31, 2019. The WHO stood up its Incident Management Support Team on January 1, 2020.
- The significance of this event was clear in the public health community.

If pressed on why a GPHIN alert was not sent for COVID-19

- Canada's response to the initial report of cases of pneumonia of unknown cause in China was swift. Enhanced surveillance and reporting began immediately. A GPHIN alert would not have made Canada's response to COVID-19 faster or more effective.
- The information on the pneumonia of unknown cause in China had already been disseminated widely through a number of mechanisms.

If asked why there was a period of time when alerts were not issued in 2019-2020

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- At no time did GPHIN cease its information gathering or dissemination activities. During that period GPHIN management was examining their processes for generating and disseminating alerts to ensure they continued to meet the needs of end users.
- It is important to note that alerts are not a first response to emergency situations requiring immediate action. Rather, they highlight health events that meet certain criteria and merit closer scrutiny. GPHIN Daily Reports highlight these same health events, but do not incorporate this additional analysis function.

If asked about the most recent Alert issued (August 6, 2020)

- GPHIN analysts undertake thoughtful consideration when developing a recommendation to issue an alert. The team developed a document, based on available information and other considerations to ensure the system is signaling the appropriate issues and highlighting health events that meet specific criteria.
- A GPHIN alert was issued on Thursday, August 6, 2020 based on an article published in the Global Times titled “Novel bunya virus infection caused by tick bites can pass from person to person: expert”.
- GPHIN’s domestic and international users received a timely alert respecting internationally-accepted assessment practices.

If asked about the GPHIN renewal project with National Research Council

- The objective of the GPHIN Renewal Project was to create an enhanced web-based platform that allowed for greater automation in the collection, collation and analysis of open source information.
- The platform would also be fully compliant with Government of Canada information technology policy requirements.
- The project was designed as a collaboration between PHAC and the National Research Council.
- Work began in January 2016, and the initial upgraded capability was delivered in August 2016. The final version went live in September 2018 and the technical components of the project were completed in July 2019.
- The GPHIN Renewal Project met the following objectives:
 - GPHIN can leverage the variety, volume and velocity of data available—including from social media and from more websites—and provide visual representation of events in place and time with built-in analytics and assessment capacity as well as automated summaries of articles.
 - The system’s artificial intelligence can learn and improve its relevance scoring accuracy.
 - The platform is compliant with information technology policies, guidelines and standards.
 - The Government of Canada has the ability to further implement improvements and innovations to the system.



If asked about GPHIN's budget

- The annual budget for GPHIN is approximately \$2.8 million, including both human and operating resources.
- The estimated cost of the GPHIN Renewal Project was \$8.24 million; the actual cost was \$7.85 million.

If asked about GPHIN's information flow and approval process

- Any GPHIN analyst may identify an emerging issue to management for consideration.
- All other GPHIN reports, such as the Situational Awareness Daily Report, continue to be distributed directly from GPHIN to subscribers, including senior management at PHAC and other government departments.
- At no time has there been any direction to cease sharing information.
- GPHIN continues to provide information to its users on COVID-19 related issues in its Daily Report and other reports as requested.

If asked about a domestic focus for GPHIN:

- GPHIN's primary role as a global event-based surveillance system remains unchanged.
- As public health threats emerge, GPHIN conducts subject-specific surveillance, to support PHAC's situational awareness and analysis.
 - This can include domestic issues, such as vaping, or international issues, such as Ebola.
- GPHIN continues to compile and disseminate international surveillance reports, in addition to its subject-specific surveillance.

If asked about GPHIN's sources of information:

- Every given day, about 7,000 articles are captured in the GPHIN system. The web-based application in the GPHIN system continuously scans and acquires news sources of information worldwide in nine languages (Arabic, Farsi, English, French, Portuguese, Russian, Spanish, and simplified and traditional Chinese).
- GPHIN's main data provider is Factiva, a global news database and research platform that contains nearly 33,000 sources, including newswires, newspapers, and trade publications. GPHIN also mines specific RSS feeds from relevant publications and twitter accounts.
- In addition, GPHIN analysts have programmed specific Google Alerts and monitor other news aggregators applications, such as ProMED and HealthMap, to further increase the variety of what is included in GPHIN.
- GPHIN analysts have extensive lists of websites and social media accounts from official governmental sources, medical expert forums and other relevant sources that they monitor on a

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daily basis. Once the data are in the GPHIN system, they are processed, validated, and assessed.

Canadian COVID-19 Genomics Network (CanCOGeN)

- The Canadian COVID-19 Genomics Network (CanCOGeN) will provide Canadian public health authorities with important genome sequencing data to help guide the public health response during the pandemic.
- The Public Health Agency of Canada's National Microbiology Laboratory is directing the Government of Canada's participation in CanCOGeN, which is led by Genome Canada.
- CanCOGeN is coordinating all COVID-19 genome sequencing efforts throughout Canada. Genome sequencing helps scientists better understand coronavirus transmission patterns.
- The results of CanCOGeN's work will be available to researchers globally to support additional research, including Canadian vaccine development efforts.
- The Government of Canada contributed \$40 million to support the creation of CanCOGeN to help understand the genetic variations of the virus as it evolves.

Mutations of COVID-19

- Every day, we are adding to our knowledge of COVID-19, keeping pace with the rapid growth of new scientific evidence as it emerges.
- The Government of Canada contributed \$40 million to support the creation of the Canadian COVID-19 Genomics Network (CanCOGeN) to help understand the genetic variations of the virus as it evolves.
- As genetic variants become established in a population, they form a lineage (with a common ancestor and descendants) that can be used to inform the origin of new cases. By comparing viral genome sequences, scientists can monitor the spread of these established lineages in Canada.
- The genomic data from identified cases can also provide additional evidence to identify related cases or matches in cluster investigations, especially when contact tracing is not available or inconclusive. As travel restrictions are eased, the genomic data will be used to monitor the origins or source of new cases and help inform the effectiveness of public health interventions.
- One of the goals is to sequence as many viral genomes as possible to adequately capture the circulating lineages in Canada and compare these with global sequences. At this time, it is premature to speculate whether Canada has distinct virus lineage.

If pressed on why it is important to understand genetic variations:

- Monitoring genetic variations combined with interprovincial and international spread of the virus will become increasingly important as public health measures are slowly lifted and cross-border

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travel resumes. Understanding genetic variations could impact the sensitivity and performance of current COVID-19 diagnostic methods.

- A detailed characterization of genetic variations can also help researchers to:
 - understand the viral and host mechanisms leading to disease and recovery;
 - understand how it spreads through populations and other potential hosts; and
 - help identify suitable drug and vaccine targets.

If pressed on the Canadian COVID-19 Genomics Network (CanCOGeN):

- The Canadian COVID-19 Genomics Network (CanCOGeN) will provide Canadian public health authorities with important genome sequencing data to help guide the public health response during the pandemic.
- The Public Health Agency of Canada's National Microbiology Laboratory is directing the Government of Canada's participation in CanCOGeN, which is led by Genome Canada.
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On pre-symptomatic and asymptomatic transmission

- Now that more countries have had large numbers of cases and have analysed transmission patterns, recent studies provide evidence that transmission of the virus can happen from infected people—before they develop symptoms. We refer to this as pre-symptomatic transmission.
- There is also evidence that some infected people who never develop symptoms are also able to transmit the virus. This is called asymptomatic transmission.
- We do not know how much of a role pre-symptomatic and asymptomatic transmission play in driving this epidemic at this time—but we know that it is occurring among those with close contact or in close physical settings.
- While the primary driver of the global pandemic of COVID-19 has been individuals with visible symptoms (coughing and respiratory droplets are key ways the virus is spread), evidence of asymptomatic or pre-symptomatic transmission points to the importance of everyone, even those who feel fine, following the proven methods of preventing transmission.

Asymptomatic Positive COVID-19 Diagnosis

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Cases of COVID-19 are diagnosed by a health care provider based on symptoms, and are confirmed through laboratory tests. People without symptoms may be found to be positive as a result of contact tracing, or testing used to screen people in certain situations.

If an individual tests positive for coronavirus, they must isolate at home for 14 days, or as directed by their local public health authority, whether they are experiencing symptoms (symptomatic) or not (asymptomatic).

If an asymptomatic individual has tested positive, and they develop symptoms during their initial at-home isolation period, they must restart their isolation for 14 days, or as directed by their public health authority.

Drugs and vaccines

- When a vaccine or drug is developed to prevent or treat COVID-19, we will take appropriate action to ensure its availability to Canadians.
- Measures include fast-tracking through the:
 - scientific review of new drugs or vaccines through a priority review or a notice of compliance with conditions
 - use of the Extraordinary Use of New Drugs pathway for making a promising new drug or vaccine available in order to secure the health of Canadians during an emergency
 - Canadian clinical trials for new vaccines, new or repurposed antivirals, or supportive therapies
- Other measures include the:
 - Special Access Program for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed or are unavailable
 - importation of a new drug authorized for sale in the United States, Switzerland or the European Union through the list of drugs for an urgent public health need.

Indemnification

- During a public health emergency such as a pandemic, a large portion of the population will be vaccinated over a short period.
- Manufacturers are working quickly to develop and manufacture a vaccine for COVID-19. They are working with regulators to expedite the development and regulatory approvals so that the necessary vaccine is available in a timely manner.
- Health Canada reviews scientific evidence of a vaccine, including from clinical trials, to assess the product's safety, efficacy and quality before it can be sold in Canada.



- For these reasons, indemnification of vaccine suppliers against third party legal claims is a standard international practice. Current Government of Canada contracts for pandemic influenza vaccine include indemnification provisions. These provisions are informed by risk assessments weighing the potential financial costs of indemnifying the manufacturer against the public health need to provide Canadians with access to a safe and effective vaccine.
- There is no COVID-19 vaccine yet. Should one be developed and approved for use in Canada, indemnification may be considered. However, before making such a decision, the Government of Canada's risk assessment would weigh the potential financial cost of indemnifying pandemic vaccine suppliers against the urgent need for a safe and effective pandemic vaccine supply for the Canadian population.

No-Fault Injury Compensation

- The safety of vaccines is of the utmost concern to the Government of Canada.
- Health Canada conducts rigorous scientific review and testing to assess the quality, safety and efficacy of vaccines before they are approved for use.
- Following vaccine approval, Canada's comprehensive vaccine safety monitoring system helps alert public health authorities to report adverse events or any unusual adverse events not previously reported so that prompt action can be taken.
- Vaccination in Canada is a shared responsibility among the federal, provincial and territorial governments. Health Canada regulates the safety and effectiveness of vaccines for use in Canada, and the provinces and territories are responsible for the delivery of vaccination programs with the support of the Public Health Agency of Canada.
- As such, the decision to offer a vaccine injury compensation program lies within provincial and territorial jurisdiction. The province of Quebec is currently the only province that has a vaccine injury compensation program in place.

U.S. Research Paper links Influenza Vaccine to COVID-19 Risk

- The Public Health Agency of Canada is aware of the U.S. study published in January 2020 that suggests that the influenza vaccine could increase the risk of illness from coronaviruses.
- Based on currently available data, the Public Health Agency of Canada does not support the theory that influenza vaccination will increase the likelihood of infection or severe outcomes associated with COVID-19.
- A research study published in May 2020 by researchers from the Canadian Sentinel Practitioner Surveillance Network looked at seven years of data and did not find evidence of the influenza vaccine increasing the risk of other coronaviruses.

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- The Canadian paper also found several scientific flaws in the way the U.S. study was conducted. For example, the U.S. study:
 - used samples from only one influenza season (2017-18), (which does not include data on COVID-19);
 - used a statistical test that did not account for other factors that could have an independent relationship on the outcome, such as age or season;
 - did not use standardized samples to make sure the study was comparing like with like;
 - included specimens that tested positive for influenza, which should have been excluded, according to the statistical technique being used (test-negative study);
 - used a population that was not representative of the general population.
- *As the US Centre for Disease Control puts it “the preponderance of evidence suggests that (...) influenza vaccination does not, in fact, make people more susceptible to other respiratory infections.” A single study, with significant methodological flaws, does not negate that greater weight of evidence suggesting that influenza vaccination does not make people more susceptible to other respiratory infections.*
- Canada has a rigorous system in place to ensure that vaccines are safe and effective in preventing disease, before they are approved for use. Once a vaccine is in use, health authorities continue to monitor it to ensure the highest standards of safety.
- The Public Health Agency of Canada will continue to promote evidence-based information for health professionals and the public on the safety and effectiveness of vaccination.

Supplemental messages: On the Canadian Sentinel Practitioner Surveillance Network

- The Canadian Sentinel Practitioner Surveillance Network (SPSN) is an internationally renowned study that has used robust methodology to monitor how well the influenza vaccine protects people from influenza viruses circulating in the community each year.
- This pioneering team first developed the test-negative design for monitoring influenza vaccine effectiveness in 2004 and is uniquely qualified to comment on the strength of evidence in this area of research design. The SPSN method is now used by multiple countries globally to monitor annual influenza vaccine protection.
- The SPSN relies on a network of primary care practitioners in participating provinces to collect and submit respiratory specimens for testing and analysis.
- Information generated by the SPSN is used to help inform Canada’s vaccine policies and the World Health Organization’s (WHO’s) vaccine strain selection process.

Guidance for Influenza Vaccine Delivery in the Presence of COVID-19

- The Government of Canada is preparing for the next flu season this fall/winter, given the pressures on the health care system that are expected due to COVID-19.

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- The Public Health Agency of Canada (PHAC) released guidance on the delivery of the seasonal influenza vaccine in the fall of 2020, after consultation with multiple expert working groups and external stakeholders that provide advice on immunization, public health measures, and infection prevention and control.
- The purpose of the guidance is to support program planners with setting up safe environments for flu shot clinics for the upcoming flu season.
- The guidance advises that priority should be given to providing influenza vaccine to persons at high risk of influenza complications and those capable of transmitting infection.
- The guidance complements provincial and territorial public health policies and procedures. It suggests a wide range of strategies to deliver the influenza vaccine with the aim of increasing vaccine uptake and reducing influenza infections.
- Vaccination is one of the most effective ways to prevent the spread of infectious diseases, including influenza.

Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19

- To support efforts to develop COVID-19 therapies, the Minister of Health has signed an Interim Order to make the authorization process for clinical trials related to COVID-19 more efficient and flexible, without compromising the safety of participants or the reliability of trials' findings.
- Clinical trials play a critical role in advancing research and evaluation of investigational products, while protecting the safety of Canadians.
- Health Canada's top priority is protecting the health and safety of clinical trial participants. The Department will continue to conduct rigorous reviews of each clinical trial application and protocol under this Interim Order, as it does for all clinical trials.
- Currently, there are no drugs specifically authorized to prevent, treat or cure COVID-19 in Canada.
- The Government of Canada continues to monitor and support emerging science, and is committed to ensuring that our domestic efforts and international contributions are supported by the best available evidence and aligned with global efforts.

Canadian hospitals to join global drug trials

- COVID-19 is a global pandemic that requires a global solution.
- The participation of countries, including Canada in this unprecedented mega-trial to test potential treatments for COVID-19, is truly a new model for global collaboration.
- This global trial coordinated by the World Health Organization will test multiple potential drugs to treat COVID-19. By using a common study design across countries, it ensures that results can be obtained more rapidly and be more robust.

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- As with any unproven therapy, there are potential harms as well as benefits. Therefore, all potential therapies are best accessed through a clinical trial.
- The Government of Canada has invested nearly \$1 million through the Canadian Institutes of Health Research to support the Canadian portion of this global trial. This is part of our \$275 million commitment towards supporting medical research for the COVID-19 pandemic.
- Canada is home to some of the most skilled and brightest researchers in the world who are working hard to support international efforts to fight this pandemic. The Canadian portion of this global trial plans to recruit up to 20 sites across Canada.
- To help advance research and vaccine development for COVID-19, the World Health Organization, along with the Coalition for Epidemic Preparedness Innovations, is coordinating an international collaboration in which Canada is participating.

Collection and use of COVID-19 convalescent plasma collected from Canadians

- The health and safety of Canadians is our top priority.
- Canada's voluntary blood-for-transfusion donor system is not changing. Currently, some provinces allow donors to be paid for plasma when it is collected for use in plasma products.
- Choosing to prohibit payment for plasma donors is a decision under the authority of the provinces and territories. Health Canada works to ensure that all plasma collectors follow the correct procedures to produce a safe and effective product for patients.
- Convalescent plasma is the plasma of patients who have recovered from a virus, which generally means they have developed the antibodies necessary to fight off that virus. These antibodies develop in the body's plasma to help protect against future infection from the same virus.
- All establishments, such as Canadian Plasma Resources and Prometic Plasma Resources, that wish to collect convalescent plasma for clinical trials must meet quality and safety requirements in accordance with the applicable Health Canada authorization.
- To date, Health Canada has authorized three clinical trials on the use of convalescent plasma to treat COVID-19. These trials aim to contribute to domestic and global efforts to study COVID-19 convalescent plasma as a potential treatment.
- Health Canada's regulatory review is based on scientific evidence and helps ensure the blood and plasma products available to Canadians are safe. Health Canada's regulatory review does not take into account other factors, such as international trade considerations, when making product authorization decisions.
- The Government of Canada considers international cooperation critical to protect and promote the health of Canadians. This is of particular importance during the COVID-19 pandemic.

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Experimental Therapies

- Every drug or health product making a therapeutic claim sold or marketed in Canada needs to be approved by Health Canada for safety, efficacy and quality. This approval process starts with manufacturers filing a submission of a drug or health product with Health Canada.
- To provide Canadians with the fastest access possible to health products related to COVID-19, Health Canada is expediting the review of any COVID-19 related submissions.
- Currently there are no drugs specifically authorized to treat or prevent COVID-19. For drugs that show an early promise in treating COVID-19, the best way to access therapies is through clinical trials.
- Health Canada encourages health care professionals prescribing or using experimental therapies for COVID-19 patients to contact the Department to initiate a clinical trial.
- The Department continues to monitor the safety and effectiveness of drugs and health products once they are on the market.

If pressed on accelerating access to treatments:

- Health Canada recognizes that Canadians want faster access to new and promising drugs and health products, particularly when limited treatment options are available.
- As an emergency public health measure, the Minister of Health has signed Interim Orders to allow expedited access to COVID-19-related medical devices and drugs.
- Health Canada will continue to use all tools at its disposal to expedite the supply of safe and effective health products related to COVID-19.

If pressed on off-label use:

Additional context: Some healthcare providers are prescribing drugs “off-label” to help treat COVID-19 symptoms. This means they are prescribing drugs that are authorized and labelled to address other medical conditions to treat COVID-19.

- In Canada, a health care professional's decision to prescribe or use a particular drug for a labelled or off-label indication is part of the practice of medicine, which falls under the jurisdiction of provincial and territorial professional regulatory authorities.
- While Health Canada regulates the sale of drugs in Canada, it is the responsibility of health care professionals to consider information from the Canadian Product Monograph, approved product labels and other credible references such as medical journals, case reports, peer-reviewed studies, and medical practice experience to ensure that the potential benefit of a drug outweighs the risk for each patient.
- An off-label use may not be supported by the same level of scientific evidence as an authorized use. The justification for off-label prescribing can range from rigorous clinical studies to anecdotal evidence without substantial scientific validation.
- The product's label is designed to support the authorized use and therefore may not provide all the necessary information for safe and effective off-label use. This means there may be less information available regarding potential drug interactions and other adverse reactions that could occur with off-label uses.

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- It is illegal to directly or indirectly advertise either experimental therapies or the off-label use of, authorized drugs.
- Health Canada encourages health care professionals to study the off-label use of drugs for COVID-19 in the context of a clinical trial, so that data can be collected and used to inform future prescribing practices.

If pressed on clinical trials:

- Clinical trials play an essential role in advancing research and the evaluation of investigational products to help respond to emerging health issues.
- Clinical trials are conducted to investigate whether the use of a drug or a medical device is safe and effective for human use.
- A clinical trial requires the informed consent of patients and puts in place oversight and safeguards to protect the people who take part in clinical trials.
- Clinical trials enable the healthcare community to systematically collect information on the effectiveness of the treatment and potential associated risks so that the results can help treatment decisions for other patients.

Treatment of COVID-19

- The health and safety of Canadians is our top priority.
- Canadians who are ill with COVID-19 need access to safe and effective drugs and health products.
- At this time, there are no drugs or vaccines that have been proven safe and effective for the treatment or prevention of COVID-19. Several new promising therapies are in development, and existing drugs are being assessed for this potential.

The best way to access experimental therapies for COVID-19 is through clinical trials. Health Canada has authorized [clinical trials](#) on the use of chloroquine or hydroxychloroquine in COVID-19.

- In view of recent trials showing lack of efficacy, Health Canada has requested additional information from clinical trial sponsors in order to determine whether clinical trials it has approved should continue.
- Patients and healthcare professionals are reminded to report any suspected side effects to Health Canada. Health Canada will continue to closely monitor the safety and effectiveness of chloroquine, hydroxychloroquine, and other drugs used in the treatment of COVID-19, and will take appropriate and timely action if and when any new health risks are identified, including informing Canadians as necessary.

If pressed on Health Canada actions to mitigate shortages linked to COVID-19:

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- Health Canada is actively monitoring the impact of the COVID-19 pandemic on the supply of drugs in Canada. This includes proactively looking at the Canadian supply chain to identify areas where supply may be vulnerable and addressing those vulnerabilities before shortages develop.
- The Department has also increased surveillance efforts and is regularly engaging provinces and territories, industry, healthcare and patient groups—in some cases on a daily basis. Health Canada is also working with international regulatory partners, including the European Medicines Agency, the United States Food and Drug Administration, the Australian Therapeutic Goods Administration, and the World Health Organization to share information on any signs of global supply disruptions. This engagement has enabled us to better identify early shortage signals, potential mitigation strategies, and to coordinate responses.
- As part of the whole-of-government response to the COVID-19 pandemic, the COVID-19 Emergency Response Act was passed on March 25. The amendments to the *Food and Drugs Act* enable Health Canada to put in place more robust tools to support efforts to alleviate shortages that occur and prevent shortages from happening when possible.
- On March 30, the Minister of Health signed an Interim Order permitting the exceptional importation and sale of drugs, medical devices, and foods for a special dietary purpose needed to prevent or alleviate the effects of shortages directly or indirectly related to COVID-19.
- The Interim Order permits the exceptional importation of specified drugs that may not fully meet Canadian regulatory requirements, such as bilingual labelling, but are manufactured according to comparable standards to safeguard the Canadian drug supply and protect the health of Canadians during this time.
- Only drugs included on the List of Drugs for Exceptional Importation and Sale are eligible for the exceptional importation and sale provisions in the Interim Order. At this time, the list only includes drugs that have been designated as Tier 3 shortages.
- Health Canada will continue to work with other federal departments, provincial, and territorial governments, international partners, and industry so that Canadians have access to the drugs and medical devices they need during the COVID-19 pandemic.

Supplementary Messages on Drugs and Vaccines

- When a vaccine or drug is developed to prevent or treat COVID-19, we will take appropriate action to ensure its availability to Canadians.
- Measures include:
 - scientific review of new drugs or vaccines through a priority review or a notice of compliance with conditions;
 - use of the Extraordinary Use of New Drugs pathway for making a promising new drug or vaccine available in order to secure the health of Canadians during an emergency; and
 - Canadian clinical trials for new vaccines, new or repurposed antivirals, or supportive therapies.
- Other measures include the:

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- Special Access Program for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed or are unavailable; and
- importation of a new drug authorized for sale in the United States, Switzerland or the European Union through the list of drugs for an urgent public health need.

Approved Clinical Trial for the use of Hydroxychloroquine in Hospitalized Children

- The health and safety of Canadians is our top priority.
- Canadians and their families, including children, who are ill with COVID-19 need access to safe and effective drugs and health products for diagnosis and treatment.
- Hydroxychloroquine has been approved in Canada for the treatment of lupus, rheumatoid arthritis and malaria.
- As the use of this medication to treat COVID-19 is in its early experimental stage, Health Canada recommends that healthcare practitioners prescribing this therapy for COVID-19 patients do so through a clinical trial.
- On May 2, 2020, Health Canada authorized a clinical trial from the Research Institute of the McGill University Health Centre to study the safety and effectiveness of hydroxychloroquine as a treatment for COVID-19 in hospitalized children.
- There has been some preliminary evidence from studies outside of Canada suggesting that hydroxychloroquine may be effective in reducing the viral load in certain groups of patients with COVID-19, as well as in treating respiratory tract infections related to COVID-19. However, there have been mixed results and so more studies are needed, especially in children.
- Like all medications, the use of hydroxychloroquine is associated with known risks, which can be limited and closely monitored in a clinical trial.
- A clinical trial requires the informed consent of patients (and parent/guardian, if applicable) and would enable the healthcare community to systematically collect information about the risks and benefits of the treatment.

Regulatory Flexibilities for Promising COVID-19 Therapies

- Ensuring that Canadians have access to needed medications and medical devices during the COVID-19 pandemic is a top priority for Health Canada.
- Health Canada is prepared to consider certain rarely used regulatory flexibilities to allow for the earlier filing of submissions for drugs that show promise to treat or prevent COVID-19.
- Health Canada may accept new evidence as it becomes available from ongoing clinical trials, while ensuring that the review is still subject to the same levels of safety, efficacy and quality.

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This process can lead to a more efficient review by Health Canada and shorten the overall review time for a new drug, while maintaining high scientific review standards.

- The available evidence must always demonstrate that the drug is safe, effective and of high quality before Health Canada will authorize the drug for use by Canadians.
- A similar approach was taken previously to approve the H1N1 vaccine.

On using this approach for remdesivir:

- Potential promising therapies such as remdesivir could be reviewed under this model.
- Health Canada is currently in discussions with Gilead Sciences Canada Inc. regarding a drug submission for remdesivir.
- Remdesivir is an antiviral medication originally developed to treat Ebola.

Remdesivir for the treatment of COVID-19

- The Government of Canada has signed an agreement with Gilead Sciences and McKesson Canada to secure a supply of up to 150,000 vials of remdesivir, with initial deliveries beginning this month and continuing into early 2021.
- Remdesivir is the first antiviral drug that Health Canada has authorized specifically for the treatment of COVID-19.
- Initial doses of remdesivir are being deployed to provinces and territories for immediate use in the health care system. Beginning in October, additional supply will be delivered to Canada on a monthly basis.
- The Government of Canada is working closely with provincial and territorial partners to equitably allocate supply, while recognizing the need for flexibility in future allocations given the number of patients severely ill with COVID-19 across the country.
- Remdesivir is indicated for the treatment of adult and adolescent patients with severe symptoms of COVID-19; that is, patients who have pneumonia and require supplemental oxygen. It is administered intravenously and can be used only in health care facilities where patients can be monitored carefully while being treated.

Supplementary Messages on Importation and Labelling:

- Given the medical necessity of this product in Canada, Health Canada is temporarily permitting importation of remdesivir intended for clinical trials and with English-only labelling from the US to be distributed and used in Canada. Remdesivir with English only U.S. labelling has been added to the List of Drugs for Exceptional Importation and Sale.
- This temporary allowance will provide earlier access to this product for Canadian patients ahead of the marketing of Canadian-labelled remdesivir (brand name VEKLURY®).

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- Health care providers are advised that the US clinical trial-labelled remdesivir for injection is the same as the Canadian approved product and should be used in the same way to treat COVID-19 in adults and adolescents (i.e., aged 12 years and older with a body weight of at least 40 kg) with pneumonia requiring supplemental oxygen.
- The drug meets Health Canada's requirements for safety, quality and effectiveness. Only the labelling is different.
- As with all drugs, Health Canada will continue to monitor the safety and effectiveness of remdesivir and will take appropriate action if any safety concerns arise.
- Health care facilities will receive the drug shipment together with a letter addressed to health care providers with important safety recommendations. This letter is distributed in both official languages.

Supplementary Messages on Unilingual Labelling:

- Remdesivir is distributed only to health care providers. It is not available for sale or distribution to the general public in Canada.
- Health Canada has notified health care providers so that they are aware of the English only packaging and labelling.
- Remdesivir is being delivered to health care facilities with a letter addressed to health care providers with important safety recommendations. This letter is distributed in both official languages.
- Health Canada is strongly committed to meeting the requirements of the *Official Languages Act* and fostering linguistic duality.
- Generally, bilingual labelling, instructions, and safety information are required for all products sold in Canada.
- In light of the unprecedented demand and urgent need for products to help limit the spread of COVID-19, Health Canada is facilitating access, on a temporary basis, to certain imported products that may be labelled in only one official language to increase access to products that are in high demand.

EMA safety review of Remdesivir

- Health Canada is aware of the European Medicines Agency's safety review of Veklury (remdesivir) and reports of acute kidney injury in some patients.
- Health Canada has also initiated a priority safety review, and will be evaluating all of the available safety information, including information being requested from the manufacturer, to determine whether there is a link between Veklury and the reports of acute kidney injury.
- Health Canada has been working with the manufacturer to monitor domestic and international cases of acute kidney injury since the approval of Veklury, as kidney injury was identified as an important potential risk to be monitored during the pre-market review process.

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- The product safety information for Remdesivir (Veklury) includes the risk of renal toxicity and advises patients to have their kidney function determined prior to starting the drug. Remdesivir (Veklury) should not be used in patients with severe kidney problems, and should be stopped immediately if experiencing severe kidney problems.
- Health Canada will inform healthcare professionals and Canadians regarding the conclusions from this priority review.

Clinical Trial Application for the Medicago COVID-19 vaccine

- On July 9, 2020, Health Canada approved a clinical trial application from Medicago R&D Inc. for a COVID-19 vaccine. This is the second clinical trial authorized in Canada for a vaccine specifically designed to prevent COVID-19, and the first from a Canadian company.
- This decision followed careful review of the application, which Health Canada determined met the necessary requirements for safety and quality.
- Health Canada reviewed the submission according to its expedited review process for all clinical trials for COVID-19 products.
- Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to ensure vaccines are safe and effective in preventing the diseases they target.

Supplies and medical devices

Canada's supply of PPE and medical supplies

- We are aware of the shortage of personal protective equipment (PPE) and medical supplies across Canada and are committed to doing what is necessary to protect the health of Canadians, especially frontline healthcare workers, from COVID-19.
- The Government of Canada is coordinating with provincial and territorial governments to quickly assess needs for PPE items such as N95 respirators, surgical masks, face shields, nitrile gloves, gowns and other protective clothing, as well as medical supplies such as sanitizer, ventilators, swabs and testing kits.
- To meet these needs, we are purchasing large quantities of equipment and supplies, working with Canadian companies to increase their manufacturing capacity to produce additional supplies, and investing in COVID-19 testing.
- We have also received donations from international and domestic organizations.
- Canada is working to rapidly allocate PPE and medical supplies to the provinces and territories as per an approach agreed upon by federal-provincial-territorial (FPT) Ministers of Health.
- The Public Health Agency of Canada (PHAC) is also deploying PPE and ventilators from its National Emergency Strategic Stockpile (NESS) to provinces and territories submitting requests for assistance.

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- Canada's NESS contains supplies that provinces and territories can request in emergencies, such as infectious disease outbreaks. The purpose of the NESS is to help supplement provincial and territorial resources through the provision of surge support.
- Provinces and territories are responsible for preparing and maintaining their own supply capacities.

Regulatory Measures to improve access to medical devices including PPE

- To support the Government wide response to COVID-19, in recent weeks we have:
 - allowed expedited access to COVID-19-related medical devices such as test kits.
 - expedited licensing of establishment and product licences.
 - addressed shortages by permitting the importation and sale of medical devices that are not approved in Canada, subject to certain requirements.
 - facilitated access to products that may not fully meet current regulatory requirements, such as bilingual labelling, including personal protective equipment (such as masks and gowns), swabs, hand sanitizers, and hard-surface disinfectants.
 - amended the *Food and Drugs Act* and the *Patent Act* to support efforts to help prevent and alleviate shortages.
- Health Canada will monitor and assess the safety, quality, and efficacy of all products allowed for import and sale under these special measures.

National Emergency Strategic Stockpile Preparedness and Stock (response to the May 2020 House of Commons appearance)

- Since 2012-2013, the National Emergency Strategic Stockpile (NESS) budget, including salaries and operating, has consistently been around \$3 million annually.
- In addition, there have been investments made for particular initiatives and medical countermeasures, such as a four-year investment in medical countermeasures against smallpox and anthrax that began in 2015-16. Over the last 10 years, these investments have varied year over year, and have amounted to over \$79 million.
- The NESS was built on the assumption that provincial, territorial and local governments would be prepared for the most common emergencies. Consequently, it was designed to provide health emergency assets when local and provincial and territorial resources were exhausted, and to be the sole provider of certain niche assets required for rare public health emergencies, for example, costly and rarely used vaccines or antidotes.
- Jurisdictions have traditionally sourced personal protective equipment (PPE) directly from known suppliers, and the NESS has historically only carried relatively small amounts.
- The supplies in the NESS are regularly reviewed and purchased on a regular basis.

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- The Canadian Pandemic Influenza Plan is a federal, provincial, and territorial guidance document for the healthcare sector to assist jurisdictions with their emergency planning. The most recent guidance from 2011 recommends that availability of PPE supply should be addressed during pandemic planning, and that stockpiling should be considered. However, it does not specify a certain quantity of supply.
- In January 2020, the Public Health Agency of Canada began monitoring the coronavirus outbreak in China and started assessing its NESS inventories and procuring supplies needed to respond to a possible outbreak in Canada.
- With the unprecedented nature of the current pandemic, the government is providing significant funding as the NESS steps into a much more active and expanded role in procurement.

If pressed on whether advice related to the NESS was ever provided to Cabinet:

- Departments and all public servants are bound to uphold Cabinet Confidentiality.

Shortages of gowns

- Gowns are essential to protect health care providers during the COVID-19 pandemic; however, increasing worldwide demand for gowns has created a temporary shortage in Canada and around the world.
 - To help health care settings develop strategies to continue to keep health care workers safe while caring for patients, the Public Health Agency of Canada and Health Canada have developed recommendations for conserving and prioritizing gown use, and gown alternatives and expired gowns.
 - The Government of Canada is working hard to get personal protective equipment (PPE) and medical supplies to health care workers through bulk procurement in collaboration with the provinces and territories, ramping up domestic production capacity, and identifying potential alternatives, and ways to extend product life.
 - The Government of Canada has ordered gowns and is starting to receive shipments from both international and domestic suppliers. The Public Health Agency is working rapidly to allocate these items to provinces and territories as per an approach agreed upon by federal-provincial-territorial (FPT) Ministers of Health.
- Conservation strategies***
- To conserve the inventory of gowns that provide protection from droplets and fluids, health care settings should implement environmental and administrative controls to minimize the strain on gown use.
 - These controls could include:
 - providing physical barriers between health care workers and potentially infectious individuals at screening points;
 - reducing, postponing or cancelling non-essential activities or procedures that may require gowns;
 - exploring ways to launder and return reusable gowns more quickly;

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- limiting the number of visitors to patient rooms where a gown would normally be required; and
- using gowns not usually used in this context (e.g., surgical gowns), if inventory and surgical workload permit.

Protective gown alternatives

- Gown alternatives or supplements to gowns (e.g., coveralls, laboratory coats, aprons); may be more complex to put on and take off than protective gowns, possibly increasing the risk of contamination.
- It is also important to note that alternatives or supplements to gowns provide varying levels of protection against droplets and fluids.
- To extend the use of protective gowns, health care workers could consider wearing an apron they could change between patients over the gown.
- If protective gowns are not available, combinations of gown alternatives may need to be considered to provide adequate protection where there may be exposure to body fluids.

Expired and reusable gowns

- Health Canada does not recommend using expired disposable medical gowns without confirming that they are still fluid resistant.
- Reusable (i.e., washable) gowns may be cleaned after each use, following the manufacturer's instructions with respect to sterility and laundering requirements for health care settings. This includes the number of times gowns can be laundered to maintain performance, safety and effectiveness.
- Reusable gowns can be used beyond their recommended life span provided they are free of damage. Expired gowns should be visibly inspected for damage prior to use.

Orders and domestic production of medical gowns

- The global demand for PPE has resulted in material usually used for the production of gowns being diverted to the production of masks. This has caused manufacturers around the world to have difficulty fulfilling their orders, resulting in delays in production and shipment.
- To help meet national needs, Canada has built up its domestic production capacity. Innovation, Science and Economic Development Canada and Public Services and Procurement Canada have galvanized Canadian industries, and with a number of Canadian companies retooling to produce gowns, domestic deliveries have already begun.
- To date, Public Service Procurement Canada has ordered more than 130 million gowns. More than 200,000 have been delivered to PHAC, with more deliveries expected within the next few weeks.

Procurement contracts to increase supplies in Canada

- Innovation, Science and Economic Development Canada and Public Services and Procurement Canada continue to galvanize Canadian industries to increase domestic manufacturing

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capacity, including re-tooling facilities to produce equipment and supplies including portable ventilators, surgical masks, and rapid testing kits.

- Through these efforts, the Government of Canada has signed new procurement agreements with Canadian companies such as Thornhill Medical, Medicom, and Spartan Bioscience.
- The Government has also signed letters of intent with companies such as Precision Biomonitoring, Fluid Energy Group Ltd., Irving Oil, Calko Group, and Stanfield's to produce test kits, hand sanitizer, and protective apparel, including masks and gowns.
- Canada Goose received its medical device establishment licence from Health Canada to proceed with the retooling of its manufacturing facility to enable it to make gowns.
- Throughout this process, PHAC, Health Canada and National Research Canada are playing a critical role, conducting technical reviews to verify that the products meet the Government of Canada technical specifications for COVID-19 as available on the Public Services and Procurement Canada's [buy and sell website](#).
- The Government of Canada has also awarded a contract to Amazon to manage the logistics of distributing PPE and supplies to support the COVID-19 response.
- Amazon will work directly with Canada Post to provide warehousing, and leverage its current third-party delivery channels, through Canada Post and Purolator, to deliver the products to provincial and territorial health authorities, across the country, for the frontline healthcare response.

Invitation to Submit an Expression of Interest for Logistics Services

- The Government of Canada is working hard to procure and deliver personal protective equipment (PPE) for front-line health care workers across Canada.
- To support these efforts, the Government of Canada is soliciting interest from companies to provide logistics services to help receive and distribute an extraordinary volume of orders of PPE across Canada in a timely manner.
- This new expression of interest relates to an end-to-end logistics solution that is different than what the existing Amazon agreement provides for. It includes warehousing, customs documentation and brokerage, and inventory management.
- PHAC will continue to maintain oversight on the amounts of PPE and supplies available, which provinces and territories are requesting them, and where they are being shipped.



Authorizations for Made-in-Canada Ventilators under the Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19

- In response to the COVID-19 pandemic, Health Canada continues to authorize medical devices under an expedited regulatory review process.
- On June 16, 2020, Health Canada authorized the Made-in-Canada Baylis Medical V4C-560 and the CAE Aer1 ventilators.
- These ventilators are manufactured by companies that responded to Innovation, Science and Economic Development Canada's (ISED) Call to Action as part of the Plan to Mobilize Industry to fight COVID-19.
- Both ventilators were authorized under the [Interim Order](#) for COVID-19 medical devices, which enables Health Canada to authorize devices under an expedited scientific review process.
- A list of devices authorized through this Interim Order is available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/other.html>
- Health Canada completed a thorough scientific review to ensure that these devices meet Health Canada's requirements for safety, quality and effectiveness.
- Health Canada continues to monitor the safety, quality, and effectiveness of all medical devices for use in the diagnosis, treatment, mitigation and prevention of COVID-19 once they are on the market. As with all medical devices, manufacturers must follow strict post-market safety requirements, such as mandatory problem reporting, recall procedures and complaint handling.

If pressed on ISED's role

- Ventilators for Canadians and CAE both responded to ISED Call to Action as part of the Plan to Mobilize Industry to fight COVID-19. Contracted to produce 10,000 ventilators each for the Government of Canada, these Made-in-Canada ventilators are part of the up to 40,000 ventilators that the Government of Canada purchased following the Call to Action.
- Through the Call to Action, the Government of Canada identified four Canadian companies capable of manufacturing Made-in-Canada ventilators in support of the fight against COVID-19. Each has been contracted to provide up to 10,000 made in Canada ventilators (for a total of up to 40,000): Ventilators for Canadians (Baylis Medical), CAE, Canadian Emergency Ventilators/Starfish and Vexos
- As a condition of the contracts, each company's ventilator must be authorized by Health Canada.
- ISED and Public Services and Procurement Canada continue to actively support Canadian industries to increase domestic manufacturing capacity, including re-tooling facilities to produce equipment and supplies including ventilators, surgical masks and testing kits.

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- Through these efforts, the Government of Canada continues to sign new procurement agreements with Canadian companies that can provide urgently needed equipment. Throughout this process, PHAC, Health Canada and the National Research Council of Canada are playing a critical role, conducting technical reviews to verify that the products meet the Government of Canada technical specifications for COVID-19 as available on the Public Services and Procurement Canada's buy and sell website.

Concerns with the CAE Air1 Ventilator for COVID-19

- Canadians and their families rely on safe and effective health products, including ventilators and other medical devices.
- After Health Canada authorizes a medical device for use in Canada, the Department continues to monitor for safety and effectiveness once the product is on the market. If concerns arise, Health Canada takes appropriate action to protect the health and safety of Canadians.
- The CAE Air1 ventilator was authorized by Health Canada on June 16, 2020, under the *Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19*.
- In late June, several ventilators were delivered to the Public Health Agency of Canada (PHAC) for quality assurance testing. During testing, a number of concerns were raised regarding oxygen delivery, stability and monitoring that could affect patient safety. There were also minor problems with the packaging and labelling text.
- As a result, on July 10, 2020, Health Canada issued conditions on the authorization of the CAE Air1 ventilator to ensure that the ventilator is not distributed until all identified issues are addressed. No ventilators were distributed in Canada other than to PHAC.
- PHAC has subsequently conducted quality assurance testing on modified CAE ventilator units and shared its findings with both CAE and Health Canada on September 11.
- CAE is not authorized to distribute its ventilator until such time as all issues have been addressed to Health Canada's satisfaction.
- Health Canada and PHAC continue to work with the company to help resolve the problems with the ventilators so that they can be used safely by Canadians.

Supplementary Messages on Authorization:

- In response to the COVID-19 outbreak, Health Canada continues to authorize medical devices under an expedited regulatory review process.
- Health Canada completes a thorough scientific review to ensure that devices meet Health Canada's requirements for safety, quality and effectiveness.
- Health Canada continues to monitor the safety, quality and effectiveness of all medical devices once they are on the market. Manufacturers must follow strict post-market safety requirements, such as mandatory problem reporting, recall procedures and complaint handling.



- A list of devices authorized through the Interim Order is available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/other.html>

If pressed on ISED's role (Questions related to these items may be referred to ISED)

- CAE responded to ISED's call to action as part of the Plan to Mobilize Industry to fight COVID-19.
- Through the Call to Action, the Government of Canada identified four Canadian companies capable of manufacturing made-in-Canada ventilators in support of the fight against COVID-19. Each has been contracted to provide up to 10,000 made-in-Canada ventilators (for a total of up to 40,000): Ventilators for Canadians (FTI Professional Grade Inc.), CAE, Canadian Emergency Ventilators/Starfish and Vexos.
- As a condition of the contracts, each company's ventilator must be authorized by Health Canada.
- ISED and Public Services and Procurement Canada (PSPC) continue to actively support Canadian industries to increase domestic manufacturing capacity, including re-tooling facilities to produce equipment and supplies including ventilators, surgical masks and testing kits.
- Through these efforts, the Government of Canada continues to sign new procurement agreements with Canadian companies that can provide urgently needed equipment.
- Throughout this process, PHAC, Health Canada and the National Research Council of Canada are playing a critical role, conducting technical reviews to verify that the products meet the Government of Canada technical specifications for COVID-19 as outlined on PSPC's [BuyandSell website](#).

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- In response to the COVID-19 outbreak, Health Canada continues to authorize medical devices under an expedited regulatory review process.
- Health Canada completes a thorough scientific review to ensure that devices meet Health Canada's requirements for safety, quality and effectiveness.
- Health Canada continues to monitor the safety, quality, and effectiveness of all medical devices once they are on the market. As with all medical devices, manufacturers must follow strict post-market safety requirements, such as mandatory problem reporting, recall procedures and complaint handling.
- A list of devices authorized through the Interim Order is available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/other.html>

If pressed on ISED's role (Questions related to these items may be referred to ISED)



- CAE responded to ISED's call to action as part of the Plan to Mobilize Industry to fight COVID-19.
- Through the Call to Action, the Government of Canada identified four Canadian companies capable of manufacturing made-in-Canada ventilators in support of the fight against COVID-19. Each has been contracted to provide up to 10,000 made-in-Canada ventilators (for a total of up to 40,000): Ventilators for Canadians (Baylis Medical), CAE, Canadian Emergency Ventilators/Starfish and Vexos.
- As a condition of the contracts, each company's ventilator must be authorized by Health Canada.
- ISED and Public Services and Procurement Canada (PSPC) continue to actively support Canadian industries to increase domestic manufacturing capacity, including re-tooling facilities to produce equipment and supplies including ventilators, surgical masks and testing kits.
- Through these efforts, the Government of Canada continues to sign new procurement agreements with Canadian companies that can provide urgently needed equipment.
- Throughout this process, PHAC, Health Canada and the National Research Council of Canada are playing a critical role, conducting technical reviews to verify that the products meet the Government of Canada technical specifications for COVID-19 as available on the PSPC's [buy and sell website](#).

Health Canada's assessment with respect to non-compliant KN95 respirators

- Health Canada understands that health care professionals providing care to Canadians rely on personal protective equipment (PPE), including respirator masks to keep them safe. The quality, effectiveness and safety of health products are always top of mind for Health Canada.
- Health Canada continues to assess all sources of information related to respirators that may not meet safety and effectiveness standards, and takes action to ensure that products that do not meet the applicable standards are relabelled as face masks for use in settings where 95% filtration is not required. In addition to the testing conducted by the National Institute for Occupational Safety and Health (NIOSH), Health Canada has assessed results from other laboratories and will continue to update the [list](#) of devices that must be relabelled as face masks in order to be distributed in Canada.
- The Department is contacting all companies that may have imported or distributed impacted products to request that they confirm whether the products have been distributed. Companies that have confirmed importation or distribution will be directed to stop sale and relabel the products as face masks.

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- In Canada, relabelling of a medical device that fails to conform to claims relating to its effectiveness is considered a recall in accordance with the Medical Devices Regulations. Health Canada posts a list of all respirator recalls and will continue to update it as required.
- Health Canada will ensure that any companies that have distributed affected products take appropriate action to stop selling any impacted products, notify customers and relabel existing stock as face masks instead of respirators. Should additional safety concerns be identified, Health Canada will take appropriate action and inform Canadians, as necessary.
- Provincial and territorial health authorities and healthcare institutions should review their inventories of KN95 respirators to confirm that they meet the Government of Canada technical specifications for healthcare settings for COVID-19 response.

Supplementary Messages – Products Procured by the GoC

- This action does not implicate KN95 respirators purchased by the Government of Canada and tested by the Public Health Agency of Canada (PHAC). Before allocating any personal protective equipment to the provinces or territories for frontline healthcare workers, PHAC conducts a quality verification. For KN95 respirators, this includes a visual inspection to check for defects in design and construction, and testing, supported by the National Research Council, to confirm that they meet filtering specifications.
- KN95 respirators distributed to provinces and territories by PHAC meet the Government of Canada’s technical specifications for healthcare settings for COVID-19 response.
- If PHAC cannot account for the quality, it will not be allocated to the provinces and territories for frontline healthcare response. Supplies that do not meet specifications are subsequently assessed for potential use in non-healthcare settings.

Supplementary Key Messages on Work with the US FDA

- On May 7, 2020, the US FDA issued revised guidance, indicating that certain respirator masks may not provide adequate respiratory protection, and issued a letter to health care providers indicating that certain devices currently being sold in the US do not meet expected filtration standards and are no longer authorized to be marketed or distributed in the United States as respirators. They may be relabeled as face masks and authorized if certain criteria are met.
- Health Canada works closely with other regulators, such as the US FDA, and takes comparable actions when necessary to help ensure the quality, effectiveness and safety of medical devices for the Canadian market.
- Health Canada is actively engaged and urgently responding to the US FDA’s change to its Emergency Use Authorization for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China.
- The NIOSH assessment webpage includes a list of KN95 respirators manufactured in China that have been tested and the test results. Health Canada will continue to take action to ensure

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that devices that do not meet the appropriate standards are relabelled for use in settings where a 95% filtration is not required before they can be distributed in Canada.

Supplementary Messages on Market Authorization of N95 and KN95 respirators and the Interim Order

- There are two ways for companies to sell and import COVID-19 Class I medical devices to the Canadian market. They can apply for a market authorization by Health Canada through the Interim Order for Expedited Access to Medical Devices for COVID-19 pathway or apply for a Medical Device Establishment Licence (MDEL).
- Health Canada reviews the scientific evidence provided by the manufacturers through the Interim Order pathway to support the safety and effectiveness of devices before issuing authorizations for these devices.
- MDEL holders have been advised that they are not permitted to import or distribute respirators that have failed NIOSH testing unless they are relabelled as face masks. As Health Canada continues to assess additional sources of information related to respirators that may not meet safety and effectiveness standards, it will continue to advise MDEL holders of their responsibilities.
- N95, KN95 and equivalent respirators are Class I medical devices, which do not require pre-market approval. However, in order to enable Health Canada to conduct a scientific review in advance of authorizing the sale of these devices, manufacturers are encouraged to submit applications through the Interim Order pathway as opposed to the Medical Device Establishment Licence (MDEL) regulatory pathway.

Supplementary Messages on Testing and Status of KN95 Respirators

- In Canada, manufacturers of Class I medical devices, which include N95 and KN95 respirators, previously have had the option of two regulatory pathways: a medical device establishment licence (MDEL) or an Interim Order (IO).
- While Health Canada will continue to accept equivalent alternate standards to the NIOSH N95, including KN95 and FFP2, it will now request evidence of quality manufacturing and validated test results. Health Canada may request results from independent testing facilities as a condition of authorization under the Interim Order.

Supplementary Messages for Healthcare Settings

- Health Canada is committed to ensuring that the medical devices available to Canadians meet standards of safety and effectiveness. Health Canada is monitoring potential issues on the Canadian market and will take action as necessary.

Supplementary Messages on Compliance and Enforcement Options



- A number of compliance and enforcement options are available to correct non-compliance or to mitigate a risk to Canadians including on-site visits, recalls, public communications, and product seizures.
- Health Canada takes a risk-based approach that takes into account the circumstances of each case to protect the health and safety of Canadians.
- The primary objective of Health Canada's compliance and enforcement approach is to manage the risks to Canadians using the most appropriate level of intervention.
- In this case, while some KN95 respirators may not meet the standards required for frontline healthcare workers, they could still be used as face masks in settings where 95% filtration standards are not needed; thus requesting that the impacted respirators be recalled and relabelled as masks addresses the risk posed.

Supplementary Messages on Canada's Supply of PPE and Medical Supplies

- Health care workers need medical masks, including surgical masks, medical procedure masks, and respirators, such as N95 respirators. It is extremely important to maintain the supply of medical masks where it is needed.
- The Government of Canada is working to ensure that health care workers have the PPE and medical supplies they need. We are doing this through collaborative bulk procurement with the provinces and territories, building domestic production capacity, and identifying potential alternatives and ways to extend device life.
- Canada is working to rapidly allocate PPE and medical supplies to the provinces and territories as per an approach agreed upon by federal, provincial and territorial Ministers of Health.
- PPE and medical supplies received by the Government of Canada, whether procured internationally or domestically, are verified by PHAC to ensure they meet Government of Canada technical specifications for healthcare settings for COVID-19 response. It is the same process for donations.
- If PHAC cannot account for the quality of devices, they will not be allocated to the provinces and territories for frontline healthcare response.
- The process for verification varies depending on the medical device. For example, KN95 respirators, as an accepted alternative to N95 respirators, are visually inspected to check for defects in design and construction, and tested to confirm they meet specifications for filtering face pieces.
- To date, a large majority of the devices received by the Government of Canada have met the technical specifications for healthcare settings for COVID-19 response; however, as a result the Public Health Agency of Canada's stringent review process, approximately 10 million KN95 respirators were assessed as not meeting the technical specifications

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Procured and Donations of PPE

- Personal protective equipment and medical supplies received by the Government of Canada, whether donated or procured, is verified by PHAC that it meets the Government of Canada technical specifications for COVID-19 as available on Public Services and Procurement Canada's buy and sell website.
- The process for verification varies depending on the medical device. For example, KN95 respirators, as an accepted alternative to N95 respirators, are visually inspected to verify for defects in design and construction, and tested to assess that flow rate, pressure drop and penetration meet specifications for filtering face pieces. Gowns are visually inspected and tested for fluid penetration.
- Recognizing that some of the supplies might not be familiar to our healthcare providers, items that meet the appropriate technical specifications will be deployed to provinces and territories with accompanying documentation that confirms that the products meet specifications and offers instructions for use.
- For example, items received from China might have labeling in Mandarin. To ensure rapid deployment, PHAC is not able to re-label each individual item. To that end, provinces and territories are advised to follow the PHAC instructions provided with the supplies, conducting the appropriate training with frontline healthcare workers.
- Another example is the KN95 mask. Normal procedure for an N95 mask is to conduct a fit test; however, the KN95 cannot be tested this way; therefore, PHAC will be instructing provinces and territories to conduct facefit testing. This process may be unfamiliar to healthcare workers; therefore, instructions will be provided.
- The Government of Canada appreciates the donations of PPE generously provided by international and domestic organizations, including the Jack Ma Foundation/Alibaba, Home Depot, Apple, CBC/Radio-Canada, Shell, AstraZeneca, and many others.
- We are pleased to see so many Canadians stepping up and lending support to those who need it most.

Coordinated Government of Canada response to purchasing equipment and supplies

- The Government of Canada is leading a coordinated approach to provide needed supplies and equipment across the country:
 - **Public Services and Procurement Canada:** PSPC is leveraging existing supply arrangements, as well as engaging with the broader domestic and international supply communities to identify and purchase required products.
 - The department is asking all suppliers to come forward with products and/or services they could offer to support Canada's response.

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- **Public Health Agency of Canada:** PHAC is leading collaboration with federal partners, provinces and territories to identify needs and requirements for the COVID-19 response. The Agency is also overseeing Canada's National Emergency Strategic Stockpile, which contains supplies that provinces and territories can request for surge support.
- **Health Canada:** As the regulatory body for health products, Health Canada is expediting access to the health products Canadians need to help limit the spread of COVID-19.
 - On March 18, the Minister of Health signed an Interim Order to allow expedited access to COVID-19-related medical devices. Health Canada also introduced an interim measure to facilitate access to certain products, such as PPE.
 - Under the Interim Order, a medical device licence or authorization is needed to sell and import higher risk medical devices to Canada.
 - Health Canada will review all COVID-19-related submissions and applications as quickly as possible while maintaining standards for patient safety.
- **Innovation, Science and Economic Development Canada: ISED** is leading Canada's Plan to Mobilize Industry to fight COVID-19 by introducing new measures to directly support businesses to rapidly scale up production or re-tool their manufacturing lines to develop products made in Canada that will help in the fight against COVID-19. On March 20, ISED issued a call to action for manufacturers and business.
- **National Research Council of Canada:** The NRC's Industrial Research Assistance Program is building on its existing relationships with thousands of Canada's most innovative small and medium-sized businesses to issue challenges to the marketplace for innovative solutions to fight COVID-19.

Re-Use of Single-Use Medical Devices

- As with other hospital-based practices, the purchase and use of reprocessed devices by individual healthcare facilities falls under provincial and territorial jurisdiction.
- Given shortages of some critical medical devices due to COVID-19, Health Canada is working on guidance for the cleaning and sterilization of single-use devices.
- Additional urgent measures have also been taken by the Government of Canada in the last few weeks to support access to new COVID-19 diagnostic tests and hand sanitizers, disinfectants, personal protective equipment, and swabs for diagnosis.

N95 Masks – Decontaminating and Reuse

- The N95 masks used by healthcare workers are labelled as single-use products.
- The Government of Canada, like many other countries, is looking at ways to extend the use of personal protective equipment (PPE), such as N95 masks, through decontamination as a way of helping Canada meet its supply needs.

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- The Government of Canada has asked provinces and territories, as well as healthcare providers, to keep their used N95 masks and store the masks according to their local biosafety standards and guidelines while we verify processes for successful mask decontamination.
- Health Canada has already authorized certain machines to decontaminate N95 masks under the Interim Order for Medical Devices. Products and manufacturing processes must meet the requirements for safety, quality and effectiveness to protect the health and safety of Canadians.
- The Government of Canada has procured decontamination units to increase provincial and territorial capacity to reprocess N95 masks, if needed.
- Other countries, including the United States, have taken this approach.
- The Government of Canada is working hard to get PPE and medical supplies to healthcare workers through bulk procurement in collaboration with the provinces and territories, ramping up domestic production capacity, and identifying potential alternatives and ways to extend product life.

On the Public Health Agency of Canada's Procurement of Decontamination of Devices for the Reprocessing of Single Use N95 Respirators during the COVID-19 Response

- The Government of Canada put in place a contract with Stryker Canada, on April 15, 2020, to procure 82 decontamination devices.
- These units will provide a total additional national capacity to reprocess approximately 275,500 N95 respirators a week.
- These devices are the result of Canadian research and development efforts and are manufactured in Canada.
- The Government of Canada continues to work closely with all provinces and territories on their potential needs for additional decontamination and reprocessing capacity.
- The National Research Council has purchased 20 Clean Flow Healthcare Mini medical devices to share with hospitals to study mask decontamination.

On Health Canada's Considerations for the Reprocessing of Single Use N95 Respirators during the COVID-19 Response

- The Government of Canada recognizes that reprocessing masks is a potential solution that would provide an additional supply of masks for healthcare workers who rely on them for protection.
- Because of potential shortages of PPE during the COVID-19 response, the Government of Canada continues to work with manufacturers to identify additional technologies that enable

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effective decontamination of single use N95 respirators, which would allow their safe reuse by frontline healthcare professionals.

- Decontamination is an acceptable way to make the masks safe for reuse. Companies are required to provide evidence that demonstrates their processes are capable of adequate decontamination for reuse.
- Health Canada has posted a notice to inform manufacturers of important regulatory requirements that would need to be considered to demonstrate that their decontamination methods for single use N95 respirators would meet key safety and effectiveness requirements.
- A notice with important considerations for healthcare professionals has also been posted that provides further information about Health Canada's evidence requirements ensuring that products and manufacturing processes meet the standards required for safety, quality and effectiveness.
- Manufacturers wishing to reprocess medical devices for use for COVID-19 can apply for expedited authorizations under the March 18, 2020 Interim Order—a streamlined regulatory process to respond to the health crisis.
- There are two approaches that may be taken:
 - companies may provide sterilization or decontamination devices or systems to healthcare facilities for use in reprocessing single use N95 respirators, or
 - companies may themselves reprocess and redistribute single-use N95 respirators to healthcare facilities.
- Healthcare facilities with sterilizers capable of reprocessing N95 respirators in house do not require Health Canada authorization to conduct the activity. However, Health Canada highly recommends that healthcare facilities use only technologies that have been authorized by Health Canada.
- The Government of Canada continues to engage with the healthcare community, and provinces and territories to monitor the supply of PPE, as well as options for reprocessing N95 masks.
- Our goal is to identify options quickly and to effectively address the healthcare community's critical need for safe and effective PPE.

Counterfeit respirators

- Health Canada is warning Canadians about the risks of using counterfeit respirators as they may not protect Canadians against the virus that causes COVID-19.
- If your mask is counterfeit, stop using it as it may not protect you against COVID-19.
- Health Canada is working to ensure that the medical devices available to Canadians meet standards of safety and effectiveness. The Department is monitoring the Canadian market for counterfeit devices and will continue to take action to prevent their distribution in Canada.



- Selling or advertising counterfeit health products is illegal in Canada. Health Canada takes the risks posed by these products seriously and takes action to address them.
- Canadians are encouraged to report to Health Canada if they suspect the false and misleading advertising or sale of products in Canada.

Supplementary Messages on Compliance and Enforcement Options

- If a person or company is found to be selling counterfeit products, a number of compliance and enforcement options are available to correct non-compliance or to mitigate a risk to Canadians, including on-site visits, recalls, public communications, and product seizures.
- Health Canada takes a risk-based approach that takes into account the circumstances of each case to protect the health and safety of Canadians.
- The primary objective of Health Canada's compliance and enforcement approach is to manage the risks to Canadians using the most appropriate level of intervention.

Supplementary Messages on Canada's Supply of Personal Protective Equipment (PPE) and Medical Supplies

- Health care workers need medical masks, including surgical masks, medical procedure masks, and respirators, such as N95 respirators.
- The Government of Canada is helping to ensure that health care workers have the PPE and medical supplies they need. We are doing this through collaborative bulk procurement with the provinces and territories, building domestic production capacity, and identifying potential alternatives and ways to extend product life.
- The Public Health Agency of Canada (PHAC) is working to rapidly allocate PPE and medical supplies to the provinces and territories as per an approach agreed upon by federal, provincial and territorial ministers of health.
- PPE and medical supplies received by the Government of Canada, whether donated or procured, are verified by PHAC to ensure they meet Government of Canada technical specifications for healthcare settings for COVID-19, as available on the buy and sell website of Public Services and Procurement Canada. If PHAC cannot account for the quality of products, they will not be allocated to the provinces and territories for the front-line health care response.
- The process for verification varies depending on the medical device. For example, KN95 respirators, as an accepted alternative to N95 respirators, are visually inspected to check for defects in design and construction, and tested to confirm they meet specifications for filtering face pieces.

Supplementary Messages on Market Authorization of N95 and KN95 Respirators and the Interim Order

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- There are two main ways for companies to sell and import COVID-19 Class I medical devices to the Canadian market. They can apply for a market authorization by Health Canada through the Interim Order for Expedited Access to Medical Devices for COVID-19 pathway or the Medical Device Establishment Licence (MDEL) pathway.
- Health Canada reviews the scientific evidence provided by the manufacturers through the Interim Order Authorization pathway to support the safety and effectiveness of devices before issuing authorizations for these devices.
- N95, KN95 and equivalent respirators are Class I medical devices and therefore do not require product authorization prior to sale in Canada. However, to enable Health Canada to conduct a scientific review in advance of authorizing the sale of these devices, manufacturers are encouraged to submit applications through the Interim Order pathway as opposed to the MDEL regulatory pathway.
- Health Canada will continue to accept equivalent alternate standards to N95, including KN95, but will request evidence of quality manufacturing and validated test results from independent testing facilities before the Department will authorize such devices via the available filing mechanism of the Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19.

COVID-19 stability of the virus on personal protective equipment used in healthcare settings

- New information on COVID-19 emerges every day. Researchers and scientists in Canada and around the world are working hard to better understand the virus and its impacts on people and communities.
- Scientists from the Public Health Agency of Canada's (PHAC) National Microbiology Laboratory (NML) have conducted research on how long the virus that causes COVID-19 lives on surfaces and materials commonly used as personal protective equipment (PPE) in healthcare settings, including 100% cotton.
- The study found that the length of time that live virus can be detected varied greatly depending on the surface and material and focused on conditions in hospital settings. The range of time spanned from less than 24 hours for 100% cotton to 21 days for detection of trace amounts of live virus on plastic.
- This research will provide evidence to inform and support infection prevention and control measures for healthcare settings and communities both in Canada and around the world including:
 - Underscoring the importance of washing your hands often with soap and water for at least 20 seconds, and using alcohol-based hand sanitizer if soap and water are not available.
 - Reinforcing the need to strictly adhere to best practices surrounding handling of PPE and cleaning and disinfection of any reusable equipment and surfaces.
 - Providing valuable insight as to the most protective materials to use for non-medical masks and how to help protect the health of Canadians.



- The Government of Canada has made significant investments in science and research related to COVID-19. Evidence gained through this research is proof that we are seeing results from those investments and are learning important information about the virus that causes COVID-19.

On the specifics of the research study:

- NML scientists examined eight different materials commonly found in healthcare settings. They applied a high dose of the virus to the materials and allowed the virus to dry. They periodically assessed the materials for 21 days to determine the amount of live virus that remained over time.
- It is important to note that only a trace amount of live virus was detected on plastics towards the end of 21 days and the amount of live virus decreased on a daily basis.
- Additional studies are required to determine how much live virus is needed to cause a COVID-19 infection. This study did not address the amount of virus required to cause infection, nor did it assess whether contact with contaminated materials would transmit the virus and cause infection.
- While efforts were taken to replicate the environmental conditions found in healthcare settings, this study took place in NML's Level 4 laboratory. Environmental conditions inside healthcare settings will differ from those inside a Level 4 research lab. Further research studies are required to determine whether the environmental conditions typically found inside healthcare settings impact actual virus deterioration and the timelines found in the study.

Authorizations under the Interim Order for Medical Devices

- Health Canada has invited applications from medical device companies with extensive experience manufacturing the equipment used in decontamination and reprocessing to authorize these technologies to safely and effectively reprocess N95 respirators and other PPE. As with all COVID-19-related products, Health Canada is expediting applications for these products and making them our top priority.
- Under the Interim Order for Medical Devices ([link](#)), Health Canada has authorized expanding the intended use of sterilizers and authorized new devices to reprocess N95 respirators.
- A list of the authorized devices is available [here](#) (look for “sterilizer” or “decontamination” under the “technology” column). This list will be updated regularly as devices receive authorization.
- Health Canada will continue to monitor current international trends and assess the evidence supporting various decontamination and sterilization methods/strategies for the reprocessing of other PPE such as single use surgical masks in the context of the COVID-19 pandemic.

On existing guidance

- In May 2016, Health Canada published a [notice](#) to industry on re-use of single-use medical devices.



- Companies that reprocess and distribute medical devices originally authorized and labelled for single use to Canadian healthcare facilities will be held to the same Health Canada requirements as manufacturers of new devices.
- Each manufacturer of an authorized sterilizer or decontamination device has their own guidelines to provide details to users on how to operate it for the purpose of decontaminating respirators, including:
 - Instructions for healthcare facilities;
 - Instructions for healthcare personnel; and
 - N95 decontamination fact sheet.
- A notice with important considerations for healthcare professionals has also been posted that provides further information about Health Canada's evidence requirements ensuring that products and manufacturing processes meet the standards required for safety, quality and effectiveness.

On the Report to the Chief Science Advisor of Canada: Task Force on N95 Face Masks Reprocessing

- Experts from PHAC and Health Canada were among the members of the Task Force that examined available evidence on reprocessing and re-use of N95 face masks (also referred to as N95 respirators or respirators) in light of potential shortages of these devices.
- The Task Force conducted an expedited review of options for mask reprocessing using ultraviolet light, heat/microwave and chemicals such as hydrogen peroxide.
- The recommendations made in this report are in line with the current practices and plans supported by PHAC and Health Canada.
- Since the report was submitted, Health Canada has approved additional technologies for reprocessing. The Department continues to assess all technologies related to COVID-19 in an expedited manner.

Legislative Amendments

- To assist in Canada's response to COVID-19, these new legislative amendments will give the Minister of Health new powers to:
 - make regulations to help prevent or alleviate shortages of drugs and medical devices;
 - seek additional information from companies who produce food, drugs, cosmetics or medical devices to assess the risks and benefits of the new products, and to confirm that these products are safe for Canadians; and
 - seek authorization for third-party manufacturers to supply needed patented inventions, such as a medication or medical equipment, to the extent needed to address this pandemic.
- These measures received Royal Assent on March 25, 2020, and took effect immediately.

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- The amendments to the Food and Drug Act and the Commissioner of Patents' ability to issue authorizations will remain in place until September 30, 2020.
- Health Canada is committed to taking necessary action to continue to protect the health and safety of Canadians during this pandemic and will take any necessary actions in collaboration with the provinces and territories and other stakeholders to help protect the supply of needed medications and medical devices in Canada.

On how these changes work with the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law):

- These amendments complement the powers received through Vanessa's Law by:
 - Providing the authority to gather additional safety information to inform decisions about new products being brought on to the Canadian market or that are already on the market; and
 - expanding the scope of powers to other potential new products, including cosmetics and foods for special dietary purposes that may be needed to help address shortages during this pandemic.

Temporary exemption under the Controlled Drugs and Substances Act for medical treatments

- Many people with substance use disorder or who live with chronic pain may find it challenging to effectively practice physical distancing without changes to prescribing and dispensing practices. In this time of emergency measures, we must do everything we can to allow them to access the medicine they need.
- Health Canada is working with provinces and territories to take action to help patients and practitioners reduce their social interactions, without limiting access to critical medicine.
- On March 19, 2020, Health Canada issued a six-month national exemption for prescriptions of controlled substances (such as narcotics) under the Controlled Drugs and Substances Act and its regulations. This exemption temporarily authorizes pharmacists to prescribe, sell or provide controlled substances in limited circumstances, or to transfer prescriptions for controlled substances.
- As permitted by the laws and regulations of the province or territory in which the pharmacist is entitled to practice, this exemption will:
 - Permit pharmacists to extend and renew prescriptions;
 - Permit pharmacists to transfer prescriptions to other pharmacists; and
 - Allow pharmacy employees to deliver controlled substances to patients' homes or wherever they may be.
- To accommodate physical distancing, and to reduce the stress on emergency rooms and healthcare practitioners across Canada during the COVID-19 pandemic, the exemption also permits prescribers, including nurse practitioners, to temporarily issue verbal orders (i.e., over the phone) to extend or refill a prescription.
- The exemption will be in effect until September 30, 2020, but can be extended or ended earlier by Health Canada if required.



- Legislative or regulatory changes may be required in some provinces and territories in order to put in place these new activities for pharmacists and nurse practitioners. Health Canada recommends contacting your pharmacist or provincial or territorial regulatory authority to check when and if these activities are available in your area.
- The Government of Canada will continue to collaborate with our provincial and territorial partners to effectively implement the exemption, and to assess any additional barriers to Canadians' access to controlled substances for medical reasons during the pandemic.
- Health Canada issued a similar exemption during the Newfoundland and Labrador's 2020 snowstorm.

COVID-19 Drugs Licensing Interim Order, Special Access Program CG II and Remission of Fees Ministerial Order

- The Government of Canada recognizes the essential role treatments and vaccines will play in a safe recovery from the COVID-19 pandemic, all while ensuring the safety of Canadians. That is why the government is taking action to expedite the review process and authorization for COVID-19 drugs, without compromising Canada's high standards for safety, efficacy, and quality.
- To ensure Canadians have prompt access to new COVID-19 treatments and vaccines, when they become available, Health Canada is implementing new measures that will facilitate emergency access and product authorizations.
- Health Canada has finalized changes to the *Food and Drug Regulations* to modernize the Special Access Program (SAP) and the Emergency Drug Release program [insert link to regs].
- These regulatory changes will improve the processes used by health care providers and reduce the administrative burden for requests to access unapproved drugs that meet certain conditions that are not authorized for sale in Canada, including COVID-19 drugs.
- To further prioritize and expedite the review process and authorization for COVID-19 drugs, without compromising Canada's high standards for safety, efficacy and quality, the Minister of Health signed the *Interim Order Respecting the Importation, Sale, and Advertising of Drugs for Use in Relation to COVID-19* on September 16, which will be valid for one year.
- This Interim Order allows the Minister of Health to expedite the availability of COVID-19 drugs, and vaccines, for Canadians, while ensuring the safety of Canadians. The expedited authorization of drugs to help treat COVID-19 will allow these medically necessary drugs to be made available quickly for Canadians.
- Health Canada will not authorize any drug or vaccine unless evidence demonstrates that its benefits outweigh the risks and these drugs and vaccines are supported by sufficient evidence of safety, efficacy and quality. Health Canada continues to monitor their safety and effectiveness once they are on the market.



- The Interim Order also facilitates timely access to COVID-19 drugs and vaccines by introducing a mechanism to import promising drugs to treat or prevent COVID-19 to be placed in Canadian facilities before their authorization. This mechanism is called pre-positioning.
- Finally, Health Canada is removing the financial barriers to support access to drugs needed to respond to COVID-19. Health Canada will not charge fees for the review of drug authorization applications filed under the Interim Order. An additional related Ministerial Order [link] grants remission of the fees associated with establishment licences related to COVID-19 drug activities.
- Health Canada will continue to work with companies to ensure that COVID-19 drugs are supported by evidence of safety, effectiveness and quality. Health Canada will monitor the safety and effectiveness of these drugs and will take immediate action, including the suspension or cancellation of authorizations or establishment licences, if required, to protect the health and safety of Canadians.

If asked about the Interim Order

- Many pharmaceutical companies and academic institutions worldwide are developing potential treatments and vaccines for COVID-19, and some pharmaceutical companies and researchers are also testing whether drugs already on the market may be effective in treating COVID-19 patients.
- To ensure Canadians will have prompt access to drugs for COVID-19 when they become available, the Minister of Health has signed the Interim Order to expedite their authorization.
- The Interim Order introduces temporary regulatory tools that will allow Health Canada to:
 - expedite authorizations for importing, selling and advertising COVID-19-related drugs and vaccines;
 - authorize drugs that are not yet licensed in Canada (or elsewhere) with a modified set of requirements;
 - authorize drugs based on its authorization by another trusted foreign regulatory authority; and
 - expand the use of already-authorized drugs to include a COVID-19 indication based on the available evidence with or without a submission from the market authorization holder.
- Health Canada continues to ensure that these drugs are supported by sufficient evidence of safety, efficacy and quality before they are authorized.
- Drugs authorized under the Interim Order will be subject to similar post-market surveillance requirements as drugs authorized through normal mechanisms, including reporting of adverse drug reactions and foreign actions.
- The Interim Order provides the authority to impose terms and conditions on any authorization or establishment licence at any time, such as risk mitigation measures and periodic assessments of safety information. This will allow the Minister to act quickly to gather important safety information or mitigate risks in a timely manner.



- Health Canada will monitor the safety and effectiveness of these drugs and will take immediate action, including the suspension or cancellation of authorizations or establishment licences, if required, to protect the health and safety of Canadians.

If asked about the Special Access Program Regulatory Modernization

- Through Health Canada's Special Access Program (SAP) for drugs, doctors have been able to gain access to supportive treatments that are otherwise not authorized in Canada for COVID-19 patients.
- Modernizing the SAP will improve access to drugs for Canadians, including treatments for COVID-19, by:
 - Reducing the administrative burden on health practitioners trying to access treatments for their patients. The changes will allow practitioners to make requests for drugs without submitting data on the use, safety and efficacy of the drug, if it was previously authorized through the program for the same indication and meets certain conditions.
 - Allowing the SAP program to consider requests for drug companies to import a drug to a Canadian facility in anticipation of it being requested by a practitioner. This would speed up access by reducing the time it takes to ship the drug to health practitioners in situations where timely delivery is essential.
 - Providing more timely access to drugs for rural patients by allowing drugs to be shipped to community pharmacies.
- The changes would also apply to the EDR program and improve emergency access to veterinary drugs by:
 - Allowing the program to consider requests for drug companies to import a drug to a Canadian facility in anticipation of it being requested by a practitioner, reducing the time it takes to ship the drug to a health care provider, a pharmacist or a commercial medicated feed mill that mixes and manufactures medicated feed.
 - Reducing the administrative burden on health practitioners by removing the requirement to submit data on the use, safety and efficacy of a drug for the same medical emergency, if certain conditions are met.

If asked about the Remission of Fees Ministerial Order

- Health Canada is supporting access to drugs needed to respond to the COVID-19 pandemic by removing financial barriers related to drug establishment licensing for COVID-19 drugs.
- The *Establishment Licence Fees Remission Order (Indication of an Activity in Respect of a COVID-19 Drug)* grants remission of establishment licence fees associated with COVID-19 drugs approved under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. This includes fees for the examination of applications for new establishment licences, for amendments to establishment licences, and for annual reviews of establishment licences.
- An Order is not necessary for the remission of fees associated with medical device applications under the *Interim Order Respecting the Importation, Sale and Advertising of Medical Devices for Use in Relation to COVID-19*, as these applications do not trigger the *Fees in Respect of Drugs and Medical Devices Order*.



If asked about intellectual property protection

- The Interim Order was designed to provide an expedited and flexible temporary market authorization pathway for COVID-19 drugs, needed to address the pandemic.
- The Interim Order is valid for one year until (XX date). A transition pathway will be put in place before the Interim Order expires so that products authorized under the Interim Order can be approved under the *Food and Drug Regulations*.
- Drugs authorized under the Interim Order will not receive data protection. However, the Interim Order does not allow for generic applications unless the sponsor of the innovative drug is unable to sufficiently supply the Canadian market.
- Before accepting a generic application, Health Canada would consult with the innovator company.
- Measures to address intellectual property, specifically data protection under the *Food and Drug Regulations*, will be pursued as part of the transition pathway. Eligible products will have the opportunity to apply for these protections.

If pressed on vaccine safety:

While every effort in Canada is being made to expedite COVID-19 vaccine development, safety, efficacy and quality will not be compromised. COVID-19 vaccine(s) will be subject to the same rigorous scientific reviews, quality standards, testing and post-market surveillance as all other vaccines that are approved for use in Canada.

Before a vaccine is deemed safe for the market, it goes through a series of six stages of testing and trials in Canada:

1. Non-clinical testing (laboratory and animal testing);
2. Three phases of clinical trials with human volunteers;
3. Validation of each step in the manufacturing process, from seed lot or cell bank production to delivery and related quality control tests;
4. On-site evaluation of manufacturing process by Health Canada product specialists to evaluate production processes and facilities;
5. Consistency testing where Health Canada laboratories test samples from 3 or more consecutive lots; and
6. Drug Establishment licensing with a site visit by Health Canada inspectors or trusted international regulatory partners to evaluate the drug establishment for good manufacturing practices and, as needed, including sample analysis as well as a review of new and annual licence applications.

Vaccine safety applies not only to vaccine development but also to immunization practises for as long as a product is used. Health care providers have important roles to play in vaccine safety, including gaining and maintaining public confidence in the safety of vaccines.

Once a vaccine is in use, Canada has a comprehensive vaccine safety monitoring system to alert public health authorities to changing trends or unusual adverse events not previously reported. These alerts trigger expert medical reviews, which are conducted on all serious adverse events to identify any safety concerns and respond to these quickly and appropriately. Together, this system, referred to as

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post-market surveillance is an essential part of the Government of Canada's ongoing monitoring to ensure the continued quality, safety and effectiveness of all vaccines and other health products that are in use in Canada.

Interim Order Respecting COVID-19-related Medical Devices

- Early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada.
- As an emergency public health measure, the Minister of Health has signed an Interim Order to allow expedited access to COVID-19-related medical devices.
- With the Interim Order, two new diagnostic tests are made readily accessible in Canada:
 - the Roche Molecular Systems Inc. cobas SARS-CoV-2 diagnostic device; and
 - the ThermoFisher Scientific TaqPath™ COVID-19 Combo Kit
- An Interim Order is one of the fastest mechanisms available to the Government of Canada to help make health products available to help address larger-scale, public health emergency situations.

If pressed on the US directive to allow unauthorized health products:

- Health Canada will continue to use all tools at its disposal to expedite supply of safe and effective health products related to COVID-19. However, the department is not providing blanket approval of unauthorized drugs or devices. We will update Canadians with any new information as it arises.
- The Interim Order will also ensure that other COVID-19-related medical devices are available to treat, mitigate, or prevent COVID-19, as necessary.

If pressed on Cost Recovery:

- To remove impediments for manufacturers in this time of public health need, Health Canada will waive all application fees for COVID-19 medical devices subject to this Interim Order

Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19 May 23, 2020

- To support efforts to develop COVID-19 therapies, the Minister of Health has signed an Interim Order to make the authorization process for clinical trials related to COVID-19 more efficient and flexible, without compromising the safety of participants or the reliability of trials' findings.
- Clinical trials play a critical role in advancing research and evaluation of investigational products, while protecting the safety of Canadians.
- Health Canada's top priority is protecting the health and safety of clinical trial participants. The Department will continue to conduct rigorous reviews of each clinical trial application and protocol under this Interim Order, as it does for all clinical trials.
- Currently, there are no drugs specifically authorized to prevent, treat or cure COVID-19 in Canada.



- The Government of Canada continues to monitor and support emerging science, and is committed to ensuring that our domestic efforts and international contributions are supported by the best available evidence and aligned with global efforts.

NACI Advice for Vaccine Clinical Trials

- Making a safe, effective vaccine available to all Canadians is a key aim of our strategy to fight COVID-19.
- Because of the severity of the COVID-19 pandemic, we are expediting the process of testing candidate vaccines, but that does not mean cutting corners. Clinical trials must proceed safely and ethically, to ensure that participants are not put at increased risk, and that the results are scientifically sound.
- The National Advisory Committee on Immunization (NACI) has developed new recommendations to inform clinical studies of candidate vaccines for COVID-19, once they have passed successfully through laboratory trials and animal models.
- NACI is issuing this guidance to inform Health Canada, vaccine industry partners, and vaccine researchers (including the Canadian Immunization Research Network) of the research priorities for clinical trials.
- The recommendations identify populations who should be included in clinical trials, once safety and efficacy is established in healthy adults. To guide the use of scarce research resources, NACI recommends targeting certain groups for clinical trials, recognizing that not all population groups can be included in clinical trials at the same time.
- There are people who are more likely to be exposed to COVID-19 and/or more likely to become severely ill if infected, so it makes sense to target those populations in clinical studies. These risk factors include:
 - age or pre-existing health conditions, for example:
 - adults aged 60 and over
 - people with chronic lung disease
 - working or living conditions, for example:
 - healthcare workers
 - residents of long-term care facilities
 - people living in crowded or remote settings
 - suboptimal immune response to vaccination, for example:
 - children and adolescents
 - adults who are immunocompromised
 - pregnant women

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In its guidance, NACI also outlines important considerations for ethics, equity and feasibility of COVID-19 vaccination. For example, NACI recommends that clinical trials and post-market investigations assess inequities related to social vulnerabilities (e.g., low socioeconomic status, race/ethnicity) and occupational vulnerabilities (e.g., healthcare and long-term care workers).

PHAC rapid stakeholder survey on COVID-19 vaccine program strategies

- The Public Health Agency of Canada (PHAC) is consulting a wide range of stakeholders to determine the most effective strategy to dispense the vaccine for COVID-19, when it becomes available.
- It will not be feasible to vaccinate all Canadians immediately when a vaccine becomes available because supplies will be limited at first. We need to design a targeted vaccine program that achieves our outbreak response goals as efficiently, effectively and equitably as possible.
- Our over-arching public health goals in this outbreak are to minimize serious illness and overall deaths (due to all causes), and to minimize social disruption, including reducing the burden on health care resources.
- PHAC is seeking input from:
 - scientific and medical experts
 - federal, provincial and territorial public health experts
 - health professional associations
 - other governmental departments
 - patient and community advocacy representatives and experts
- The results of the consultation will inform the National Advisory Committee on Immunization's (NACI) recommendations to the PHAC on target groups for early COVID-19 vaccination when the first doses of an authorised pandemic vaccine become available in Canada.
- NACI's decision-making process will include a review of the ethics, equity, feasibility and acceptability of any given course of action.

Gavi, the Vaccine Alliance

- Ensuring Canadians' access to vaccines and antivirals is a top priority. The Government of Canada has announced more than \$1 billion in support of a national medical research strategy to fight COVID-19, which includes vaccine development and the production of treatments. There are currently several candidate vaccines in research and development, and it is not possible to determine which ones will be successful in preventing COVID-19 infection.
- The Government of Canada is supporting multiple organizations that are working at unprecedented speed to develop candidate vaccines.
- Participation in the COVAX Facility as a self-financing country could be one way for Canada to secure vaccine doses for use domestically.

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- The Government of Canada is looking forward to ongoing engagement with Gavi and other supporting countries on the COVAX Facility, with the aim of working together to develop a mechanism that works for all countries and supports equitable global access to safe, effective and affordable COVID-19 vaccines, once developed.
- Canada is committed to global collaboration to end this pandemic. The COVAX Facility, and the Advance Market Commitment within it, is designed to guarantee rapid, fair and equitable access to COVID-19 vaccines for every country in the world to slow the pandemic.
- Supporting other countries in their fight against COVID-19 and other infectious diseases is an investment to protect Canada and Canadians.
- The Government of Canada continues to monitor and support emerging science, and is committed to ensuring that our domestic efforts and international contributions are supported by the best available evidence, and aligned with global efforts.
- The Government of Canada is closely monitoring vaccine development efforts—domestically and internationally—and will work quickly to negotiate advanced purchase agreements with vaccine manufacturer(s) to secure supply for Canadians as soon as it is feasible.
- On July 15, 2020, Prime Minister Trudeau joined the leaders of Ethiopia, New Zealand, South Africa, South Korea, Spain, Sweden and Tunisia, in signing an op-ed in the Washington Post. The leaders are:
 - calling for equitable access to a coronavirus vaccine when one is developed; and
 - urging countries to co-operate on manufacturing and distributing a vaccine to ensure that less-developed countries don't lose out to rich ones.

COVID-19 Vaccine Global Access (COVAX) Facility

- Ensuring Canadians' access to vaccines and antivirals is a top priority. The Government of Canada has announced more than \$1 billion in support of a national medical research strategy to fight COVID-19, which includes vaccine development and the production of treatments. There are currently several candidate vaccines in research and development, and it is not possible to determine which ones will be successful in preventing COVID-19 infection.
- The Government of Canada is supporting multiple organizations that are working at unprecedented speed to develop candidate vaccines.
- Through this announcement, the Government of Canada has committed \$220 million to the COVAX Facility, securing Canada's choice options to purchase doses for 20% of Canada's population. Today's announcement also provides equal funding to procure doses for low- and lower-middle-income countries through the Advance Market Commitment.



- By joining this initiative, Canada is contributing funds towards collective efforts to develop a safe, effective and accessible COVID-19 vaccine for 172 participating economies across the world.
- Through this mechanism, Canada will secure additional options for vaccine doses for use domestically. This approach complements the bilateral arrangements Canada has in place with vaccine manufacturers and diversifies our investment in potential supply.
- Canada is committed to global collaboration to end this pandemic. The COVAX Facility is designed to support rapid, fair and equitable access to COVID-19 vaccines for all participating countries to slow the pandemic. Its pooled vaccine procurement mechanism offers a unique multilateral response to a complex global problem.
- Supporting other countries in their fight against COVID-19 and other infectious diseases is an investment to protect Canada and Canadians.
- The Government of Canada looks forward to ongoing engagement with this coalition of international organisations and economies.
- Canada continues to monitor and support emerging science, and is committed to ensuring that our domestic efforts and international contributions are supported by the best available evidence, and aligned with global efforts.
- The Government of Canada is closely monitoring vaccine development efforts—domestically and internationally—and will work quickly to negotiate advanced purchase agreements with vaccine manufacturers to secure supply for Canadians as soon as it is feasible.

Unilingual Labelling on Products for COVID-19

- Health Canada's top priority is the health and safety of Canadians, and the Department is doing everything possible to facilitate access to products needed to slow the spread of COVID-19.
- Health Canada is strongly committed to meeting the requirements of the *Official Languages Act* and fostering linguistic duality.
- Generally, bilingual labelling, instructions, and safety information are required for all products sold in Canada.
- In light of the unprecedented demand and urgent need for products to help limit the spread of COVID-19, Health Canada is facilitating access, on a temporary basis, to certain imported products that may be labelled in only one official language to increase access to products that are in high demand.
- Many global suppliers have indicated that they are labelling products in English only to expedite production and that they will ship only to countries that will accept English-only labelling.
- These products include household cleaners, cleaning products used in the workplace, hand and body soaps, hard-surface disinfectants and hand sanitizers.

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- Effective immediately, all new importers of these products through the interim measure must have bilingual labelling text available to consumers. Importers previously authorized are required to have bilingual label text available on their websites and a means for sellers to inform consumers of this website at the time of sale no later than June 8, 2020.
- Effectively immediately, all new Canadian manufacturers of these products must use bilingual labelling. Canadian manufacturers of hand sanitizers who are currently licensed and are using unilingual labelling under the interim measures will be required to move to bilingual labeling no later than June 8, 2020.
- To mitigate risks associated with unilingual labelling, importers are required to post bilingual label text on their websites and provide sellers with a means to inform consumers, at the time of sale, of the website where bilingual text is posted. This could be made available through a sticker applied directly to the products, or posters or signage with take-away pamphlets at the point of sale.
- Health Canada continues to strongly encourage the use of bilingual labels by all companies importing products into Canada.
- Health Canada will lift interim measures when the regular supply stabilizes.

If pressed on interim measures providing quicker market access to certain hard-surface disinfectants and hand sanitizers:

- Health Canada is allowing the importation of hand sanitizers and disinfectants from countries with similar regulatory frameworks and quality assurance requirements as an interim measure to address a shortage of these products.
- While Health Canada is facilitating access to imported products that may be in only one official language during a period of shortage, the use of bilingual labels remains strongly encouraged.
- To mitigate risks associated with unilingual labelling, importers will be required to post bilingual text on their websites and to provide sellers with a means to inform consumers, at the time of sale, of the location where bilingual text is posted. This could be made available through a sticker applied directly to the products, or posters or signage with take-away pamphlets at the point of sale.
- Effective immediately, all new importers of these products through the interim measure must have bilingual labelling text available to consumers. Importers previously authorized are required to have bilingual label text available on their websites and a means for sellers to inform consumers of this website at the time of sale no later than June 8, 2020
- Effective immediately, all new Canadian manufacturers of these products must use bilingual labelling. Canadian manufacturers of hand sanitizers who are currently licensed and are using unilingual labelling under the interim measure will be required to move to bilingual labeling no later than June 8, 2020.
- Health Canada will take a risk-based approach to addressing any non-compliance identified.

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If pressed on how long these measures will remain in place:

- Health Canada's priority is that Canadians have access to products needed to slow the spread of COVID-19.
- Health Canada will lift interim measures when the regular supply stabilizes.

If pressed on interim policies to provide quicker access to household and workplace cleaners, and hand and body soaps:

- The *Canada Consumer Product Safety Act*, the *Food and Drugs Act* and the *Hazardous Products Act* require that labels and, where applicable, safety data sheets be in both official languages. One of the flexibilities being introduced by the interim policies is to facilitate access to products where this information may be in only one official language.
- This flexibility was deemed necessary to meet an actual or potential shortage in the supply of cleaning products and hand and body soaps that may be used to help fight the COVID-19 pandemic. The flexibility will facilitate the importation of these products from the United States, where the product label may not be available in both official languages.
- While Health Canada is facilitating access to imported products that may be in only one official language during a period of shortage, the use of bilingual labels remains strongly encouraged.
- In order to benefit from the interim policies, importers are required to provide sellers with a means to inform consumers or employers, at the time of sale, of the website where bilingual label text and, if applicable, bilingual safety information is posted. This could be made available through a sticker applied directly to the products, or posters or signage with take-away pamphlets at the point of sale or use. This requirement comes into effect for all new importers of these products through the interim policies as of now; importers who have previously submitted a form are to meet this requirement by June 8, 2020.
- Domestic manufacturers of cleaning products and hand and body soaps are not included in these interim policies as they are still in a position to provide bilingual labelling and safety data sheets (where applicable) for their products. As such, Canadian companies of these products are required to continue to manufacture products with labels and, if required, safety data sheets in both official languages.
- Health Canada is also making efforts to reach out to Canadians, in both official languages, via our Recalls and Safety Alerts database and social media to inform Canadians about these products. Canadians are also being encouraged to consult the Health Canada website for links to information in both official languages from industry websites.
- Health Canada will take a risk-based approach to addressing any non-compliance identified.
- Health Canada will lift these interim policies when the regular supply stabilizes.

Packaging of Hand Sanitizer Products

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- Some manufacturers of hand sanitizer products are facing challenges in producing or finding bottles normally used for household products.
- In light of global supply shortages, the Government of Canada has issued [guidance to industry](#) on acceptable packaging materials and sizes for hand sanitizer products.
- Health Canada has encouraged manufacturers to consider the appearance of containers to avoid potential confusion by consumers.
- Health Canada recently issued [an advisory](#) about the risk of poisoning from hand sanitizers sold in beverage containers.
- All hand sanitizer products that have been authorized for sale by Health Canada have an eight-digit Drug Identification Number (DIN) or Natural Product Number (NPN) on the label, and are listed on the [List of Hand Sanitizers Authorized by Health Canada](#).

Additional Packaging and Labelling Requirements for Alcohol-Based Hand Sanitizers in Beverage Containers to Minimize Risks of Unintentional Ingestion

- Health Canada is publishing additional packaging and labelling requirements for alcohol-based hand sanitizers that are sold in beverage containers to minimize the risk of unintentional ingestion.
- The revised policy will require manufacturers to use a closure, such as a pump or dispensing cap, on the package, to differentiate hand sanitizer packages from beverage containers.
- The policy will also require additional labelling including a front-of-pack warning that displays a red octagon with the text: “Do not drink / Ne pas boire” and “Health Canada / Santé Canada.”
- These new requirements will apply to hand sanitizers distributed in beverage or food containers after November 27, 2020.
- Health Canada also expects that companies will make every effort to transition to more traditional hand sanitizer packages, as they become available.

Supplementary Messages:

- Some manufacturers of hand sanitizer products are facing challenges in producing or finding bottles normally used for household products.
- This has resulted in some companies distributing hand sanitizer in containers commonly used for drinks, such as water and soda bottles. Others are using containers that they already have in their inventory, such as wine and liquor bottles.

Technical-grade ethanol in hand sanitizers



- The COVID-19 pandemic has led to an unprecedented demand and urgent need for hand sanitizers. Recent data released by Statistics Canada showed a seven-fold increase in sales of hand sanitizer in mid-March compared to the same one-week period last year.
- Given current supply shortages of pharmaceutical- and food-grade ethanol, on April 15, 2020, Health Canada permitted the temporary use of technical-grade ethanol in alcohol-based hand sanitizers. Health Canada will continue to monitor and evaluate the supply of ethanol as the COVID-19 crisis evolves, and take appropriate action as necessary
- Before allowing the use of technical-grade ethanol in hand sanitizers, Health Canada thoroughly assessed the risks and benefits and determined that the public health benefit of using technical-grade ethanol hand sanitizers to limit the spread of COVID-19 outweighs the risks when the products are used for a short period and as directed. The summary of the risk assessment can be found here.
- Health Canada is committed to protecting the health and safety of Canadians. The Department has put stringent measures in place to minimize the potential safety risks associated with the use of technical-grade ethanol in hand sanitizers.
- Health Canada recently updated its April 2020 risk assessment and conducted an analysis of the supply and demand for hand sanitizers over the next 12 months. Based on this analysis, the Department has decided to allow the production of technical-grade ethanol to be used in hand sanitizers until October 31, 2020, and the use of technical-grade ethanol in finished products until December 31, 2020. Mandatory warning statements on hand sanitizers containing technical-grade ethanol remain in place.

Supplementary Messages:

- Health Canada continues to work with industries interested in manufacturing ethanol for use in hand sanitizer to overcome critical supply shortages in Canada. Strict procedures are in place for evaluating and ensuring that hand sanitizers sold in Canada are safe and effective.
- Companies wishing to produce technical-grade ethanol for use in hand sanitizers must apply for Health Canada authorization.
- Health Canada conducts a case-by-case safety risk assessment for each submission to determine whether a particular source of technical-grade ethanol is suitable for use in hand sanitizers.
- If the technical-grade ethanol is found to be acceptable, Health Canada imposes strict conditions on its production and use in hand sanitizers.
- These conditions include additional labelling (mandatory warning statements) on finished products and controls to make it easier to trace the product once it enters the market. Health Canada will take prompt action if health issues arise from using this product.
- This approach is consistent with Health Canada's interim guide for industry on the production of ethanol for use in alcohol-based hand sanitizers, which outlines quality requirements to ensure that hand sanitizer products are safe for consumers.

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- Health Canada authorized its first supplier of technical-grade ethanol on April 6, 2020, and additional suppliers have since been authorized.
- A [list of suppliers](#) authorized to produce technical-grade ethanol for use in hand sanitizers and a [list of manufacturers](#) of hand sanitizers using technical-grade ethanol have been posted online.
- If an unauthorized product is found on the market, the Department will not hesitate to take appropriate action, and will inform Canadians.

Health Canada is working with suppliers to ensure they continue refining their technical-grade ethanol to reduce levels of impurities.

Emergency Drug Release

IMVIXA (lufenuron): Veterinary drug used in aquaculture for sea lice

- Health Canada is committed to protecting the health and safety of Canadians and the food supply.
- In response to the unprecedented circumstances caused by COVID-19, Health Canada has authorized the limited release of the veterinary drug IMVIXA under the Emergency Drug Release program to prevent sea lice infestations in Atlantic salmon for the upcoming aquaculture season.
- The limited release of this drug aims to protect human and animal health during the COVID-19 pandemic. Health Canada has authorized IMVIXA for use in select locations with high sea lice concentrations that would otherwise require labour-intensive interventions to manage.
- This limited release will help aquaculture producers follow occupational health and safety measures to protect workers' health and safety (e.g., physical distancing).

Supplementary Messages:

- IMVIXA is not approved for general sale in Canada. Since 2016, Health Canada has permitted limited access to it by veterinarians to prevent sea lice infestations on a case-by-case basis under the Emergency Drug Release program.
- All authorized drug releases are subject to strict risk management measures to mitigate any risks to human and animal health. Health Canada requires comprehensive monitoring by users to assess the effectiveness of these measures and improve our understanding of the environmental impacts of the drug.

If pressed on the Emergency Drug Release program:

- Health Canada's Emergency Drug Release program considers requests on a case-by-case basis for emergency access to unapproved drugs from veterinarians treating animals with serious or life-threatening conditions, in cases where conventional therapies have failed, are unsuitable, or unavailable.

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- The EDR program allows veterinarians to access unapproved drugs for serious or life-threatening conditions when conventional treatments have failed, are unsuitable, or are unavailable. As part of each EDR request, Health Canada examines all available information to evaluate the safety and efficacy of a drug, including food safety.

Travelling

Border measures

- The Government of Canada continues to introduce border measures to limit the introduction and spread of COVID-19.
- The Canada Border Services Agency (CBSA) is working closely with the Public Health Agency of Canada (PHAC) to help prevent the spread of 2019 novel coronavirus into Canada at all international ports of entry.
- PHAC is responsible for advising the CBSA of any required enhanced measures to be implemented at the Canadian border to help prevent the spread of serious infectious diseases into Canada.
- Canadian citizens, permanent residents and Registered Indians under the *Indian Act* continue to enter Canada by right, and are subject to COVID-19 entry screening measures.
- To protect Canadians and to ease the potential burden non-essential travellers could place on our health care system and its frontline workers, the CBSA has implemented new travel restrictions across all ports of entry in all modes of transportation – land, sea, air and rail.
- A travel ban is currently in place for most people entering Canada*, including:
 - All foreign nationals entering Canada by air;
 - All travellers from the U.S., across all modes, for recreation and/or tourism purposes;
 - Foreign nationals entering Canada if they arrive from a foreign country other than the United States, with some exceptions, including temporary foreign workers and international students; and,
 - Foreign nationals with signs or symptoms of respiratory illness.

**There are exceptions to these bans that are spelled out in the Orders in Council.*

- Canada and the US have also entered into a reciprocal arrangement to direct back all asylum seekers. Exceptions may be made for unique circumstances, such as an unaccompanied minor.
- All persons entering Canada – no matter their country of origin or mode of entry - are REQUIRED to isolate or quarantine for 14 days.
- There are exemptions in place on mandatory quarantine to ensure that critical infrastructure, essential services and economic supply chains continue between Canada and the USA. Workers who are critical to our economy and infrastructure will be permitted to enter Canada, including truck drivers, firefighters and medical workers.
- Cross-border supply chains are vital to ensure the continued flow of goods, including food and medical supplies for all Canadians. As such, the CBSA is working with other federal partners to share information with commercial stakeholders to provide assurances that commercial traffic is not impeded.

International students

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- The Government of Canada remains committed to protecting the health and safety of Canadians and reducing the spread of COVID-19 in Canada.
- We recognize that temporary travel- and health-related measures have affected foreign nationals looking to study in Canada.
- Under travel restrictions in place since March 2020, only international students who held a valid study permit, or were approved for one on or before March 18, 2020 are allowed to travel to Canada, and only in cases where their travel was non-discretionary.
- The Government of Canada has been working in close collaboration with provinces and territories. No new categories of international students will be permitted to arrive at a designated learning institution (DLI) in Canada until federal, provincial/territorial and local public health authorities are all ready.

If pressed on the importance of international students in Canada:

- International education is a major economic driver in Canada for designated learning institutions and for the communities in which they are located. International students bring tremendous cultural and social benefits to Canada, while contributing more than \$21 billion to the economy annually in recent years.
- Due to their age, education, skills and experience, international students are a key source of future permanent residence applicants after they graduate. Tens of thousands of former international students immigrate permanently each year.

If pressed on what an acceptable COVID-19 plan includes:

- The Government of Canada has provided guidelines for designated learning institutions that plan to resume welcoming international students. Designated learning institutions are expected to provide information to the provinces and territories about travel and health requirements before students arrive, provide quarantine arrangements, help them plan for their transportation to their place of quarantine after they arrive, and provide guidance or assistance in acquiring necessities during their quarantine.

If pressed on what non-discretionary purposes means:

Examples of non-discretionary travel for students could include the following:

- they were already living in Canada and are returning to their residence here;
- their school is re-opening for some classroom learning; and
- their program can't be delivered online and/or requires them to use a laboratory, workshop or other specialized location.



Quarantine Planning for Travellers

- Unless exempted, all persons entering Canada are required to isolate or quarantine for 14 days. This applies to all travellers arriving in Canada no matter their country of origin or mode of entry. This includes travel of short durations to and from the United States.
- If you have COVID-19 symptoms, you must isolate for 14 days.
- If you don't have COVID-19 symptoms, you must quarantine for 14 days while you're still at risk of developing symptoms and infecting others.
- Foreign national travellers who have symptoms of COVID-19 will not be allowed to enter Canada.
- All travellers coming to Canada should ensure they have a plan for their mandatory quarantine prior to travelling.
- Travellers are encouraged to use the Government of Canada's [ArriveCAN](#) app or website to input their quarantine or isolation information and to help reduce their wait time at the border.
- Travellers can submit information via the ArriveCAN app or website within 48 hours before arriving in Canada—instead of submitting their mandatory information at the border. This will speed up travellers' time at the border and limit their physical interaction with border officials.
- When travellers arrive to Canada, a Government of Canada representative will ask them questions to determine the suitability of the traveller's plan for quarantine to ensure they:
 - Prevent contact with individuals at increased risk of more severe outcomes related to COVID-19 such as older adults, or people with compromised immune systems or other underlying medical conditions;
 - Prevent the transmission of COVID-19 to others in their place of residence/quarantine (e.g., not in a group living arrangement); and
 - Allow for access to the necessities of life such as food and medication through the assistance of a family, a neighbour, a friend or delivery service to help with essential errands (e.g., picking up prescriptions, buying groceries).
- We expect that most travellers will quarantine in their own home or in the same place that they are visiting in Canada. If this is not possible, travellers should consider alternative arrangements for quarantine accommodations that are within their own financial means.
- A traveller may be transferred to a federal designated quarantine facility when deemed necessary by a public health officer designated under the *Quarantine Act*, and only when travellers are confirmed to have no other suitable quarantine or isolation options available. This measure is used only as a last resort, regardless of whether the traveller is asymptomatic or symptomatic.
- When preparing quarantine plans, travellers should be aware that the period of quarantine starts again if, during that 14-day period, the traveller develops any signs and symptoms of COVID-19 or is exposed to another person subject to this Order who exhibits signs and symptoms of

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COVID-19 or tests positive for COVID-19. Travellers should plan for this potential extension of the quarantine period.

- Government of Canada awareness resources are available online at Canada.ca/coronavirus to provide Canadians and all visitors to Canada with more information on how to suitably plan for quarantine or isolation.

On travel advice to Canadians:

- Currently, Canadians are advised to avoid non-essential travel outside of Canada and avoid all cruise ship travel until further notice. Canada's [official global advisory](#), [cruise ship advisory](#) and [pandemic COVID-19 travel health notice](#) are still in effect.
- Travelling Canadians need to understand the role that they play personally and the potential risk that they may have been exposed to the virus during any travel outside the country and the risk that they in turn may pose to other Canadians including those most at risk of serious illness.
- Canadians who choose to travel outside Canada have a responsibility to ensure that planning for their mandatory quarantine upon return is part of their travel planning.
- Travellers who are confirmed to be unable to find a suitable place to quarantine or isolate, including an inability to pay for alternate accommodations, will be referred to a Quarantine Officer who will determine suitability for transfer to a designated quarantine facility.

On the role of Government representatives at the border:

- All persons entering Canada are required to provide all relevant information requested at the time of entry and throughout the 14-day period, and any extension of quarantine, following their entry. Travellers must also confirm with a Government representative at the point of entry that they have a suitable location to quarantine or isolate in Canada.
- Failure to provide accurate information is an offence under the *Quarantine Act*. In addition, violating any quarantine or isolation instructions provided to you by a screening officer or quarantine officer when you entered Canada is also an offence under the *Quarantine Act* and could lead to up to:
 - 6 months in prison; **and/or**
 - \$750,000 in fines.
- Public Health Agency of Canada (PHAC) designated officers are available to ports of entry to carry out COVID-19 enhanced screening measures including:
 - screening travellers for symptoms of COVID-19;
 - conducting health assessments;
 - determining whether a traveller has a suitable plan for quarantine or isolation; and
 - taking necessary action under the *Quarantine Act*.
- To limit the spread of COVID-19, a representative of the Government of Canada will:
 - administer the Emergency Orders for COVID-19;
 - determine if an individual's travel purpose for travelling to Canada falls within the definition of the exemptions of the Emergency Orders;

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- determine the suitability of travellers' plans for quarantine or isolation;
- determine if a traveller without symptoms can continue domestic travel to their place of quarantine;
- determine if a traveller is required to be transferred to a designated quarantine facility; and
- assess travellers for potential risks to public health, in accordance with the *Quarantine Act*.

On federally operated designated quarantine facilities:

- Travellers are strongly urged to make housing arrangements for their quarantine prior to their arrival in Canada.
- Travellers who are unable to quarantine in their own place of residence should consider alternatives within their financial means such as booking a hotel/motel room or other paid housing alternative, or staying with friends or family.

When deemed necessary by a public health officer designated under the Quarantine Act, a traveller may be transferred to a federally designated quarantine facility.

If pressed on considerations for determining suitability for transfer to a designated quarantine facility...

- Under certain circumstances, both symptomatic or asymptomatic travellers may be sent to a quarantine facility for up to 14 days (subject to any extension), at the discretion of the quarantine officer. Considerations include:
 - Severity of symptoms or illness;
 - Whether travellers have a place in which to quarantine or isolate;
 - Whether they have private transportation to get to their home or place of isolation, or if the distance to get home is too far for PHAC-arranged medical transportation;
 - Whether they live with one or more vulnerable persons (for example adults aged 65 years or over and people with certain pre-existing medical conditions); and/or,
 - Whether they have a suitable place to isolate or quarantine where they will have access to basic necessities, such as food and medication.

If pressed on service limitations at a designated quarantine facility...

- Travellers quarantined in a federally designated quarantine facility will typically be lodged in a room. Also, federally designated quarantine facilities offer very limited amenities. For example, individuals are prohibited from:
 - Taking videos and photos due to site confidentiality;
 - Using hotel amenities, including hotel services, and room service;
 - Receiving personal deliveries including meals, online shopping and care packages from loved ones;
 - Smoking, vaping or consuming alcohol or cannabis (unless medically prescribed) in their quarantine room;
 - Unescorted access to outdoor areas, including for the purposes of smoking or vaping
- Within a private place of quarantine or isolation, the traveller is able to:

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- Chat and communicate virtually using video with family and friends;
 - Choose to purchase and receive contactless deliveries including food and online shopping; and
 - Enjoy private outdoor living spaces such as a balcony or yard (if not symptomatic).
- In addition to the above, all travellers in isolation must:
 - Go directly to the place of quarantine or isolation directly, and without stopping; and
 - Stay inside and not leave unless it is to seek medical attention.

If pressed on the requirement to provide contact information and plans for quarantine....

- Travellers are required by law to provide contact information during their quarantine or isolation period and failure to do so, or provision of false or misleading information is an offence that can result in fines and imprisonment under the *Quarantine Act*.
- Failure to provide accurate information is an offence under the *Quarantine Act* and the traveller can be subject to fines and imprisonment.
- Traveller contact information will be used for public health follow up and to conduct spot checks to verify compliance.
- The ArriveCAN app and website are the recommended tools for anyone coming or returning to Canada, as it provides travellers the ability to enter the necessary information before, during and after their arrival at the border.
- Upon entry into Canada, all travellers are provided with handouts containing the following information:
 - The Mandatory Isolation Order;
 - Instructions for quarantine or isolation;
 - A list of provincial and territorial public health authorities website and phone numbers;
 - Compliance monitoring, verification and enforcement activities; and
 - Consequences of non-compliance such as fines and imprisonment.
- PHAC shares contact information with the respective provinces and territories so that they are aware of travellers who have recently entered their jurisdictions and can contact them to make them aware of local public health services that are available to them.
- PHAC works closely with the Royal Canadian Mounted Police and provincial law enforcement agencies to verify the compliance of returning travellers.

If pressed on what is considered a suitable quarantine site...

- Accommodations that may be deemed suitable include one's home, whether it is an apartment, condominium, single family home, houseboat or mobile home.
- For travellers arriving in Canada and who must make alternative arrangements for their quarantine and who are not able to quarantine in their own place of residence, the following are considered appropriate to quarantine for 14 days:



- Hotels/motels or other paid housing alternatives including websites connecting travellers with property owners; and
- Staying with family or friends as long as they will not expose individuals that are not part of their travel group; and will not be in contact with a person at risk of more severe outcomes from COVID-19.

If pressed on penalties and violations...

- Any traveller who provides false or misleading answers about their health during screening prior to boarding a flight to Canada could be subject to a penalty of up to \$5,000 under the *Aeronautics Act*.
- Knowingly providing false information to Government of Canada representatives is an offence under the *Quarantine Act* and could lead to up to 6 months in prison or \$750,000 in fines.
- Further, a person who causes a risk of imminent death or serious bodily harm to another person while willfully or recklessly contravening this act or the regulations could be liable for a fine of up to \$1,000,000 and/or imprisonment of up to 3 years.

If pressed on whether the Government of Canada is reimbursing persons for alternate quarantine accommodations

The Government of Canada does not reimburse travellers for expenses incurred for quarantine accommodations.

ArriveCAN Mobile Application

- Emergency Orders implemented under the *Quarantine Act* require all individuals who enter Canada to quarantine (self-isolate) or isolate themselves for 14 days.
- To ensure compliance with the Order, all travellers entering Canada are required to provide basic contact information to the Government of Canada upon entry. This also includes a self-assessment of symptoms and confirmation on whether a quarantine plan has been considered by each incoming traveller.
- Currently, this information is collected using a paper or online form (“Coronavirus Form”) upon entry into Canada.
- The ArriveCAN App, launched during the week of April 29, will be an alternative to paper forms. It will enable faster processing at the border for travellers returning to Canada, and we encourage travellers to use it.
- The ArriveCAN App allows travellers to input their information quickly, easily and securely upon arrival in Canada. The App works by digitizing the information collected under the Coronavirus Form.
- This electronic collection method also limits physical contact between travellers and Border Services Officers and Quarantine Officers. This helps to protect both the travellers and the officers.

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- The App captures information requested under the Coronavirus Form in much the same way as the paper and the online form.
- Additional information is now required, such as flight or border crossing information, and there is a new question on whether travellers are exhibiting symptoms of COVID-19 and whether they have a quarantine plan.
- Personal information collected by Border Services Officers and Quarantine Officers, either via the paper form, the online form or the App, will be used by the Public Health Agency of Canada to verify travellers' compliance with the Quarantine Act. Information will be shared with provinces and territories, as well as with law enforcement, to monitor and enforce compliance with the Order.
- The protection of Canadians' personal information is a priority for the Government of Canada, and any tool used to collect personal information undergoes a rigorous privacy assessment.
- Personal information is used to administer and enforce the *Minimizing the Risk of Exposure to COVID-19 in Canada Order (Mandatory Isolation)*, No. 3 authorized under the Quarantine Act and/or Department of Health Act. Personal information may be used and/or disclosed for the following purposes: (1) to monitor, verify and/or enforce compliance with the Mandatory Isolation Order, (2) to provide the traveller with information to promote compliance with the Mandatory Isolation Order, and (3) for public health follow-up.
- The *Privacy Act* and its regulations require CBSA and PHAC to retain personal information under their control. Personal information used for an administrative purpose, as is the case for this App, is kept for a period of at least two years after the last time it was used.
- The ArriveCAN app supports Canada's digital strategy for services to Canadians and enhances efforts to go green.

Phase II

- Emergency Orders implemented under the Quarantine Act require all individuals who enter Canada to quarantine or isolate themselves for 14 days.
- As part of Canada's efforts to reduce the spread of COVID-19 and prevent importation, all travellers to Canada are required to provide specific information upon and after entry into Canada. This includes providing an appropriate quarantine plan, contact information, and updates on symptoms through self-assessment. This information is crucial to slowing the spread of COVID-19.
- Failure to provide accurate information is an offence under the *Quarantine Act* and the traveller can be subject to fines and imprisonment.
- The ArriveCAN app is the recommended tool for anyone coming or returning to Canada, as it provides travellers the ability to enter the necessary information before, during and after their arrival at the border.
- By downloading the ArriveCAN App and entering information before arriving at customs, travellers can fast-track their arrival in Canada.



- Thousands of travellers to Canada are using the ArriveCAN app. This means that they are spending less time with Border Services Officers, public health officers and other travellers, and in lineups.
- The app allows travellers to input their information quickly, easily and securely up to 48 hours in advance of arriving in Canada.
- The app enables the Government of Canada to reach travellers after they arrive in Canada to validate their 14-day quarantine or isolation plan, helping to slow the spread of COVID-19 by verifying travellers' compliance with the *Quarantine Act*.
- By using an electronic collection method, physical contact between travellers and Border Services Officers and public health officers is limited, including the exchange of paper, which helps to protect the health of both travellers and officers.
- The ArriveCAN app supports Canada's digital strategy for services to Canadians and enhances efforts to go green.

If pressed on alternative options:

- While the app is the recommended option, alternative and accessible formats will remain available upon request to those who require them.

Protection of personal information:

- Personal information collected by Border Services Officers and Quarantine Officers, via the app or paper and online alternatives, is used by PHAC to verify travellers' compliance with the *Quarantine Act*.
- Information is shared with provinces and territories to facilitate their sharing public health information with travellers, as well as with law enforcement, to monitor and enforce compliance with the applicable Emergency Order.
- The ArriveCAN app only collects information needed to verify compliance with the mandatory requirement to isolate or quarantine for 14 days upon arrival in Canada, and includes a traveller's contact information, quarantine plan details, and self-reported symptoms. It does not use any other technology or data, such as GPS, to monitor self-isolation.
- Personal information is used to administer and enforce the *Minimizing the Risk of Exposure to COVID-19 in Canada Order (Mandatory Isolation)*,
- authorized under the *Quarantine Act* and/or *Department of Health Act*. Personal information may be used and/or disclosed for the following purposes: (1) to provide the traveller with information to promote compliance with the Mandatory Isolation Order; (2) to verify and/or enforce compliance with the Mandatory Isolation Order; and (3) for public health follow-up by the provinces and territories.



- The *Privacy Act* and its regulations require CBSA and PHAC to retain personal information under their control. Personal information used for an administrative purpose, as is the case for this app, is kept for a period of at least two years after the last time it was used.
- Provinces, Territories and local law enforcement, with whom this information is shared, have their own privacy legislation and retention periods.
- The protection of Canadians' personal information is a priority for the Government of Canada, and any tool used to collect personal information undergoes a rigorous privacy assessment.

Increased Public Health Agency of Canada Presence at Canadian Points of Entry

- Managing COVID-19 requires continued coordination with provincial, territorial and federal government to protect the health of Canadians, while addressing the evolving economic and social impacts of the COVID-19 outbreak.
- Since January 23, 2020, Canada's border screening measures have evolved in response to the outbreak.
- Currently, all points of entry, including airports and land borders, have 24/7 access to Quarantine Officers through a telehealth Central Notification System.
- As we plan for an eventual re-opening of borders, we are taking steps to minimize the risk of importation of COVID-19 cases to Canada. PHAC is increasing the presence of officers at 36 points of entry across the country. These high-volume points of entry receive more than 90% of all inbound travellers during normal operating circumstances.
- We will deploy PHAC Officers to high-volume points of entry to conduct traveller health assessments and to determine the suitability of the traveller's quarantine and isolation location, as required under the *Quarantine Act*.
- Travellers are encouraged to use the Government of Canada's ArriveCAN app to input their quarantine and isolation information in advance. Using the app can help reduce wait times at the border and limit physical contact with others.
- The Government of Canada continues to work closely with provincial and territorial governments and jurisdictions to ensure border measures are in place to safeguard the health of Canadians and travellers. These measures will continue to evolve with the situation.

Key messages for PHAC and CBSA unions (Internal Communications)

- PHAC Officers at points of entry will provide regular support and advice to the Border Service Officers and make decisions related to the implementation and enforcement of the *Quarantine Act* and related Orders in Council.



- The roles and responsibilities of PHAC Officers, as mandated by the *Quarantine Act*, have been communicated to Border Services Officers and support the Canada Border Services Agency's (CBSA) national Standard Operating Procedures adapted to each point of entry site layout.
- PHAC's presence will support CBSA's presence at land border points of entry to carry out COVID-19 enhanced screening measures, including conducting health assessments, determining suitable place to quarantine and isolation and any other actions deemed necessary under the *Quarantine Act*.
- PHAC Officers will not provide interpretation or guidance on the admissibility of travellers.
- At all points of entry, when there is no physical PHAC officer presence, the CBSA border services officer will have access to PHAC's 24/7 Central Notification System telehealth line, for a remote assessment by a Quarantine Officer.

On essential Travel Restriction (Canada-US)

- On March 18, 2020, the Governments of Canada and the United States announced that both countries would be implementing collaborative and reciprocal measures to suspend optional (discretionary) travel along the Canada-U.S. border in response to the spread of COVID-19.
- All travel of an optional or discretionary nature, including tourism and recreation, is prohibited. Travel by healthy people who have to cross the border to go to work or for other essential purposes, such as medical care, will continue.
- Some examples of non-discretionary travel purposes are:
 - Crossing the border for work and study;
 - Economic services and supply chains;
 - Critical infrastructure support;
 - Health (immediate medical care), safety and security;
 - Shopping for essential goods such as medication or goods necessary to preserve the health and safety of an individual or family
- Canadian citizens and permanent residents and Registered Indians under the *Indian Act* enter Canada by right. They will be provided with a Public Health Agency of Canada pamphlet that advises travellers of the mandatory isolation order for 14 days from the date they enter Canada.
- Green EN: <https://www.canada.ca/en/public-health/services/publications/diseases-conditions/2019-novel-coronavirus-information-sheet.html>
- Orange EN: <https://www.canada.ca/en/public-health/services/publications/diseases-conditions/covid-19-information-essential-service-workers.html>
- Red EN: <https://www.canada.ca/en/public-health/services/publications/diseases-conditions/travellers-with-symptoms-return-canada.html>

Upon arriving in Canada

- All travellers entering Canada are given a Public Health Agency of Canada handout with information on mandatory quarantine or isolation for 14 days.



Travellers with symptoms are given information on mandatory isolation, and those without symptoms are given information on mandatory quarantine.

Enforcement:

- Spot checks will be conducted by the Government of Canada to verify compliance.

Government of Alberta Introducing Increased Screening Measures at Border Crossings and Ports of Entry

- Government of Canada officials are responsible for screening all travellers entering Canada. In fulfilling this role, they adhere to the latest guidelines which include the requirement for individuals who are experiencing COVID-19 symptoms, to self-identify.
- The Government of Canada is aware of new measures Alberta is taking in terms of additional health screening measures at ports of entry, including temperature checks.
- To prevent the spread of COVID-19 from international ports of entry, the Government of Canada works closely with all levels of government to ensure the alignment of public health measures across jurisdictions.
- In developing its response to the Covid-19 pandemic, the Government of Canada collaborates with its provincial, territorial and international partners to develop risk-based approaches based on the latest science and situational assessments of what is occurring in various jurisdictions across Canada.
- Public health authorities are closely monitoring for continued and stable slowing of the epidemic in Canada, while carefully considering approaches to ease public health restrictions when and where this may be possible.
- The epidemiology of COVID-19 is different in each jurisdiction, so public health measures will vary between provinces and territories and may vary between regions within each jurisdiction.

On foreign nationals seeking to make a refugee claim

- Foreign nationals who enter Canada in between official ports of entry to make an asylum claim will continue to be directed back to the U.S., a designated safe-third country.
- Any foreign national arriving from the U.S. who presents at an official land port of entry and **meets** one of the STCA exemptions – whether symptomatic or not – is exempted from the prohibition on entry, and may enter to make a claim for refugee protection.
- Claimants who are unable to meet Canada’s mandatory quarantine/isolation requirements will be transferred to a federal location.

On enforcement of this Order

- Failure to comply with this Order is an offense under the Quarantine Act.

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- Maximum penalties include a fine of up to \$750,000 or imprisonment for six months, or both. Further, a person who causes a risk of imminent death or serious bodily harm to another person while willfully or recklessly contravening this Act or the regulations could be liable for a fine of up to \$1,000,000 or imprisonment of up to three years, or both.
- In addition, amendments have been made to the Contraventions Regulations to make non-compliance with specific requirements under the *Quarantine Act* contraventions for which tickets can be issued.
- The fine amounts for these contraventions will range from \$275 to \$1,000. The fine amount for contraventions committed by young persons is \$100.

On essential travel of foreign nationals to Canada via the United States

- Essential travel will continue unimpeded. Both governments recognize the importance of preserving vital supply chains between the two countries. These supply chains ensure that food, fuel, and life-saving medicines reach people on both sides of the border.

Foreign nationals who are permitted to enter into Canada, include:

- A person who arrived at an official land port of entry and is permitted to make a claim for refugee protection pursuant to the Safe Third Country Agreement;
- A person registered as an Indian under the *Indian Act*; and
- A person who is a protected person.
- In addition, provided they seek to enter for a purpose that is not discretionary or optional and they are not exhibiting symptoms of COVID-19, foreign nationals in the following categories also would be permitted to enter into Canada.

Screening of Canadian Travellers Returning to Canada

- As part of Canada's enhanced border measures to contain further introduction and spread of COVID-19, airlines will conduct a health check of all travellers before boarding a flight to Canada.
- The health check is based on guidance from the Public Health Agency of Canada, in line with the World Health Organization's recommendations.
- Individuals will be screened for the following symptoms by airline personnel:
 - Fever
 - Cough
 - Difficulty breathing
- If air operators observe a traveller with symptoms or if the passenger answers yes to any of the questions on the health check, they will be refused boarding for a period of 14 days or until they provide a medical certificate confirming that their symptoms are not related to the COVID-19 virus.
- Further instructions and advice will be provided to travellers who are denied boarding advising them to follow the guidance of local public health authorities. These travellers will also be directed to the appropriate consular services.

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- These measures will help protect the health of all Canadians.

On the health check

- Airline staff will be advised to maintain distance between themselves and travellers at all times, and to encourage travellers to do so as well.
- Airline staff will observe if travellers are showing symptoms of COVID-19 and will ask every traveller if they have a fever, cough or difficulty breathing.
- They will also ask if travellers have been denied boarding in the past 14 days due to a medical reason related to COVID-19.
- However, there is allowance for travellers to provide a medical certificate certifying that any symptoms they have are not related to COVID-19.
- These measures are focused on travellers, not flight crew members.

On enforcement

- Any traveller who provides false or misleading answers about their health during screening could be subject to penalty of up to \$5,000 under the *Aeronautics Act*.

Upon arriving in Canada

- All travellers assessed in the air to be symptomatic on arrival at a Canadian airport are met and escorted by border officers away from other travellers to be attended to by public health personnel.
- All persons arriving in Canada at an air, land, marine or rail border will be asked about the purpose of their visit and whether they are feeling ill or unwell. The border services officer may ask additional questions to make their determination.
- CBSA officers will observe for signs of illness and refer any traveller suspected of being ill for a further medical assessment by the Public Health Agency of Canada, regardless of how travellers respond to screening questions.
- All travellers — no matter their country of origin or mode of entry — are assessed on arrival to Canada. Entry screening is an important public health tool amongst others during periods of uncertainty and part of a multilayered government response strategy.
- CBSA officers remain vigilant and are highly trained to identify travellers seeking entry into Canada who may pose a health and safety risk.
- CBSA officers are providing symptomatic travellers with surgical masks and instructions on how to use them.
- These measures complement routine traveller screening procedures already in place to prepare for, detect and respond to the spread of serious infectious diseases into and within Canada.
- The following questions are now being asked by all border services officers at the primary inspection line at all air, land, ferry and rail ports of entry:
 - “Do you currently have a cough, difficulty breathing, or feel you have a fever?”
 - “I/we acknowledge that I/we must self-isolate for 14 days to prevent the potential spread of COVID-19.”

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- CBSA Officers not only query travellers on the state of their health, they are trained to observe visible signs of illness and will refer any traveller who they suspect of being ill, regardless of how the traveller responded to the health screening question.
- Travellers presenting symptoms consistent with COVID-19 will be referred to a PHAC staff member for further assessment.
- These travellers are provided with a kit that includes a mask and instructions.
- All travellers entering Canada are given a Public Health Agency of Canada handout with instructions to self-isolate for 14 days. Symptomatic people are given a red pamphlet, and asymptomatic people are given a green pamphlet.
- If a person has a question regarding entry to Canada, it can be directed to phac.emergencymorder-decreturgencecovid19.aspc@canada.ca.

Order in Council 20 (replaces OIC 17) – Minimizing the Risk of Exposure to COVID-19 Coronavirus Disease in Canada Order (Prohibition of Entry into Canada from Any Country Other than the United States)

- In the interest of reducing the spread of COVID-19, we will continue to enforce temporary measures barring entry of foreign nationals into Canada unless entry is for essential purposes, including reuniting or keeping together immediate family members of Canadian citizens or permanent residents if they intend to stay for at least fifteen days.
- Foreign nationals such temporary foreign workers, some students, persons delivering urgent medical supplies and asylum seekers arriving at official land points of entry who are permitted to make a claim pursuant to the STCA would generally not be prohibited from entering.
- All foreign nationals that enter Canada are required to meet the requirements of the Emergency Orders made under the *Quarantine Act*, and follow the quarantine and isolation protocols established previously.
- These border measures are currently in effect until August 31,2020.
- The Government of Canada, in close coordination with provincial, territorial, and international partners, continues to work to limit the spread of COVID-19 and do what is necessary to protect the health of Canadians.
- As previously announced, the immediate family members of Canadians and permanent residents entering Canada will be able to enter the country, provided they meet all other criteria for entry into the country as outlined in the Order and in conjunction with the Immigration and Refugee Protection Act.

On enforcement of this Order:

- Failure to comply with this Order is an offence under the *Quarantine Act*.



- Maximum penalties include a fine of up to \$750,000 or imprisonment for six months, or both. Further, a person who causes a risk of imminent death or serious bodily harm to another person while willfully or recklessly contravening this Act or the regulations could be liable for a fine of up to \$1,000,000 or imprisonment of up to three years, or both.
- In addition, the Government of Canada has made amendments to the *Contraventions Regulations* to make non-compliance with specific requirements under the *Quarantine Act* contraventions for which law enforcement can issue tickets.
- The fine amounts for these contraventions will range from \$275 to \$1,000. The fine amount for contraventions committed by young persons is \$100.

If pressed:

Foreign nationals who are permitted to enter into Canada include:

- A person who arrived at an official land port of entry and is permitted to make a claim for refugee protection pursuant to the STCA;
- A person registered as an Indian under the *Indian Act*; and
- A person who is a protected person.

Foreign nationals in the above categories must still demonstrate that they are travelling to Canada for non-optional, non-discretionary purposes, must have a plan for how they will quarantine for 14 days, and must be asymptomatic. Any foreign national showing symptoms of COVID-19 will not be permitted entry.

Border Measures – Easing of Travel Restrictions:

- The Government of Canada is working closely with all levels of government to help ensure that border measures safeguard the health of Canadians, while addressing the evolving economic and social impacts of the COVID-19 pandemic.
- As other levels of government consider the easing of some public health measures, current border restrictions remain in place.
- All travellers arriving in Canada will continue to be screened for COVID-19. Entry screening is an important public health tool and is part of a multilayered government response strategy.
- Effective March 25, 2020, the Government of Canada implemented a federal Emergency Order under the *Quarantine Act*. With some limited exceptions, anyone entering Canada, whether by air, land or sea, is required to quarantine or isolate for 14 days to limit the introduction and spread of COVID-19.
- Any decision to ease border restrictions at Canadian ports of entry will be made in consultation with provincial and territorial governments, and in consideration of international border measures.

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Travelling Update June 21

- Currently, Canadians are advised to avoid non-essential travel outside Canada and avoid all cruise ship travel until further notice. Canada's [official global travel advisory](#), [cruise ship advisory](#) and [pandemic COVID-19 travel health notice](#) are still in effect.
- While a small number of countries have or are in the process of flattening their curve, [globally the daily number of cases continues to rise](#). Unfortunately, the situation in many countries is getting worse.
- Therefore, our travel advice to Canadians remains the same.
- We will continue to evaluate this advice based on the evolving situation in Canada and in other countries.
- Do not travel if you are sick or if you have been in contact with a confirmed or probable COVID-19 case in the past 14 days.
- If you are well and must travel, it's important to be aware of the risks involved and to keep the following in mind:
 - Older people and people with a weakened immune system or underlying medical condition are at a higher risk of developing severe forms of the disease.
 - It's possible to become infected while in transit and even in areas reporting low or no transmission, so follow precautions recommended by local government and transportation system officials.
 - Travel health insurance may be difficult to obtain and may not offer coverage for COVID-19-related medical treatment.
 - Consult the Government of Canada's Travel Advice and Advisories and to get information on the latest COVID-19 situation at your destination, including entry or quarantine requirements, travel restrictions, and local public health measures that you will have to obey. You should also consult official foreign government websites for additional information on local public health measures.
 - Consult the Government of Canada's Travel Advice and Advisories to get information on the latest COVID-19 situation at your destination, including entry or quarantine requirements, travel restrictions, and local public health measures that you will have to obey. You may also consult the official websites of foreign governments for additional information on local public health measures.
 - Register with the Registration of Canadians Abroad service to get the latest updates on the situation for your destination.
 - Know and carry with you the contact information for the [Canadian Embassy or Consulate](#) in the region you are considering travelling to, in the event that there is an unforeseen lockdown or local health services become overwhelmed.
- All air travellers to and from Canada are required to bring and wear a non-medical mask or face covering. Make sure your mask is made with at least two layers of tightly woven fabric, constructed to completely cover the nose and mouth without gaping, and secured to the head by ties or ear loops. Be sure to have a mask for your departing and return flights.

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- While travelling, it is important that you monitor your health. If you become sick when you are travelling and think you may have COVID-19, avoid contact with others, follow local public health advice and seek care.
- As a precaution, you should avoid spending time in large crowds and practise physical distancing. In situations where physical distancing is difficult to maintain, wear a non-medical mask or face covering. Also, avoid contact with people who are sick, including those with fever, cough or difficulty breathing. Wash your hands frequently using soap and warm water. If that's not possible, use an alcohol-based hand sanitizer.
- When you return to Canada, you will need to undergo a mandatory 14-day quarantine. You will be required to fill in a form or provide details in the ArriveCAN app that will enable the Government to do follow-up to make sure you are abiding by the quarantine rules and so that public health officials can provide you with information on resources nearby. You must fill in the information accurately or your case may be referred to local law enforcement for follow-up. You can visit Canada.ca/coronavirus for more information on requirements for all travellers entering Canada, including the use of the ArriveCAN app to provide your quarantine plan before or at the time of arrival.

On Entry of Foreign Nationals and Refugee Claimants into Canada via the United States:

- Travel between Canada and the United States continues, unless it is for an optional or discretionary purpose. For example, both governments recognize the importance of maintaining vital supply chains between the two countries. These supply chains ensure that food, fuel and life-saving medicines reach people on both sides of the border.
- The temporary prohibition of all optional or discretionary travel at the border has been extended until July 21, 2020.
- The Order in Council (OIC) continues to apply to the entire Canada-U.S. border, with the Safe Third Country Agreement (STCA) applying to refugee claimants at land ports of entry.
- Any refugee claimant who qualifies for a specific and limited exception to the OIC or STCA must follow the legal requirements to isolate and quarantine, as with all travellers to Canada.
- The Government of Canada will be responsible for the transportation and accommodation of any claimants who are unable to isolate or quarantine themselves.

Additional Screening Measures at Canadian Ports of Entry:

- As the COVID-19 pandemic evolves, public health authorities are closely monitoring for continued and stable slowing of the epidemic in Canada, while carefully considering approaches to ease public health restrictions, when and where this may be possible.



- Although the epidemiology of COVID-19 is different in each jurisdiction and public health measures may vary between provinces, territories and jurisdictions, federal public health measures (as outlined in the Emergency Orders) apply to all ports of entry.

Temperature Screening for Air Travel

- Temperature screening is one of several measures being taken by the Government of Canada at Canadian ports of entry in response to COVID-19.
- Other measures include:
 - Enhanced screening, including health assessments;
 - Inspections/assessments of public in transit at ports of entry; and
 - Confirming the requirement for travellers to have a suitable place to quarantine for 14 days as per the Government of Canada's Emergency Order under the *Quarantine Act*.
- This is in addition to measures being taken by air carriers and operators of other means of transport.
- Public health measures that airlines have taken to prevent the spread of COVID-19 include:
 - Enforcing the use of non-medical masks,
 - Encouraging physical distancing and,
 - Educating travellers on what they can do to minimize their risk of contracting COVID-19.
- Temperature screening is one way to identify individuals who may be sick. It may also act as a deterrent for mildly ill air travellers.
- It is important to note that temperature checks do not detect all COVID-19 cases, as fever is not usually the first symptom of COVID-19. In some cases, a fever never develops. However, it is an additional cautionary tool to identify potentially ill travellers.

If pressed of evidence from SARS:

- During the SARS outbreak, 2.3 million travellers were screened using thermal scanners, but despite this intensive screening effort, no cases of SARS were detected using this method.
- *An additional message for the CPHO:* I provide scientific evidence-based advice for decision-makers to incorporate within their own contexts. The science is evolving, and I support decision-makers taking cautionary approaches in certain instances.

Stricter rules and conditions for foreign nationals transiting through Canada to Alaska

- The Government of Canada remains committed to protecting the health and safety of Canadians and reducing the spread of COVID-19 in Canada.
- The Canada-U.S. temporary border restriction put in place on March 21 at 12:01 am EDT continues. All discretionary/optional travel remains prohibited.
- The CBSA is announcing stricter rules and additional entry conditions for travellers transiting through Canada to Alaska for a **non-discretionary** purpose such as work or going to primary

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residence. These measures are put in place to further reduce the risk of introduction of COVID-19 cases and to minimize the amount of time that in-transit travellers are in Canada.

- In-transit travellers will be required to enter Canada at one of the five (5) identified CBSA ports of entry (POE): Abbotsford-Huntingdon (British Columbia); Coutts (Alberta); Kingsgate (British Columbia); North Portal (Saskatchewan); Osoyoos (British Columbia).
- In addition, in-transit travellers will be imposed a reasonable period of stay to carry out their transit; be limited to travel within Canada using the most direct route from the POE to the intended POE of exit, while avoiding all national parks, leisure sites and tourism activities; and, be required, before entering the U.S., to report to the nearest CBSA POE to confirm their exit from Canada in accordance with the conditions imposed on entry.
- In-transit travellers will be issued a vehicle 'hang tag' to be attached to their rear view mirror for the duration of their trip to or from Alaska to support compliance while they are in Canada. The front of the tag will make it clear that the travellers are transiting and include the date they must depart Canada. The back of the tag will remind travellers to comply with all conditions imposed upon entry and the Quarantine and Emergencies Acts and include a list of public health and safety measures to follow.
- Travellers who arrive at a non-identified POE for the purpose of transiting to Alaska will be denied entry and advised to go to one of the five identified POEs. No matter the reason for travel, all foreign nationals who have COVID-19 or exhibit any signs or symptoms of COVID-19 will not be allowed to enter Canada.

Travel Restrictions

- All travel of an optional or discretionary nature, including tourism and recreation is prohibited. Travel by healthy people who have to cross the border to go to work or for other **non-discretionary** purposes, such as medical care, will continue.
- Some examples of non-discretionary travel purposes are:
 - Crossing the border for work and study;
 - Economic services and supply chains;
 - Critical infrastructure support;
 - Health (immediate medical care), safety and security;
 - Shopping for essential goods such as medication or goods necessary to preserve the health and safety of an individual or family; and
 - Other activities at the discretion of the border services officer (BSO).
- Canadian citizens and permanent residents and Registered Indians under the *Indian Act* enter Canada by right. They will be provided with a Public Health Agency of Canada pamphlet that advises travellers that they must quarantine or isolate for 14 days from the date they enter Canada.

Enhanced Border Measures & Information Collection

- Travellers should consult the respective provincial/territorial websites to ensure that they are aware of the provincial/territorial entry, quarantine and public health requirements and can abide by those requirements.



- As of March 31, 2020, anyone arriving in Canada in any mode (air, land or marine) must provide their contact information to a border services officer (either by paper, online, via the [ArriveCAN App](#) or verbally to the officer) when seeking entry. This information is collected on behalf of the Public Health Agency of Canada to support their compliance and enforcement of the 14-day quarantine or isolation requirement outlined in Order in Council [2020-0524](#).
- All travellers are encouraged to download the mobile [ArriveCAN App](#), prior to arrival to reduce wait times and limit contact at the border. The App is available on the Apple App and Google Play stores.

Camp in Bracebridge where travellers were quarantining together

- Mandatory quarantine or isolation after international travel is one of our primary public health measures that is proven to work in reducing the spread of COVID-19.
- Travelling Canadians, and those entering Canada, need to understand the role that they play, the potential risk that they may have been exposed to the virus during any travel outside the country, and the risk that they in turn may pose to other Canadians including those most at risk of serious illness.
- All travellers entering Canada must arrange for a suitable place to quarantine or isolate, within their own financial means, where they can stay for at least 14 days and have access to basic life necessities (e.g., water, food, medication and heat). This place should be away from any vulnerable individuals and cannot be a group or communal living setting. All travellers must stay at their place of quarantine or isolation for 14 days, and only leave to seek medical assistance if needed.
- If federal and provincial/territorial quarantine guidelines differ, travellers should follow the most precautionary and stringent requirements.
- The Public Health Agency of Canada (PHAC) works closely with the Royal Canadian Mounted Police (RCMP) and provincial law enforcement agencies to verify the compliance of travellers entering Canada.
- Failure to provide accurate information is an offence under the *Quarantine Act* and the traveller can be subject to fines and imprisonment.
- PHAC is working with the local public health authorities and the local police to confirm that these travellers are abiding by the local and provincial quarantine requirements.

Travel Health Notices

- The Public Health Agency of Canada issues travel health notices to inform Canadian travellers of an increased or unexpected potential health risk in a country or region outside of Canada.
- The travel health notices also provide information on preventative measures travellers can take to help reduce these risks.
- The following is considered when adding countries or areas to the COVID-19 affected areas list:
 - Multiple instances of spread have occurred at the community level (multiple clusters—not in definable settings such as a household);
 - Evidence of geographical spread; and

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- Whether cases can be linked to an exposure (i.e., to another case or because of travel to another country with ongoing transmission of COVID-19).
- The COVID-19 Affected Areas List on Canada.ca/coronavirus includes all countries with Travel Health Notices related to COVID-19.

5G Technology and COVID-19

- Health Canada's top priority is the health and safety of Canadians. Our mandate regarding human exposure to radiofrequency electromagnetic fields is to carry out research into possible health effects, monitor the relevant scientific literature, and develop recommended human exposure limits in a guideline commonly referred to as [Safety Code 6](#).
- Safety Code 6, which covers the frequency range used by emerging 5G technology, is consistent with or more stringent than standards used internationally and is based on thorough evaluation of the scientific literature. The health of Canadians is protected when the exposure limits in Safety Code 6 are respected.
- There is no scientific basis for the recent suggestion linking the deployment of 5G networks and the spread of COVID-19. The [World Health Organization](#) and the [International Commission for Non-Ionizing Radiation Protection](#) have also recently communicated this message on their websites. Information about the transmission of COVID-19 is available at Canada.ca/coronavirus.

Quarantine Facility Outbreak in Australia

- The Government of Canada has established designated quarantine facilities (e.g., hotels) to prevent the potential spread of COVID-19.
- Quarantine facilities are used to lodge people entering Canada who do not have a suitable place in which to quarantine because they are unable to meet the conditions outlined in the Emergency Order under the *Quarantine Act* to isolate or quarantine in an appropriate accommodation.
- All federally designated quarantine sites have strict infection prevention and control measures in place in order to safeguard the health of Canadians.
- There has not been any transmission of COVID-19 in federally designated quarantine facilities in Canada.
- The Government of Canada continues to work closely with local, provincial and territorial law enforcement and health partners to monitor travellers entering Canada, and ensure that they comply with the requirements of the Emergency Orders under the *Quarantine Act*, including the mandatory 14-day quarantine or isolation requirement.

Supplemental Messages:

On screening and quarantine:

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- All travellers arriving in Canada continue to be screened for COVID-19.
- Entry screening is an important part of the Government of Canada's multilayered response to the COVID-19 outbreak to gather information from, and share information with, travellers as they enter Canada.
- All persons entering Canada are required to provide all relevant information requested at the time of entry and throughout the 14-day period following their entry. Travellers must also confirm with a Government representative at the point of entry that they have a suitable location to quarantine or isolate in Canada.
- When travellers arrive to Canada, a Government of Canada representative will ask them questions to determine the suitability of the traveller's plan for quarantine to ensure they:
 - prevent contact with individuals at increased risk of more severe outcomes related to COVID-19 such as older adults, or people with compromised immune systems or other underlying medical conditions;
 - prevent the transmission of COVID-19 to others in their place of quarantine; and
 - have access to the necessities of life such as food and medication through the assistance of a family, a neighbour, a friend or delivery service to help with essential errands (e.g., picking up prescriptions, buying groceries).
- Accommodations that may be deemed suitable include one's home, whether it is an apartment, condominium, single family home, houseboat or mobile home.
- We expect that most travellers will quarantine in their own home or in the same place they are visiting in Canada. If this is not possible, travellers are responsible for making alternative arrangements for quarantine accommodations that are within their own financial means.
- A traveller may be transferred to a federal designated quarantine facility if it is deemed necessary by a public health officer designated under the *Quarantine Act*, and only if travellers are confirmed to have no other suitable quarantine or isolation options available. This measure is used as a last resort.
- Under certain circumstances, both symptomatic and asymptomatic travellers may be transferred to a designated quarantine facility for their quarantine period at the discretion of a public health officer designated under the *Quarantine Act*. Considerations include:
 - Whether the traveller has symptoms of COVID-19;
 - If the traveller has a place to quarantine or isolate;
 - If the traveller's quarantine plan includes people at higher risk for serious outcomes from COVID-19 (e.g., adults aged 65 years or older and people with certain pre-existing medical conditions) living in the same place; and/or,
 - If the traveller will have access to basic necessities, such as food and medication.

On what is considered a suitable place to quarantine:

- Travellers are strongly urged to have a plan for their quarantine prior to their arrival in Canada.

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- For travellers arriving in Canada and who must make alternative arrangements for their quarantine and who are not able to quarantine in their own place of residence, the following are considered appropriate to quarantine for 14 days:
 - Hotels and motels or other paid housing alternatives, including websites connecting travellers with property owners (e.g., AirBnB);
 - staying with family or friends, as long as they will not expose individuals that are not part of their travel group and will not be in contact with a person at risk of more severe outcomes from COVID-19, including those over 65 years of age and those with underlying health issues.

On measures in place to prevent an outbreak at a Canadian quarantine facility:

- Access to federally designated quarantine sites is strictly controlled and security is onsite 24/7.
- All federally designated quarantine sites have strict infection prevention and control measures in place.
- Regular cleaning and disinfection and sanitization is undertaken.
- All staff on site have appropriate personal protective equipment and are trained on its proper use as well as donning and doffing procedures.
- Movement of all individuals in the facilities is restricted.
- Symptomatic and COVID positive travellers are segregated from asymptomatic travellers within the quarantine facilities.
- When travellers are in a quarantine facility, they are provided with three meals daily and other essentials. All of these items are delivered to their rooms.
- Outdoor/fresh air time for travellers is limited and supervised by staff.
- Travellers also receive regular daily health checks during which they can discuss any concerns they may have.

On the number of designated quarantine sites and number of people who have been housed in them:

- There are 11 federally-designated quarantine sites and two federal quarantine lodging spaces in provincial and territorial sites. Sites are located in the following cities: Whitehorse, Vancouver, Kelowna, Calgary, Regina, Winnipeg, Toronto, Montreal, Fredericton, Halifax, and St. John's.
- As of August 16, 2020:
 - there have been a total of 3,222 travellers lodged in federally designated quarantine sites to date; and,

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- there were 250 travellers lodged in federally-designated quarantine sites.
- Nationally, the federal government has approximately 1,500 rooms available for quarantine.

COVID-19 Spike in Rural Communities

- The Government of Canada is working closely with provinces and territories to ensure that all necessary and appropriate supports are available to ensure a comprehensive coordinated response to COVID-19.
- Outbreak monitoring has identified rural outbreaks in communal living settings (e.g., Hutterite and Mennonite communities) and smaller outbreaks in other rural or remote communities.
- While provinces and territories are responsible for the provision of direct health care services to Canadians, the Government of Canada is ensuring that the needs of federal populations are being met and that measures are in place to mitigate the impacts of COVID-19.
- As community-based health measures are lifted, provincial, territorial and local governments are monitoring the degree of COVID-19 transmission in their jurisdiction, and will adjust public health advice and measures as needed.
- Testing, case management and contact tracing remain the pillars of COVID-19 public health response activities in Canada.