



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



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

COVID-19 Situational Dashboard

- On April 4, the Government of Canada launched a new COVID-19 situational dashboard for Canada.
- The situation in Canada is changing rapidly and we are learning more about COVID-19 every day. Canadians need easy access to digital tools and resources to help them get the information they need about COVID-19.
- This 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.
- It provides an interactive overview of number of cases and deaths in Canada, including information on affected populations by age, sex and on how the outbreak is progressing over time.
- This tool does not provide any modelling or forecasting of what may occur in the coming weeks and months.
- New data is released daily by provincial and territorial officials. While the dashboard is continuously updated to reflect these new data, if there are any differences between the national case count and testing numbers reported by provincial and territorial public health officials, the provincial and territorial data should be considered the most up-to-date.
- The Government of Canada will continue to work collaboratively with partners at all levels of government to respond to COVID-19 and ensure that cases continue to be rapidly identified and managed in order to protect the health of Canadians.

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 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.
- 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 publicly 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.

Change in Epidemiological Data Posted on May 27

- 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 best evidence available.
- On May 26, 2020, PHAC received updated data on more than 40,000 cases of COVID-19 from the provinces and territories. We now have more complete data on 99% of all reported cases.
- This improvement in the completeness of our epidemiological data is reflected in some changes in the May 27 epidemiological update.
- These updated data provide valuable information to improve our knowledge of the epidemiological situation in Canada and will help inform decision-making.

If pressed:

- Accurate and timely reporting during an epidemic is challenging for the jurisdictions given the volume of COVID-19 cases reported across Canada. Provinces and territories are continuously improving their data and have recently submitted updated data.

Virtual Health Tools

- 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.
- 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.

Exposure Notification App

- The Government of Canada is developing a new nation-wide mobile app to let users know if they may have been exposed to COVID-19 across Canada, with testing to begin in Ontario.
- The app, which incorporates exposure notification technology provided by Apple and Google, is private, secure, and easy to use.
- Using Bluetooth technology, it will alert users if they have been near another app user who then subsequently tests positive for COVID-19.
- The protection of Canadians' privacy is a priority for the Government of Canada. The app will undergo a thorough privacy assessment, and all data provided to the app will be securely stored and protected.



- The use of the exposure notification app will keep all of us safer and healthier as we ease restrictions and restart the economy.
- While exposure notification app will be voluntary, the more Canadians who use it, the more useful it will be in preventing further infection. Ideally, 60% of Canadians would be using the app.
- The free of charge app will be national in scope. While the app itself will be available to all Canadians upon launch, the exposure reporting functionality will be launched incrementally in each province and territory in collaboration with public health authorities. Residents of Ontario will be able to receive exposure notifications in the coming weeks.
- In keeping with the principles of digital government, we intend to work in the open, communicating openly and transparently with Canadians about the development and implementation of this app.

This 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.

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.

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.
 - 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.

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.
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.
- 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.

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 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.
- 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.

Will quarantine and isolation periods remain at 14 days for travellers returning to Canada?

- Until larger studies can be done, and out of an abundance of caution to protect the health of Canadians, quarantine and isolation periods will remain at 14 days for travellers returning to Canada.
- PHAC will update public health guidance as the evidence evolves.

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 (GloPID-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.

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.

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.

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.
- 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

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



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.



- 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.

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.
- 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.

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.
- 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.

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.



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.
- 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.

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.
- 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.

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.

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 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:
 - 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.

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.



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 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.



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.
 - 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
- 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:
 - 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

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.
 - 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.

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:
 - 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.
- 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.

Use of non-medical masks (or facial coverings) by the public

- Canadian public health guidance related to COVID-19 has been changing as the evidence and our understanding of COVID-19 rapidly evolves. We are continually looking at the evidence as it is being produced and working with our partners across the country and around the world to learn more.
- To prevent transmission of COVID-19 the following measures are our best defence:
 - Staying home and away from others if you are sick
 - Washing your hands frequently
 - Covering your cough with tissues or your sleeve
 - Practicing physical distancing
 - Cleaning and disinfecting surfaces and objects
 - Protecting those most at risk from the virus
- It is critical that these measures continue, even as we shift through next phases of this pandemic and slowly start resuming daily activities.
- If used correctly, a non-medical mask can play an important role in situations where physical distancing is not possible or is unpredictable.
- Given that the science tells us it's possible to spread the virus before, during and even without having any symptoms, wearing a non-medical mask—even if you have no symptoms—is an additional measure you can take to protect others around you, in situations where physical



distancing is not possible.

- 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.
- A non-medical mask or cloth face covering **is recommended** for periods of time, particularly in crowded settings, where it is not possible to keep a two-metre physical distance from others:
 - Community settings where physical barriers and spacing aids are not in place (e.g. some retail or work spaces)
 - Enclosed environments (e.g. public or commercial transportation); and/or
 - High-risk settings where outbreaks can spread quickly (e.g. group living settings, correctional facilities)
- Wearing a non-medical mask in the community does not mean you can back off from public health measures that we know work to protect you.
- Please visit Canada.ca/coronavirus for information on the appropriate use of non-medical masks or face coverings, including how to make your own. Non-medical masks can be made at home from readily available materials, ensuring that they are accessible to all who need them. There is ongoing discussion regarding the best materials or best construction methods for non-medical masks or cloth face coverings, and the website will be updated as new information becomes available.

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.
- 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).

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.

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 (Released April 28)

- The Government of Canada is continuing to work with provincial, territorial and international partners to ensure that our response to the COVID-19 epidemic is based on the latest science and situational assessment.
- We continually analyze data and clinical and epidemiological studies as they emerge to determine when public health measures are working and when we may need to do more to control the epidemic.
- We are also collaborating with federal, provincial and territorial governments and universities to forecast the possible future spread of COVID-19 in Canada and to estimate a range of possible numbers of cases, hospitalizations and deaths that may occur in the coming weeks and months.
- Based on these models, we can prepare our health system to provide care for the projected number of patients and assess what additional public health measures we may need to change the course of the epidemic in Canada.
- The models are highly sensitive to our actions. We can all help lower the impact of COVID-19 in Canada, by keeping up our physical distancing efforts.
- Just as case rates are different across the country, so too are projections about the impacts in various provinces and territories.
- Models cannot predict what will happen. But they can help us understand what might happen, which can help us plan and take actions to achieve the best possible outcome.



- 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.
- We are continually improving the models to provide the best available information to Canadians about possible outcomes.

Quebec's rate of cases and deaths

- Several factors are contributing to Quebec's higher numbers of reported cases and deaths relative to those of other provinces and territories.
- Most importantly, both Quebec and Ontario have reported numerous outbreaks in long-term care homes and senior residences. Transmission in these settings is driving a large number of cases and deaths among older adults. More than 80% of deaths in Quebec are among residents of these homes.
- Long-term care facilities continue to experience outbreaks, which are driving cases and deaths in some provinces. Based on provincial and territorial websites and press briefings, above half of all deaths, 63% (1,157/1,834), have occurred in long-term care facilities.
- The timing of the school break in Quebec is another factor that could have contributed to the higher number of cases. Quebec's school break occurred earlier than that of other provinces, with people travelling to countries and regions that had unrecognized outbreaks.
- A difference in reporting methods may also contribute to higher case counts in Quebec. Quebec includes individuals without waiting for laboratory diagnosis if they have symptoms of COVID and have been in close contact with a laboratory-confirmed case. Quebec counts these individuals in their counts of cases and deaths whereas other provinces and territories do not.
 - Quebec's public health authority can provide more clarity on how it reports confirmed cases.
- The province of Quebec was able to ramp up its testing capacity early on in the outbreak, with a more targeted testing approach (including testing for healthcare workers, long-term care residents, hospitalized cases with respiratory illness), which enabled them to identify cases.

If pressed on whether case numbers are underestimated in other provinces and territories

- Other provinces and territories publicly include only individuals with a laboratory diagnosis in their confirmed case count.
- We know that laboratory-confirmed cases underestimate the true number of infected individuals in all provinces where the virus is circulating. This is because not every person who is sick will get tested and be recorded as a lab-confirmed case.



- People with mild illness may go undetected and unreported and some people who are infected will not experience any symptoms at all. This is why public health measures such as physical distancing are so important.

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.
- 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
 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.



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.
- 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

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 May 5, we are averaging **20,000 tests daily** in Canada, **almost double** where we were a month ago. This number continues to grow.
- Canada has been maintaining a 6% 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.
- 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 Luminultra

- 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.



- Luminultra 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.
- Luminultra shipped its first batch of reagent on April 10, 2020.
- At full capacity, Luminultra will be able to manufacture reagent for up to 500,000 tests a week.
- It is expected that, as its production capacity scales up, Luminultra 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 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.

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.

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.
- **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.*
- *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.
- 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.)
- 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.

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.

Unusable Testing Kit Swabs

- The Government of Canada is aware that there are issues with some of the testing kit swabs that were received in early April.
- These swabs were part of a bulk order of 8.85 million swabs to be delivered throughout April and May in Canada.
- The manufacturing company (ESBE Scientific) is a reputable one, licensed by Health Canada. We have been informed that the company has paused subsequent production to address issues in the manufacturing process. As a result, remaining swab shipments will likely be delayed to address quality issues.
- This issue may have implications for future orders. The Public Health Agency of Canada continues to work directly with provinces and territories to identify their medical supply needs in order to place bulk buy orders. Public Services and Procurement Canada will continue to identify all available suppliers that have the capacity to respond to Canada's needs.

Amendments to the Authorization of the Spartan Test Kit

- On March 26, 2020, Health Canada issued an authorization with terms and conditions to Spartan Bioscience Inc. for its Spartan Cube for research use only.



- 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 the basis of minimum requirements.
- On April 11, 2020, Health Canada completed its scientific review to ensure that the device was supported by evidence that it meets requirements for safety and effectiveness. The terms and conditions attached to the authorization were amended and the restriction that the product be sold for research only was lifted.
- Health Canada's regulatory decision was based on in-laboratory testing of the device and not on clinical trial data of its effectiveness. The review took into consideration that further validation would be carried out by public health laboratories in order to determine performance in clinical settings. This regulatory approach is consistent with those taken by other trusted regulators.
- On May 1, 2020, the NML provided Health Canada with a final report of clinical testing performed in three provinces (Alberta, Ontario and Manitoba) using Spartan swabs to collect specimens directly from patients under clinical conditions.
- The report identified that while the Spartan Cube performed in a laboratory setting, as per manufacturer specifications, there were performance issues identified in the clinical trial. These issues appears be related to the proprietary swab, which may not sufficiently collect mucosal material necessary for testing.
- In light of the clinical results, on May 2, 2020, Health Canada has placed conditions on the company's authorization to restrict the sale of the product to research use only, until adequate evidence of clinical performance can be provided.
- 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 only until adequate evidence of clinical performance can be provided.
- Health Canada will continue to work with Spartan as they address the regulatory requirements to enable utilization of the point of care test kit.

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

- Spartan Bioscience shared its distribution record with Health Canada on May 2nd and confirmed it has distributed 5,500 test kits for research purposes only in a clinical setting to four public health organizations:
 - Alberta Health Services
 - CHU de Québec-Université Laval
 - Ontario Agency for Health Protection & Promotion
 - Public Health Agency of Canada
- These organizations are aware of the new Health Canada conditions on Spartan's authorization.
- Health Canada asked the company to voluntarily recall the products, to prevent its use in diagnostic settings at this time. The company has indicated agreement to do so.



- The Department has sent a regulatory letter to the company on May 2nd to indicate the new conditions in accordance with Section 7 of the Interim Order. This letter also describes the steps needing to be followed for the voluntary recall.
- Health Canada has restricted the sale of the test kits to research use until adequate evidence of clinical performance can be provided and assessed.

If pressed on the details of the recall:

- The recall would include:
 - issuing an advisory to inform all customers of the risks associated with the use of the device for diagnostic purposes and steps to take to mitigate the risk;
 - requesting the recovery of all instruments and unused single use elements (e.g., reagents and swabs) from the non-laboratory-based environments and laboratory-based environments using this device for diagnostic purposes; and
 - requesting the recovery of the swabs only from laboratories that will continue to use the device for research purposes.

If pressed on Health Canada's review of the Spartan product:

- On March 26, 2020, Health Canada issued an authorization to Spartan Bioscience Inc. for its Spartan Cube that attached terms and conditions to restrict the sale of the product “for research use only.” 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 the basis of minimum requirements.
- On April 11, 2020, Health Canada completed its scientific review to ensure that the device was supported by evidence that it meets requirements for safety and effectiveness. The terms and conditions attached to the authorization were amended and the restriction that the product be sold for research only was lifted.
- Health Canada's regulatory decision was based on in-laboratory testing of the device and not on clinical trial data of its effectiveness. The review took into consideration that further validation would be carried out by public health laboratories in order to determine performance in clinical settings. This regulatory approach is consistent with those taken by other trusted regulators.
- On May 1, 2020, the NML provided Health Canada with a final report of clinical testing performed in three provinces (Alberta, Ontario and Manitoba) using Spartan swabs to collect specimens directly from patients under clinical conditions. These clinical trials are key in identifying performance issues that could not have been identified in a laboratory setting. The report identified that while the Spartan Cube performed in a laboratory setting, as per manufacturer specifications, there were performance issues identified in the clinical trial. In light of this report, Health Canada further amended the terms and conditions on the authorization, restricting the sale of the Spartan Cube for research purposes only, until such time as data are provided by the company to indicate resolution of the performance issue, as well as sales information.

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 performs test validation and assess the performance of diagnostic supplies such as COVID-19 testing kits.
- This test validation function is part of scientific research and is independent of Health Canada's regulatory approval process. While this validation process 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.
- The NML tests COVID-19 laboratory supplies for clinical diagnostic purposes to ensure they meet the gold standard used in public health laboratories. This validation process is to determine if the product can be used to obtain reliable and accurate results when diagnosing COVID-19.

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 Health Canada authorized for sale in Canada.

COVID-19 home test kits

- Early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada.
- Health Canada does not support home testing for COVID-19, 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 a pandemic.
- Health Canada has authorized the sale and importation of COVID-19 diagnostic tests intended for use only by health care professionals or trained operators.
- Health Canada has not authorized any diagnostic tests or sample collection kits intended for use by the general public to detect or self-diagnose COVID-19.
- The Government of Canada continues to work with companies across the country and internationally to ensure Canadians and health care workers have the tools they need to care for Canadians and reduce the spread of COVID-19.

About the Interim Order for medical devices:

- As an emergency public health measure, the Interim order respecting the importation and sale of medical devices for use in relation to COVID-19 allows for expedited access to COVID-19-related medical devices.



- With the Interim Order, new diagnostic tests are being made readily accessible in Canada. They are listed on [Health Canada's website](#).
- The Interim Order will also ensure that other COVID-19-related medical devices are available to treat, mitigate or prevent COVID-19, as necessary.

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 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.

If asked about serology:

- On May 12, following priority scientific review, Health Canada authorized the sale of the first COVID-19 serological test, followed by a second test on May 14. For an up-to-date list of authorized tests, check [Health Canada's website](#).
- In addition, the Public Health Agency of Canada's National Microbiology Laboratory (NML) is working on developing a number of in-house serological tests in addition to evaluating a variety of commercial tests for COVID-19.
- Serology tests provide evidence of a previous exposure to the virus that causes COVID-19 by testing for the presence of antibodies.
- 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.
- Once we have a strong scientific understanding of immunity related to COVID-19 and levels of immunity in Canada this can inform ongoing surveillance of COVID-19 and policies related to immunity and return to work, in particular for healthcare settings.
- Serological surveys can also help guide important public health decisions once a vaccine becomes available.

COVID-19 serological tests for use in Canada

- Following scientific review, Health Canada has now authorized the sale of two serological tests - the DiaSorin LIAISON® test (authorized May 12) and the Abbott ARCHITECT SARS-CoV-2 IgG Assay (authorized May 14).
- Both 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.
- Health Canada authorized the tests after completing a scientific review that was supported by evidence to ensure that the tests will provide accurate and reliable results.
- A complete list of testing devices for use against coronavirus 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>.



- 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.
- Serological surveys can also help guide important public health decisions once a vaccine becomes available.
- 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.

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 of 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 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, leading to potential misdiagnosis.
- Health Canada has confirmed that authorized COVID-19 tests are well supported by evidence that they will provide accurate and reliable results. More than a dozen 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 evaluating 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 NML validation of test kits

- The Public Health Agency of Canada's National Microbiology Laboratory does not validate medical devices, such as swabs or test kits, as part of their regular business functions. They do however, assess their suitability for testing as part of their research efforts.
- In response to the urgent nature of COVID-19, the NML is being asked by companies to assess the performance of diagnostic supplies such as COVID-19 testing kits and 3D swabs. NML assesses these COVID-19 laboratory supplies for clinical diagnostic purposes to ensure they meet the gold standard used in public health laboratories.
- This assessment process by the NML is to determine if the product can be used to obtain reliable and accurate results when diagnosing COVID-19. While this process is separate from the Health Canada's scientific review process, NML is working in collaboration with Health Canada's Medical Devices Directorate to share knowledge gained through the assessment process.
- Health Canada regulates the sale and importation of medical devices in Canada. Unauthorized medical devices may not produce accurate results, leading to potential misdiagnosis. COVID-19 tests that are authorized by Health Canada are well supported by evidence indicating they will provide accurate and reliable results.

If pressed the scientific review of the DiaSorin LIAISON® test and Abbott's ARCHITECT SARS-CoV-2 IgG Assay

- Health Canada completed the scientific review of both the Diasorin's LIAISON® serology test and Abbott's ARCHITECT SARS-CoV-2 IgG Assay under the Interim Order process
- Both tests are authorized under the Interim Order with conditions, including the requirement to:
 - Submit a plan to Health Canada that will assess the performance of the test when used in the intended sites, with a minimum of two Canadian sites.
 - Provide a summary of additional cross-reactivity studies.
 - Provide a report on reagent stability studies.



- The Abbott's ARCHITECT SARS-CoV-2 IgG Assay is supported by an evaluation of the test using samples from 31 infected individuals and 1070 negative samples.
 - Additional validation results from the University of Washington were identified in published literature and confirmed the data provided by the company.
- The DiaSorin LIAISON® test is supported by an evaluation of the Liaison test using samples from multiple Italian and French sites.
 - Additional validation results were shared by the BC provincial lab and confirmed the data provided by the company.
- Health Canada will continue to work with the NML and other Canadian public health laboratories to review any relevant results that they may develop through their validation and use of these and other testing devices.

If pressed on what serological testing means for Canadians

What is serological testing used for?

- Serology-based tests are essential to understanding the immune response to virus infection. They will play a key role in determining the extent of exposure to the virus through sero-surveillance studies.
- Serological testing is not authorized to diagnose COVID-19 infections because it detects antibodies produced by the patient's immune response. Those antibodies are not likely to develop until later in the infection, thereby giving false negative results in many cases if used too early in the disease course.
- For diagnostic testing, it is preferred to test directly for traits of the actual virus while infections are occurring, using molecular tests from swabbed specimens.

How will the results of serological testing be used?

- Using validated and effective serological tests for COVID-19 will be an important step in Canada's public health response.
- On April 23, 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.
- Rapid and representative national surveys will 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.
- Serological surveys can also help guide important public health decisions once a vaccine becomes available.

Is the government considering the possibility of serological or immunity passports or certificates to allow people with immunity to move freely again?

- There is an active international effort to assess whether those who have recovered from illness are safe to resume daily activities.
- More research is needed before making decisions in Canada.
- Other respiratory viruses generally do not provide an individual with 100% immunity after recovery.



- Right now, we just do not know whether individuals who have recovered from COVID-19 will have immunity, how long that immunity may last, or whether it's possible for individuals to experience less severe or potentially more serious illness if they get COVID-19 a second time.

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, leading to potential misdiagnosis.
- Health Canada has confirmed that authorized COVID-19 tests are well supported by evidence that they will provide accurate and reliable results. More than a dozen 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 evaluating 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](#).

Canada-Wide Study to Track COVID-19 - Immunity Task Force

- Every day, we are adding to our knowledge of COVID-19, and keeping pace with the rapid growth of new scientific evidence as it emerges. The scientific evidence gathered through the work of this task force will provide critical knowledge to inform decision-making.
- 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 on ways to bring the country back to normal or to a “new normal”.
- We are establishing a task force of organizations that will 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 is comprised of three individuals who are well-renowned for their contributions to research, academia, and innovation in both public health and healthcare both in Canada and internationally.
- The Governing Board will be 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. Tim Evans, Director, School of Population and Global Health, at McGill University, will lead the Secretariat responsible for the efficient execution of this complex endeavour.
- The task force will catalyse, support, and harmonize the design and rapid implementation of population-based studies 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 be part of the task force and will provide testing standardization and support procurement of commercial test kits (once approved) to support 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 immunity 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.

Canadian Public Health Network’s Laboratory Reference Materials for COVID-19

- The Government of Canada is working with the provinces and territories to implement public health measures that will reduce the spread of COVID-19, including laboratory testing to detect infection early.
- Canada’s public health laboratories work together through a network called the Canadian Public Health Laboratory Network to support COVID-19 diagnosis according to validated testing protocols.
- CPHLN has developed two guidance documents on the safe handling of SAR-CoV-2 samples and a position paper on serology testing.



1. **Laboratory best practices** to provide public health professionals information on how to safely handle patient samples containing the virus that causes COVID-19. The guidance includes recommendations on how to safely collect and transport specimens for lab testing. There are also recommendations on correctly running the molecular real-time PCR test to receive accurate results.
 2. A protocol document on how to handle patient samples containing **emerging respiratory pathogens**. This protocol was initially developed for the 2003 SARS outbreak and has been updated to include consideration for the virus that causes COVID-19.
 3. A **position paper on Serology Point of Care tests** for the virus that causes COVID-19. The position paper supports PHAC's recommendations on the use of serology testing for COVID-19 and outlines the most appropriate use of Point of Care Serology tests.
- The CPHLN is a network of federal/provincial/territorial public health laboratory professionals that united, strengthen Canada's public health system through coordinated laboratory services and leadership.
 - With the implementation of new diagnostic tests for the virus that causes COVID-19, Canadian public health laboratories have used the collective strengths of their network to evaluate these new tests to ensure that their accuracy while also promoting the ability to rapidly distribute testing capacity across Canada.

On CPHLN

- Established in 2001, the Canadian Public Health Laboratory Network (CPHLN) is a national network of public health laboratory professionals, which acts as a unified voice for federal and provincial member laboratories.
- The role of CPHLN is to provide a forum for public health laboratory leaders to share knowledge and best practices. CPHLN leverages its combined strength to champion efforts to provide rapid and coordinated nationwide laboratory responses to emerging and re-emerging communicable diseases such as COVID-19 and pandemic influenza.
- CPHLN recognizes the responsibility of public health laboratories (PHL) to safeguard the health of Canadians through the provision of surveillance and response capabilities, which serve as the cornerstone for all public health professionals.

On Serology Tests

If pressed on serological tests:

- A serological test is a blood test. This test 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.

- Developing and implementing a validated and effective serological test for COVID-19 has its challenges. This is an emerging virus, and little is understood about the body's immune reaction to it at this time. Further research is needed.
- The Public Health Agency of Canada's National Microbiology Laboratory is evaluating a variety of commercial tests for COVID-19.
- On March 18, the Minister of Health signed an Interim Order to allow expedited access to COVID-19-related medical devices for use by healthcare providers. Health Canada is responsible for the review of applications under the interim Order, including those for commercial serological tests, and authorizes medical devices that meet safety and effectiveness requirements.
- On May 9, Health Canada issued the first authorization for the sale of a serological test in Canada under the Interim Order process. The test is for use in laboratory settings and not at Point of Care. The list of authorized testing devices is posted on [Health Canada's website](#).
- Only diagnostic tests authorized by Health Canada can be imported or sold in Canada. Unauthorized tests may not produce accurate results, leading to potential misdiagnosis. Health Canada has confirmed that authorized COVID-19 tests are well supported by evidence indicating they will provide accurate and reliable results.
- A serological test detects the presence of virus-specific antibodies in patients' blood and allows public health professionals to identify individuals who have been infected by the COVID-19 virus.
- The ability to test for antibodies provides a deeper understanding of how the immune system responds to the virus that causes COVID-19. It also provides a tool to assess new vaccines and other therapeutics or treatments.
- Poor performances of rapid serological tests for diagnosing COVID-19 infections have been reported by jurisdictions in Europe. Use of a diagnostic test that produces false or inaccurate results can put individuals and the Canadian population at risk. Canada is being vigilant to ensure that serological testing is used appropriately, in conjunction with other tools to diagnose infection.

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.

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.
- 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.

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.
- 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.

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.
- 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.

Hydroxychloroquine and azithromycin for the treatment of COVID-19

- Canadians and their families who are ill with COVID-19 need access to safe and effective drugs and to health products for diagnosis and treatment.



- There has been some preliminary evidence from studies suggesting that hydroxychloroquine alone, or in combination with azithromycin, may be effective in reducing the viral load in patients with COVID-19, as well as in treating respiratory tract infections related to COVID-19.
- Evidence on the effectiveness of using hydroxychloroquine and azithromycin in combination to treat COVID-19 is still very limited, and like all medications, both drugs are associated with known risks.
- Both hydroxychloroquine and azithromycin have been approved in Canada for the treatment of other diseases. A Healthcare practitioner may choose to use these medications off-label based on his/her patient's needs, including the seriousness of the patient's illness, if the potential benefits outweigh the known risks of the drugs.
- Hydroxychloroquine is approved for the treatment of lupus, rheumatoid arthritis and malaria.
- Azithromycin is an antibiotic used in the treatment of pneumonia and other bacterial infections.
- It is important to preserve the supply of medications for patients who need them for approved indications.
- As the use of these medications to treat COVID-19 is in its early experimental stage, Health Canada recommends that healthcare practitioners prescribing these therapies for COVID-19 patients do so through a clinical trial.
- A clinical trial requires the informed consent of patients and would enable the healthcare community to systematically collect information about the risks and benefits of the treatment.
- All clinical trials related to the treatment of COVID-19 are being reviewed on a priority basis. Companies, clinicians, or researchers seeking to initiate a clinical trial should contact Health Canada.

If pressed on the National Emergency Strategic Stockpile

- The Government of Canada is adding hydroxychloroquine to Canada's National Emergency Strategic Stockpile (NESS). Supplies will be used first for approved indications, and then for clinical trials related to COVID-19.
- The addition of hydroxychloroquine to the NESS will be made over a period of several months, to minimize the impact on supply for approved indications.
- The NESS contains supplies that provinces and territories can request in emergencies, such as infectious disease outbreaks, natural disasters, and other public health events, when their own resources are not enough.
- The stockpile includes a variety of items such as medical equipment, pharmaceuticals, and beds and blankets.
- The purpose of the NESS is to help supplement provincial and territorial resources during a rare or high-impact public health event.
- The NESS is not intended to replace supplies that provinces and territories hold or procure. Provinces and territories are responsible for preparing and maintaining their own supply capacities.



- In January, 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.
- Globally, we have seen a tightening of supply. The federal government is continuing to work aggressively to secure necessary supplies in real time, in direct collaboration with all provinces and territories.

If pressed on the availability of hydroxychloroquine and azithromycin:

- Health Canada is closely monitoring the supply of potential treatments for COVID-19 in Canada, including hydroxychloroquine and azithromycin.
- There are four companies that currently market hydroxychloroquine in Canada: Apotex Inc., JAMP Pharma Corporation, Mint Pharmaceuticals Inc., and Sanofi-Aventis Canada Inc. Health Canada understands that all four companies are experiencing increased demand. A
- There are 16 companies that currently market azithromycin in Canada: Altamed Pharma, Angita Pharma Inc., Apotex Inc., Auro Pharma Inc., Dominion Pharmacal, JAMP Pharma Corporation, Laboratoire Riva Inc., Marcan Pharmaceuticals Inc, Pharmascience Inc., Pro Doc Limitee, Sandoz Canada Incorporated, Sanis Health Inc., Sivem Pharmaceuticals ULC, Sterimax Inc., Teva Canada Incorporated and Pfizer Canada ULC. None of these companies are reporting shortages of azithromycin in Canada.

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

- 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 will be eligible for the exceptional importation and sale provisions in the Interim Order. At this time, the list will only include drugs that have been designated as Tier 3 shortages, such as hydroxychloroquine.
- While there are no drugs currently on this list, Health Canada will consider proposals from companies to access Tier 3 shortage drugs, including hydroxychloroquine, under this new pathway and update the list as appropriate.
- 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.

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. 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

- Canadians and their families who are ill with COVID-19 need access to health products for diagnosis and treatment.
- Currently there are no drugs specifically authorized to treat or prevent COVID-19 in Canada. Health Canada has been closely monitoring developments for potential treatments for COVID-19 including remdesivir.
- Remdesivir is an investigational drug that has been used to treat some hospitalized patients who are ill with COVID-19 under the clinical trial setting. While there is some early clinical trial evidence that suggest redemsivir may help patients recover sooner, the efficacy of this drug to treat COVID-19 remains to be established and will require review of clinical data once it is submitted to Health Canada.
- Health Canada is aware that the US Food and Drug Administration (FDA) has given emergency authorization for the experimental drug remdesivir based on early clinical trial evidence coming from the National Institute of Allergy and Infectious Diseases (NIAID) in the US. This preliminary evidence suggests that remdesivir may help patients to recover sooner. For the FDA, the authorization is temporary and does not take the place of the formal new drug application submission, review and approval process.



- Health Canada has not yet received a submission for authorization of remdesivir for the treatment of COVID-19. If a submission for remdesivir is filed by the company, Health Canada will exercise regulatory flexibilities that are available only in urgent public health situations to enable the company to file a submission earlier and continue submitting information on the safety, efficacy and quality of the drug. Health Canada will assess this information on a rolling basis.
- Health Canada is working collaboratively with international counterparts and will leverage available knowledge to the extent possible to support faster review of a submission for remdesivir that is filed with Health Canada. Health Canada is also in active discussions with Gilead Sciences Canada, Inc., the manufacturer of remdesivir, to discuss an expedited regulatory pathway, including the rolling review flexibility recently made available by Health Canada, and to provide advice on how best to file an application seeking market access in Canada.
- Remdesivir is still considered an experimental therapy, and the most appropriate way to access it is through a clinical trial. To date, Health Canada has approved two clinical trials for remdesivir in the context of COVID-19 in Canada. Clinical trials provide Canadians access to new therapies aimed at treating COVID-19, as well as an opportunity for the healthcare community to systematically collect information of the effectiveness of the treatments and their associated risks. More information about the trials is available on our [website](#).
- To date, remdesivir has also been accessed on a case-by-case basis through Health Canada's Special Access Program (SAP) which provides emergency access to medications for serious or life-threatening conditions.
- Should remdesivir receive authorization for use in Canada, Health Canada will work with the company to ensure access to the drug for Canadians while recognizing global demand for this product.
- 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.

If pressed on the promising evidence for remdesivir:

- Remdesivir is an investigational drug that has not yet been approved in any country. It was originally developed as a potential treatment for Ebola virus infection, and showed some promise in the treatment of SARS-2.
- The most appropriate way to access experimental therapies that have potential to be helpful in treating COVID-19 is through a clinical trial. Clinical trials provide Canadians access to new therapies aimed at treating COVID-19, as well as an opportunity for the healthcare community to systematically collect information on the effectiveness of the treatments and their associated risks.
- The U.S. National Institute of Health (NIH) has released information from one randomized placebo-controlled clinical trial suggesting that remdesivir may have a positive effect on the outcomes of COVID-19. Specifically, in a trial conducted by the U.S. National Institute of Allergy and Infectious Diseases (NIAID), early results show that hospitalized patients



receiving remdesivir had a faster recovery rate than those receiving placebo. However, the full trial data have not yet been released to Health Canada for critical review.

- The information released by the NIH stated that patients given remdesivir had a 31% faster time to recovery than those who received a placebo. The median time to recovery was 11 days for patients treated with remdesivir, compared with 15 days for those who received placebo.
- Health Canada recognizes the urgent need for a treatment for COVID-19, and the suggested results of the NIAID trial; however, all available evidence must first undergo review by Health Canada to ensure that the drug is safe, effective and of high quality for Canadians.
- Health Canada is in active discussions with Gilead Sciences Canada, Inc., the manufacturer of remdesivir, to discuss an expedited regulatory pathway, including the rolling review flexibility recently made available by Health Canada, and provide advice on how best to file an application seeking market access in Canada.

If pressed on the availability of remdesivir:

- Remdesivir is currently not an approved product and can be accessed only through a clinical trial or Health Canada's Special Access Program (SAP).
- Should remdesivir receive authorization for use in Canada, Health Canada will work with the company to ensure access to the drug for Canadians.
- At this time, a very small number of patients have been treated with remdesivir in Canada under the Special Access or Compassionate Use programs in Canada.
- Because of the high global demand for remdesivir, access for Canadians will be primarily through clinical trials. Access through the SAP will be available for certain groups, such as pregnant women or children with confirmed COVID-19 and severe illness.
- Health Canada is in active discussions with Gilead Sciences Canada, Inc., the manufacturer of remdesivir, to discuss an expedited regulatory pathway and provide advice on how best to file an application seeking market access in Canada. The company has been made aware of the option for a rolling submission, which is only available in urgent public health situations.

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.
- 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.
- 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;
 - 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 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.

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.
- 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 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

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.
 - **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.
- 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 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.

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.



- 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.

Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19

- The current COVID-19 pandemic is having a major impact on Canadians and on the health care system. It is critical to ensure the Government of Canada can effectively respond to the needs of those affected.
- In response to the COVID-19 pandemic, the Minister of Health has signed an Interim Order to help prevent and alleviate shortages—of drugs, medical devices, and foods for a special dietary purpose—resulting directly or indirectly from the COVID-19 pandemic.
- The provision will allow products that are not approved in Canada to be imported and sold in Canada effective immediately, subject to certain requirements.
- As with all drugs and medical devices, Health Canada will assess and monitor the safety, quality, and effectiveness of all products allowed for import and sale under this Interim Order. Drug and medical device manufacturers will be required to follow strict monitoring requirements.
- The Interim Order will also require companies manufacturing and importing critical medical devices during the COVID-19 pandemic to report actual or anticipated shortages, similar to what is currently required for drugs. This will help the health system to plan and reallocate supplies as needed to help ensure continued access for Canadians.
- In addition, the Interim Order will enable faster market access for hard surface disinfectants and certain hand sanitizers.
- Together, these actions will support access to the drugs, medical devices, and foods for a special dietary purpose that Canadians need to stay healthy and safe, and help those who are ill to recover.

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.

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.
- 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.

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

- 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.

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.
- 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.
- 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.

Border measures

- The Government of Canada continues to introduce border measures to limit the introduction and spread of COVID-19.
- The Government of Canada has multiple systems in place to prepare for, detect and limit the spread of infectious disease, including COVID-19, in Canada.



- 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 entering from the U.S. 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 self-isolate for 14 days.
- There are exemptions in place on mandatory self-isolation 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.

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.
- 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. 2 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.

Non-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 non-essential travel along the Canada-U.S. border in response to the spread of COVID-19.
- As of March 21 at 12:01 a.m. EDT, there is now a temporary 30-day restriction on all non-essential travel at the Canada-U.S. border, effective for an initial period of 30 days, renewable.



- All travel of an optional or discretionary nature, including tourism and recreation, is covered by these measures. 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 essential 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 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 self-isolate for 14 days from the date they enter Canada.
- Canada will also implement measures at airports to:
 - strengthen health screening
 - increase presence to conduct further health screening and public outreach
 - increase signage throughout the arrivals area to encourage travellers to follow the latest public health guidance
 - prevent all travellers who have COVID-19 symptoms, regardless of their citizenship, from boarding international flights to Canada
 - airlines will conduct a basic health assessment of all air travellers based on guidance from the Public Health Agency of Canada
- This includes making information readily available and raising awareness among **all** travellers about what they should do if they develop symptoms of COVID-19. In addition, we continue to advise travellers coming from any location to self-monitor for signs and symptoms of COVID-19.
- We continue to monitor and assess the global risk of COVID-19. To keep pace with the evolving situation, our response measures are being adjusted and refined in accordance with the global risk assessment. This includes updating our travel health advisories with increased risk levels.

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.

Letter from a Traveller at a Fredericton Quarantine Site

- The Government of Canada's Emergency Order under the *Quarantine Act* requires persons entering Canada—whether by air, land or sea—to isolate for 14 days if they have symptoms of COVID-19, or to quarantine themselves for 14 days if they are asymptomatic, in order to limit the introduction and spread of COVID-19.
- Every traveller will need to confirm that they have a suitable place to isolate or quarantine where they will have access to basic necessities, such as food and medication. Travellers will be expected to make plans for where they will isolate or quarantine in advance of arriving in Canada.
- Travellers, whether they are symptomatic or asymptomatic, who do not have an appropriate place in which to isolate or quarantine themselves must go to a designated quarantine facility.
- There are federally designated quarantine facilities (e.g., hotels) across the country, including Vancouver, Calgary, Toronto and Montreal. These sites provide a range of services to travellers through contractual arrangements with vendors, including managing traveller requests, meal delivery to rooms, regular health assessments, security, daily cleaning, and end-of-stay disinfection.
- These measures for returning Canadians are put in place to ensure the health and safety of everyone – while maintaining a certain level of comfort and provision of necessities during this period.
- The Government of Canada continues to work closely with provinces and territories, as well as key stakeholders to implement necessary public health measures to protect the health of Canadians, including travellers.

Order in Council 10 – Mandatory Isolation and Quarantine (self-isolation)

- The Government of Canada's top priority is the health and safety of Canadians. We are taking unprecedented action to respond to the COVID-19 epidemic. This includes continuously assessing the risks to adapt our response accordingly.
- The Government of Canada's Emergency Order under the *Quarantine Act* requires persons entering Canada—whether by air, land or sea—to isolate for 14 days if they have symptoms of



COVID-19, or to quarantine themselves for 14 days if they are asymptomatic to limit the spread of COVID-19.

- An updated Order was issued to provide clarification on terminology and is based on new scientific evidence that people without symptoms may transmit the virus.
- Under the updated Order, any traveller arriving in Canada—whether they are symptomatic or asymptomatic—cannot isolate or quarantine (respectively) in a place where they would be in contact with people who are vulnerable, such as adults aged 65 years or over and people with pre-existing medical conditions.
- In addition, every traveller will need to confirm that they have a suitable place to isolate or quarantine where they will have access to basic necessities, such as food and medication. Travellers will be expected to make plans for where they will isolate or quarantine in advance of arriving to Canada. Travellers who do not have an appropriate place in which to isolate or quarantine themselves must go to a place designated by the Chief Public Health Officer of Canada. These criteria are newly applied to asymptomatic travellers.
- This Order is mandatory for anyone entering Canada on or after April 15, 2020.
- If a traveller is symptomatic and does not have private transportation or an adequate place to isolate, they will be required to isolate for 14 days in a place designated by the Chief Public Health Officer of Canada.
- Asymptomatic travellers are still at risk of infecting others and will be required to wear a non-medical mask or face covering (i.e. [HYPERLINK "https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/instructions-sew-no-sew-cloth-face-covering.html"](https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/instructions-sew-no-sew-cloth-face-covering.html) \t "_blank" constructed to completely cover the nose and mouth without gaping, and secured to the head by ties or ear loops) to proceed to their final destination where they must quarantine for 14 days, and follow instructions provided by the public health authority specified by a screening officer or quarantine officer if they develop signs and symptoms of COVID-19. They will be provided with a mask if they do not have one.
- Symptomatic travellers are also required to wear a non-medical mask or face covering during transit to their final destination for isolation and whenever they cannot maintain a 2 metre physical distance from others.
- Asymptomatic travellers without an adequate place for quarantine will be subject to the same expectations as those who are symptomatic, and must go to a place designated by the Chief Public Officer of Health of Canada.
- [HYPERLINK "https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/latest-travel-health-advice.html"](https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/latest-travel-health-advice.html) \l "a3" Certain persons who cross the border regularly to ensure the continued flow of goods and essential services, or individuals who receive or provide other essential services to Canadians, are exempt from the requirements to quarantine if they are asymptomatic (i.e., do not have symptoms of COVID-19).
- Individuals exempt from quarantine requirements must wear a non-medical mask or face covering to proceed to their final destination. Follow arrival to their final destination, exempted persons should practise physical distancing, consider the use of a mask or face covering when they cannot maintain physical distancing of 2 metres from others, self-monitor for symptoms, stay in their place of residence as much as possible and follow the instructions of their local public health authority if they feel sick.
- We've based this decision on the latest scientific evidence and following discussions with the provinces and territories.



- These additional measures will contribute to containing the epidemic and preventing further spread of COVID-19 in Canada.
- These measures will also help protect older adults and people with pre-existing medical conditions, who are at greatest risk of severe health complications related to COVID-19.
- The Government of Canada will continue to work closely with local, provincial, territorial and international partners to limit the introduction of COVID-19.

Enforcement:

- Spot checks will be conducted by the Government of Canada to verify compliance.
- Maximum penalties include a fine of up to \$750,000 or imprisonment for six months, or both, for failure to comply with this Order.
- A person who causes a risk of imminent death or serious bodily harm to another person while willfully or recklessly contravening the *Quarantine 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.
- Amendments are being 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.

Designated quarantine facilities:

- Canada's Chief Public Health Officer has designated quarantine facilities (e.g., hotels) across the country, including in Vancouver, Calgary, Toronto and Montréal.
- Canada's Chief Public Health Officer has the authority to designate any place in Canada as a quarantine facility if deemed necessary to protect public health in accordance with sections 7 and 8 of the *Quarantine Act*.

Order in Council 11 – Minimizing the Risk of Exposure to COVID-19 in Canada (Prohibition of Entry into Canada from United States)

- Foreign nationals allowed entry into Canada include temporary foreign workers, some students, persons delivering urgent medical supplies and certain groups of asylum seekers including those who both arrive at a land port of entry and are eligible to make a claim pursuant to the Safe Third Country Agreement (STCA).
- All foreign nationals permitted to enter Canada are required to meet the requirements of the Emergency Orders made under the *Quarantine Act*, including mandatory quarantine for 14 days upon entering Canada except where specifically exempted. They must also follow local and provincial/territorial health emergency orders.
- Foreign nationals generally are not permitted to enter Canada if they seek to do so for optional or discretionary purposes or if they exhibit symptoms of COVID-19 coronavirus disease.
- Foreign temporary workers are required for the continued resilience of our food and supplies sectors to ensure that Canadians have access to food and essential products during this pandemic.
- Order *Minimizing the Risk of Exposure to COVID-19 in Canada Order (Prohibition of entry into Canada from the United States,)* has effect for the period beginning on April 22, 2020 until May 21, 2020.



- Amendments to these orders will ensure that Canada continues to honour its international obligations towards refugees and asylum seekers.
- These measures will help prevent the spread of disease in Canada while ensuring that essential travel and the supply chain of goods is not interrupted.

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.
- 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.

Foreign nationals in these categories must still demonstrate they are travelling to Canada for essential purposes and must be asymptomatic.

- A person with a valid work permit or application that was approved under the *Immigration and Refugee Protection Act*;
- A person with a valid study permit who received approval under the *Immigration and Refugee Protection Act* before March 18, 2020;
- A person permitted to work in Canada as a student in a health field under paragraph 186(p) of the *Immigration and Refugee Protection Regulations*;
- A person whose application for permanent residence was approved under the *Immigration and Refugee Protection Act* before March 18, 2020;
- Immediate family members of Canadian citizens or of a permanent resident;
- Persons authorized by consular services for purposes of reuniting with immediate family;
- Conveyance crews (air, boat, etc.) or workers on marine vessels;
- Diplomats;
- Persons invited by Canada to assist with Canada's COVID-19 response;
- Persons on military flights or other Canadian-military support protected persons;
- French citizens who reside in Saint-Pierre-et-Miquelon and have been only in Saint-Pierre-et-Miquelon, the United States or Canada during the period of 14 days before the day on which they arrived in Canada;
- Those whose presence in Canada is in the national interest as it pertains to public safety and emergency preparedness;
- Persons providing essential services, or are essential for the movement of goods such as truck drivers and marine transportation;
- Emergency workers;
- Licensed health care professionals with proof of employment in Canada;
- Persons who enter Canada for the purpose of delivering, maintaining, or repairing medically-necessary equipment or devices;
- Persons who enter Canada for the purpose of making medical deliveries of cells, blood and blood products, tissues, organs or other body parts, that are required for patient care in Canada; and,
- Those who, in the opinion of the Chief Public Health Officer of Canada, do not pose a risk of significant harm to public health.

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.
- 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.”
- 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.emergencyorder-decreturgencecovid19.aspc@canada.ca.

Order in Council 12 – Minimizing the Risk of Exposure to COVID-19 Coronavirus Disease in Canada Order (Prohibition of Entry into Canada from the United States)

- The Government of Canada is extending the border measure that prohibits foreign nationals from entering Canada through the United States for optional or discretionary purposes, such as tourism, recreation and entertainment, until June 21, 2020.
- Foreign nationals (such as 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 Safe Third Country Agreement [STCA]) are generally not prohibited from entering Canada.
- They must also follow the legal requirements to isolate or quarantine as well as any local and provincial or territorial health emergency orders.
- Currently, we are generally not permitting foreign nationals to enter Canada if they are entering for optional or discretionary purposes or if they exhibit symptoms of COVID-19.
- The *Minimizing the Risk of Exposure to COVID-19 in Canada Order (Prohibition of Entry into Canada from the United States)* will be in effect for the period beginning on May 22, 2020, until June 21, 2020.



- This measure will help reduce the risk of further spread of COVID-19 in Canada while allowing for essential travel and the unimpeded flow of goods.

On foreign nationals seeking to make a refugee claim:

- Foreign nationals who enter Canada in between official ports of entry in order to attempt 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 or isolation requirements will be transferred to a federal location.

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.

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

- Essential travel will continue unimpeded. Canadian and U.S. governments both 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.

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.

Border Measures and their Exemptions

- As part of current border measures to contain the spread of COVID-19, the Government of Canada has prohibited the entry of foreign nationals who are symptomatic for COVID-19 or who are entering for an optional or discretionary purpose, such as tourism, recreation or entertainment.
- Under these measures, some asymptomatic foreign nationals may be permitted to enter Canada, when entry is for non-discretionary or non-optional reasons, such as the delivery of vital services or supplies to Canadians.
- Mandatory quarantine requirements may not apply to certain people who may be returning to or entering Canada for essential purposes, and who are not experiencing signs or symptoms consistent with COVID-19 at the time of entry.
- As the COVID-19 pandemic evolves, the Government of Canada continues to work closely with local, provincial and territorial law enforcement and health partners to monitor travellers permitted to enter Canada to ensure that they comply with the requirements of the Emergency Orders made under the *Quarantine Act*, including the mandatory 14-day quarantine or isolation requirement.



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 for an additional 30 days, until June 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.

Holding Lines on NHL Proposals

- Since the outset of this pandemic, the Government of Canada's goal has been to safeguard the health and safety of Canadians.
- Like other countries, Canada is working on plans for a measured resumption of international sports.
- We are aware some provinces and territories have approved proposals from the NHL.
- We continue to work closely with provinces and territories, so that our public health measures—in response to the outbreak—are in alignment with each other.

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
 - 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.

Cottage Season and COVID-19

- Public health guidance has been changing but that's because the situation is changing rapidly and we are learning more about COVID-19 everyday.



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- Based on the current evidence, we are asking Canadians to avoid all non-essential travel to limit the spread of COVID-19, especially to smaller and rural communities where the healthcare systems could be easily overwhelmed.
- That's why we are asking everyone to not to go to cottages, campgrounds or vacation properties during the COVID-19 pandemic.
- Unless the property is your primary residence or within the same community as your primary residence, you should delay your stays in these areas until the situation in Canada changes.
- If you get sick, you may not be able to get the help you need. If you stop along the way to get gas or groceries, you increase your risk of exposure and, if you're asymptomatic, you may pass the virus on to others.
- An influx of people into a small community can also strain the supply of food and other essentials for local residents.
- If you need to check in on your cottage for insurance purposes, you should only make a daytrip and then return directly home.
- All Canadians must continue to do everything possible to flatten the curve and keep our friends and families healthy. This includes staying home.

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.