### **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 in Canada

- We know that the coronavirus will continue spreading in the community as activities gradually resume. Accordingly, we need to proceed slowly and carefully as the pandemic progresses, at least until we have access to a vaccine.
- Most people with COVID-19 have mild symptoms. As the lockdown is lifted, we will do everything we can to protect those most likely to be severely affected by this disease. Our goal is to minimize the overall number of cases and deaths, regardless of whether they are associated with COVID-19. There are key steps that all Canadians can take to achieve this goal.
- Continue following the critical measures to limit the spread of the coronavirus: practice physical distancing, wash your hands frequently and isolate at home if you are sick.
- Get tested if you think you have the coronavirus. This will help us identify any community outbreaks and implement measures to prevent the spread of the virus.
- We hope that by restoring services for all health conditions, as well as resuming some social and economic activities, the overall burden of coronavirus and non-coronavirus disease in the community will be reduced.
- People with chronic disease and those who are 60 years of age or older or at higher risk of infection should remain highly vigilant. We need to support the most vulnerable Canadians so that they can stay at home whenever possible, avoid situations where contact outside the home is likely or avoid places where adequate physical distancing is not possible.
- Remember that we are all vectors of the coronavirus, even if we have no symptoms. It will therefore be critical to continue basic infection prevention measures and to ensure that anyone with symptoms visits a testing centre immediately.
- Even if your symptoms are mild, stay at home until you recover rather than going to work or out in the community. In this context, employers and employees need to support each other so that we can monitor transmission rates and keep the virus under control. Remember that scientific evidence shows that the coronavirus can be transmitted before and during the onset of symptoms, as well as in the absence of symptoms.

We know that many Canadians want to hold important ceremonies, including funerals and other meaningful rites. It will be critical to follow local guidelines regarding the number of participants, infection prevention measures and related activities.

## Interim Report on WHO Response to COVID-19, January–April 2020

- The constantly evolving COVID-19 pandemic is creating an unprecedented situation in which global health cooperation has never been more important.
- Canada is grateful for the leadership and coordination role that the World Health Organization (WHO) is playing in the fight against COVID-19, including its oversight of the International Health Regulations, its leadership in global research efforts to find new vaccines and effective treatments, its work with all stakeholders to address shortages of essential medical supplies and personal protective equipment and its support to the most vulnerable countries with their preparedness and response efforts.
- Canada thanks the Independent Oversight and Advisory Committee for its interim review of the WHO response and its recommendations for the WHO and member states, which are timely and will help strengthen the global response to this and future health emergencies.
- The global community as a whole, including the WHO, is learning more and more every day about the virus and the effectiveness of the response to the pandemic.
- The global community will have many lessons to learn from this pandemic; consequently, Canada supports a post-crisis review of the global response.
- The Government of Canada will carefully consider the recommendations.

# **Keeping Canadians Informed**

#### COVID-19 Situational Awareness Dashboard

- On April 4, 2020, the Government of Canada launched a new COVID-19 Situational Awareness Dashboard in Canada.
- In Canada, the situation is progressing rapidly, and knowledge about COVID-19 is changing every day. Canadians need easy access to online resources for answers to their questions about COVID-19.
- This dashboard will provide Canadians and researchers with the latest data on COVID-19, presented online in a user-friendly format that will help them better understand how the outbreak is evolving in Canada.

- The Situational Awareness Dashboard provides an interactive overview of the number of cases and deaths in Canada, with details on the most affected populations by age group and gender, and how the pandemic is evolving over time.
- This tool does not display models or forecasts of what may happen in the coming weeks or months.
- Every day, new data is released by the provinces and territories. Although the table will be continually updated to reflect new data, there may be discrepancies between the number of cases in the country and across the provinces and territories. In such cases, provincial and territorial data should be considered the most recent.
- The Government of Canada will continue to work with its partners at all levels of government to respond to the COVID-19 pandemic, and ensure that cases continue to be rapidly identified and managed in order to protect the health of Canadians.

#### Virtual Health Tools

- More than ever, Canadians need tools and resources to support their health and wellbeing, including readily accessible information, mental health support, alerts and screening tools.
- The announcement of \$240.5 million on May 3 will help Canadians access credible health information and the health services they need through virtual solutions and tools.
- Virtual tools allow Canadians to communicate securely with the regular health care providers via telephone, text or videoconferencing. They also enable patients to continue to access specialist services during these times of uncertainty.
- Improving access to virtual tools will also help Canadians access reliable information, including through the Canada COVID-19 mobile app, so they can understand and monitor their symptoms and learn more about how to protect themselves during the pandemic.
- We recognize that Canadians are facing the effects of COVID-19 and are experiencing varying degrees of stress. This investment will support Wellness Together Canada, a new free online portal that provides mental health, wellness and addiction support services.
- The Government of Canada is working closely with provinces and territories, innovators and other partners to support the rapid expansion of virtual care services and make these tools widely available to Canadians and their families.
- The expansion of virtual care and the implementation of digital solutions for Canadians will help reduce pressure on health care systems and deliver the health services and reliable information Canadians need, safely and securely.

- Last updated: May 2020
- Our Government recognizes that these are unprecedented times. We continue to work with the provinces and territories, innovators and other partners to take action and support Canadians.
- Providing Canadians with secure virtual access to credible information and the health services they need is central to the government's work to ensure that Canadians stay safe and informed.

### Canada's COVID-19 App

- Canadians need easy access to digital tools and resources to access the information they need regarding COVID-19.
- The Canada COVID-19 mobile app allows users to access trusted health resources and track their COVID-19 symptoms daily, if necessary.
- It allows Canadians to access the latest updates on COVID-19 and see Canada's response to the pandemic in real time, as well as customized recommendations and resources.
- The app builds on tools developed by the provinces and territories and is another valuable resource for Canadians.
- Health Canada continues to work closely with the provinces and territories, suppliers and stakeholders to make additional tools available to Canadians and their families.
- Canada's COVID-19 app is a key resource for accessing reliable, evidence-based information about the COVID-19 pandemic in Canada. It does not keep any personal information, nor is it used for surveillance purposes.
- Protecting Canadians' personal information is a priority for the Government of Canada. Any tool used to collect health care information will require a rigorous privacy-impact assessment.

### Domestic PPE and Medical Supplies Dashboard

- In support of the fight against COVID-19, the Public Health Agency of Canada (PHAC) is working with the provinces and territories to order large quantities of essential personal protective equipment (PPE) supplies, including masks, gloves, face shields and gowns for front-line health care workers.
- Once received, most of these supplies are distributed to the provinces and territories. Some spare capacity is maintained in the National Emergency Strategic Stockpile (NESS) to address urgent needs identified by the provinces and territories.

- Last updated: May 2020
- The NESS is typically used to supply provinces and territories with assets that they don't normally stockpile, such as scarce pharmaceuticals to combat biological threats. In the past, the PHAC has not disclosed details of these stockpiles for security reasons.
- Although the PHAC has never disclosed the NESS stockpile for security reasons, we are currently disclosing the quantity of essential PPE in the NESS—specifically gloves, masks, face shields, gowns and ventilators—as well as information on the quantities of PPE ordered, received and shipped to the provinces and territories to help them prepare for and respond to COVID-19.
- Given the current extraordinary circumstances, it is in everyone's interest to be more transparent to support the Canada-wide fight against COVID-19.

# **Federal Funding for the COVID-19 Response**

- On March 11, Prime Minister Justine Trudeau announced the creation of a whole-ofgovernment COVID-19 Response Fund of more than \$1 billion.
- Funding to the PHAC and Health Canada includes the following:
  - \$50 million for the Public Health Agency of Canada to support ongoing communications to keep Canadians informed and a national public education campaign to promote self-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 the \$50 million initially earmarked to support the immediate public health response.
  - \$275 million to strengthen our capacity to conduct research on antiviral drugs, 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 across Canada.
  - \$50 million to the Public Health Agency of Canada to support the purchase of personal protective equipment, including surgical masks, face shields and hospital gowns and medical supplies to meet federal needs and supplement provincial and territorial inventories as needed.

### Mental Health Support for Canadians

### Wellness Together Canada

- Canadians need easy access to digital tools and resources to obtain the information they need during the COVID-19 pandemic.
- In these challenging times, Canadians must be able to access effective tools to support their mental health and well-being, obtain credible and reliable information on mental health and substance use and access services.
- That is why the Government of Canada has launched Wellness Together Canada, a portal to support mental health and substance use. It is a key resource for accessing confidential mental health and substance use support during this time of COVID-19.
- Health Canada is pleased to have worked with a wide range of organizations that have a long history of providing high 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 portal provides Canadians with a virtual network of psychosocial information and support services and is available at canada.ca/the-coronavirus and in the Canada COVID-19 app.
- The Wellness Together Canada mental health and substance use support portal was designed to support existing services provided by the provinces and territories.
- Health Canada is working closely with the provinces and territories, suppliers and stakeholders to ensure that Canadians and their families have seamless access to additional tools.

## Funding to Kids Help Phone in response to increased demand for child and youth mental health services related to COVID-19

- The COVID-19 pandemic is an unprecedented and unexpected event that 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 schools closed and reduced access to community resources, Kids Help Phone is experiencing an increased demand for confidential crisis support services that are available 24/7 online, by phone and via text.
- Accordingly, the Government of Canada is providing Kids Help Phone with \$7.5 million to help the organization meet the increased demand and provide kids with the emotional support they need during this difficult time.
- With the additional support, electronic mental health services will be available in English and French to children and youth across Canada who are experiencing the

social and financial effects of the COVID-19 pandemic. As a result, vulnerable Canadian children and youth will find the help they need when they need it.

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

## **Government of Canada COVID-19 Research**

- The health and safety of Canadians is our top priority.
- Canada is home to some of the world's most qualified and distinguished researchers, and they are working hard to support the international response to the ongoing pandemic.
- Every day, we are learning more about COVID-19 by keeping abreast of new scientific data, which is being released at a rapid pace.
- To slow and ultimately stop the spread of COVID-19, we need to mobilize Canada's scientific and research community to advance research and technology.
- Accordingly, in March 2020 the Government of Canada announced the creation of a \$1 billion whole-of-government COVID-19 Response Fund, of which \$275 million will be used to expand our capacity to test antivirals, develop vaccines and fund clinical trials.
- Through the Canadian Institutes of Health Research's (CIHR) Rapid Research program, the Government of Canada has invested a total of \$54.2 million to support 99 teams of researchers across the country. These teams are working to develop and implement measures to rapidly detect, control and reduce the transmission of COVID-19. Their activities include vaccine research and the development of strategies to combat stigma, misinformation and fear.
- In addition to the CIHR, funding for the Rapid Research competition is provided through the Natural Sciences and Engineering Research Council, the Social Services and Humanities Research Council, the Canada Research Coordinating Committee, the International Development Research Centre and Genome Canada. Research Manitoba, Research Nova Scotia and Alberta Innovates have also contributed.
- The report released today showcases critical and innovative research being conducted across Canada, including solutions and tools being developed to combat and treat COVID-19.
- The goal is to build on the capabilities and expertise of Government of Canada research institutions and make strategic investments to support and enhance the research capacity of Canadian academia and industry.
- Many of the funded projects involve collaborations and partnerships with academia, government departments and industry from other countries.
- We are working together to transform important research findings and actions into action that will save lives across the country.

#### Sample projects

- The Government of Canada is investing \$150 million to support federal public health measures such as enhanced surveillance, increased testing by the Public Health Agency of Canada's National Microbiology Laboratory (NML) 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 tests and diagnostic methods, and coordination of the supply and distribution of reagents and laboratory supplies with provincial and territorial authorities to increase testing capacity across the country.
- The PHAC's NML is improving its understanding of the epidemiology of COVID-19 across Canada, which will allow us to improve our response. This important work includes analyzing blood tests to determine the immune status of Canadian populations, developing methods to perform these tests and carrying out modelling to evaluate various projections that will inform future actions to combat the virus.
- The National Research Council's (NRC) Pandemic Response Challenge program will bring together Canada's top researchers from government, academia and the private sector to develop medical countermeasures to combat COVID-19. Program members will collaborate with Canadian health experts to identify the most pressing needs. They will focus on tools to diagnose and rapidly detect the virus, drugs and vaccines to treat and prevent disease and digital health solutions to help manage Canada's pandemic response.

#### Collaborating to develop a vaccine

- Currently, there is no vaccine for COVID-19. Research to develop COVID-19 vaccines is being conducted around the world, including in Canada, and is at various stages of completion.
- We are taking the necessary steps to ensure that Canadians have access to a vaccine or drug to prevent or treat COVID-19 once it becomes available.
- These measures include investments in the following organizations:
- Medicago (Quebec City): To conduct pre-clinical and clinical trials of a plant-based viral-like particle vaccine, including expansion of manufacturing capacity.
- The University of Saskatchewan's Infectious Disease Organization International Vaccine Centre (VIDO-InterVac): To build on VIDO-InterVac's existing expertise in coronavirus research and to upgrade its manufacturing facilities to good manufacturing practices (GMP) standards; in support of these efforts, the NML and the Canadian Food Inspection Agency (CFIA) are collaborating with VIDO-InterVac at the University of Saskatchewan and the NRC to develop and test COVID-19 vaccine candidates.
- National Research Council of Canada (NRC): To upgrade the facilities at Montreal's Human Health Therapeutics Research Centre to GMP standards. Starting in late spring 2020, these facilities will be able to manufacture batches of vaccines for clinical trials as soon as vaccine candidates are available.

- Last updated: May 2020
- Health Canada is also working with vaccine developers and manufacturers to expedite the assessment of COVID-19 vaccines. This includes supporting clinical trials and preparing for accelerated reviews once they are developed.
- The Government of Canada will continue to work with international health product regulators, including the European Medicines Agency, the U.S. Food and Drug Administration, its partners in Australia, Canada, Singapore and Switzerland, and other organizations such as the International Coalition of Medicines Regulatory Authorities and the World Health Organization (WHO) to support and coordinate rapid regulatory action on potential vaccines and other medical countermeasures.
- The NRC is also working with several companies to develop candidate vaccines.
- Canada is participating in the **SOLIDARITY** multinational trial, coordinated by the WHO, which is testing several potential drugs to combat COVID-19. Patient recruitment for the Canadian portion of the trial has already begun and is expected to take place at up to 20 sites across Canada.
- This unprecedented mega-trial of potential COVID-19 treatments is truly a new model for global collaboration, whose goal is to quickly find treatments to reduce the number of COVID-19 victims.

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

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

### Collaboration with the international research community

The Government of Canada is contributing to the global research effort to fight COVID-19. It is working with international partners, including the WHO through its Collaborating Centres and R&D Blueprint initiative, to coordinate efforts and share research data and results to build knowledge worldwide.

- As an example, the Canadian Food Inspection Agency (CFIA), Defence Research and Development Canada (DRDC) and the PHAC have collaborated to create the Biosafety Level 4 Zoonotic Laboratory Network (BSL4ZNet).
- This network consists of 15 government agencies from five different countries (Canada, the United States, the United Kingdom, Germany and Australia), all of which are responsible for regulating human, animal and zoonotic pathogens with the potential to cause a pandemic.
- The BSL4ZNet has been holding emergency meetings on COVID-19 with its international partners since early January to facilitate the exchange of scientific information and sharing of research capacity needs to enhance global efforts to combat the spread of COVID-19.
- The PHAC and DRDC, in partnership with the Department of National Defence, are also members of the Medical Countermeasures Consortium through which they work with the governments of the United States, the United Kingdom and Australia to foster collaborative research, development and acquisition.
- The CMA, NRC, the PHAC and CFIA regularly consult with the Coalition for Epidemic Preparedness Innovations (CEPI)—one of the major international funding mechanisms for vaccine development. Canada has contributed \$54 million to the CEPI, which is leading efforts to develop candidate COVID-19 vaccines for clinical trials to take place by late spring 2020.
- The CIHR's response to the COVID-19 pandemic is guided by input from international partners such as the WHO and the Global Research Collaboration for Infectious Disease Preparedness (Glo-PID-R).
- The CIHR, in association with the PHAC, is building on the existing Canadian Immunization Research Network (CIRN) to tackle the COVID-19 pandemic. The CIRN received a \$1-million direct grant to collect data on COVID-19 symptoms and on potential treatments and risk factors to inform Canada's public health response to the disease.
- Health Canada, as a member of the International Pharmaceutical Regulators Program, is working with other international regulators to monitor the impact of COVID-19 on global supply.

# 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 relating to vaccination programs fall under provincial and territorial jurisdiction.

- Last updated: May 2020
- Canadians should contact their health care provider or public health authorities to find out if there have been any changes to their or their family's recommended immunization schedule as a result of the COVID-19 pandemic.
- In the current pandemic situation, it is normal to be concerned about attending routine medical and clinical appointments, particularly for immunization.
- Canadians should contact their health care provider or public health authorities:
  - To find out if there have been any changes to their or their family's recommended immunization schedule because of the COVID-19 pandemic
  - To schedule their visit
  - To find out what measures have been taken for the safe delivery of immunization services during the crisis
- Health care providers have taken precautions to prevent the spread of infection during consultations, including the following:
  - Screening patients for symptoms or other risk factors before the appointment and upon arrival
  - Posting signs in the office
  - o Promoting the use of alcohol-based hand sanitizer or a Health Canada-approved alcohol-free hand sanitizer to patients
  - Providing masks to patients when they arrive
  - Shifting appointments to support physical distancing in the office

# FLUZONE® High-Dose influenza vaccine 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 fall flu season considering the anticipated pressures on the health care system as a result of COVID-19.
- Given the likelihood of COVID-19 and flu outbreaks in the fall, we want to implement measures to protect seniors living in long-term care facilities. COVID-19 outbreaks in these facilities have been devastating, and we need to do everything we can to protect residents and staff.
- FLUZONE® High-Dose is a special flu vaccine for people 65 years of age and older that stimulates the immune system more than some standard-dose vaccines.
- FLUZONE® High-Dose® offers better protection and triggers a stronger immune response than some standard-dose vaccines for people in this age group, who are also among the most at risk of complications and hospitalization due to seasonal influenza.

 For the 2020 flu season, the Government of Canada is purchasing enough FLUZONE® High-Dose for all provincial and territorial long-term care residents aged 65 and older.

# Guidance

### Guidance for ongoing vaccination programs during COVID-19

- The COVID-19 pandemic has highlighted the importance of vaccines in promoting immunity, especially among 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 conjunction with the National Advisory Committee on Immunization and the Canadian Immunization Committee, has released interim guidelines for continuing immunization programs during the COVID-19 crisis.
- Keeping vaccines up to date is an important way for Canadians to protect themselves and those at risk, and to help reduce the burden on the Canadian health care system during these unprecedented times.
- Any delay in immunizing against serious diseases could put your child, your family and those with compromised immune systems at risk for other diseases with serious consequences.
- We expect to see a drop in vaccination coverage because vaccinators are focusing their efforts to address COVID-19 and because of the temporary closure of primary health care practices to allow for physical distancing.
- We know that it may not be possible for everyone to keep their vaccines up to date given the current situation. However, we are asking Canadians to do their best to keep their vaccinations up to date and to look for open immunization clinics.
- Canadians should consult with a health care professional to determine when they should report for an appointment and to find out what measures have been put in place for the safe delivery of immunization services during the COVID-19 pandemic.
- Individuals with symptoms and those with suspected, probable or confirmed COVID-19, as well as those in close contact with these individuals, should not attend their scheduled immunization appointments during their isolation period.
- The PHAC advises vaccinators to focus on the primary series and booster doses in children under two years of age if they are unable to continue all routine immunization programs.

- Last updated: May 2020
- Careful assessment of missed doses will be critical to ensure that the pandemic does not leave lasting disparities in vaccination coverage in Canadian communities.
- PHAC guidelines on immunization programs during the COVID-19 crisis should be interpreted in conjunction with existing provincial and territorial pandemic immunization policies.
- In light of the current pandemic, it is quite normal to feel concerned about having to go to a doctor or clinic for a routine appointment, including to get vaccinated.
- Canadians should contact a health care professional to:
  - Find out if there have been any changes to their or their family's recommended immunization schedule as a result of the COVID-19 pandemic
  - Determine when they should go for an appointment
  - Learn about the measures that have been put in place for the safe delivery of immunization services during the COVID-19 pandemic.
- As the pandemic progresses, vaccinators should follow the advice of their provincial or territorial government and the PHAC regarding the timing of any relaxation of physical distancing measures or other precautions during the COVID-19 pandemic.

# Additional guidance for persons with disabilities in Canada

- We know that some groups, including people with disabilities, are much more affected than others by the COVID-19 pandemic.
- The Public Health Agency of Canada (PHAC), in collaboration with the COVID-19 Disability Advisory Group, has identified considerations and accommodations for people with disabilities and those who provide care and support to them, and will incorporate them into the current COVID-19 guidelines.
- This document complements other key guidance documents, including Infection prevention and control for COVID-19: Interim guidance for long-term care homes and Infection prevention and control for COVID-19: Interim guidance for home care settings. These documents can be adapted for use in settings where people with disabilities reside.
- The document also provides guidance for caregivers and COVID-19 assessment centres to consider when adapting their approaches during the pandemic to facilitate access to services for people with disabilities.

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

Some people with disabilities may be at greater risk of infection or serious illness because of their age, underlying health problems or disability. Therefore, they may be

more likely to be exposed to and contract COVID-19.

Some people with disabilities may face discrimination and barriers when seeking information, social service and health care. The need to self-isolate and practise physical distancing may also create other difficulties.

## <u>Infection prevention and control for acute care facilities</u>

- Protecting Canada's health care workers from COVID-19 is essential. These health care providers, who are on the front lines of the pandemic, are caring for the most vulnerable Canadians.
- The Public Health Agency of Canada's (PHAC) infection prevention and control quidelines complement provincial and territorial public health policies and procedures.
- The PHAC's National Advisory Committee on Infection Prevention and Control, which comprises subject matter experts and front-line health care providers, worked with the PHAC to develop these guidelines.
- The FPT Special Advisory Committee on COVID-19 approved the guidelines and the technical summary.
- PHAC guidelines do not have force of law. They should be consulted in conjunction with existing provincial, territorial and local legislation, regulations and policies.

## Revised guidelines on infection prevention and control for acute care facilities

- This guidance was updated in line with our approach to keep guidance current and to provide comprehensive recommendations based on the best available evidence.
- The guidelines highlight the need for environmental and administrative controls in facilities to protect health care workers and patients, as well as the importance of training in the use of personal protective equipment (PPE).
- Precautions against droplet and contact transmission are appropriate for most patient care. Aerosol-generating medical procedures require the use of an N95 mask and other PPE.
- The guidelines will remain provisional, as they may be modified as new scientific data become available.

# Technical summary of new guidelines for wearing masks, eye protection and face shields to be worn during shifts

The PHAC recommends that all health care workers in acute care hospitals wear a medical mask and eye protection or face shield for the duration of their shifts in an acute care facility.

- Last updated: May 2020
- This recommendation is based on new data indicating that COVID-19 can be transmitted by asymptomatic and presymptomatic carriers.
- Wearing a medical mask for the full duration of shifts is an important measure that helps reduce the risk of transmission from health care workers to patients.
- Wearing a medical mask and eye protection or face shield for the entire duration of the shift is an important measure that helps reduce the risk of transmission from patients to health care workers.
- This recommendation applies to health care workers who are in direct contact with patients as well as environmental services workers who need to travel to patient care areas.
- To keep coronavirus out of health care facilities, health care workers with COVID-19 symptoms should also return home immediately and resume work only on the advice of their local public health authority.
- Health care workers should consult their provincial or territorial guidelines and facility policies on the use of masks, eye protection and other PPE, as well as any strategies in place to preserve PPE supplies.

# Canada's supply of PPE and medical supplies

- Health care workers wear medical masks, including surgical masks, medical procedure masks and respirators (e.g., N95 masks). Maintaining the supply of medical masks on an as-needed basis is extremely important.
- The Government of Canada is working to ensure that health care workers have the PPE and medical supplies they need through bulk procurement in collaboration with the provinces and territories, building national production capacity and identifying alternatives and ways to extend product life.
- Canada is working to rapidly allocate PPE and medical supplies to the provinces and territories based on an approach endorsed by the federal, provincial and territorial ministers of health.

### Canadian Federation of Nurses Unions guidelines and concerns

- We have been in regular contact with the Canadian Federation of Nurses Unions regarding their concerns about some aspects of the revised guidelines.
- The Government of Canada developed the guidelines based on the best available evidence to protect the health and safety of health care workers.

 We will continue to re-evaluate and update the guidelines as the situation evolves and as we learn more about COVID-19.

#### Point-of-care risk assessment

Prior to any interaction with or procedure on a patient, health care workers should assess the infectious risks posed to themselves, other workers and patients. This procedure, known as point-of-care risk assessment, is used to determine the appropriate PPE for the circumstances.

## Inclusion of cleaners and food suppliers potentially exposed to COVID-19

The advice in these guidelines is intended for anyone working in an acute care facility, including cleaners and food suppliers.

## Wearing surgical masks instead of N95 respirators

The decision to wear a surgical mask or an N95 mask should always be based on a point-of-care risk assessment

## Reusing PPE and guidelines for health care facilities

- N95 masks are normally single-use products for health care workers.
- Canada is reviewing ways to extend the life of N95 masks by decontaminating and reusing them. Decontaminating N95 masks has proved effective in other countries, including the United States.
- Canada is asking provinces and territories to set aside their used N95 masks until an effective decontamination process can be tested.
- Extending the life of PPE through decontamination is one way to ensure that Canada has sufficient reserves.

## Infection prevention and control for COVID-19: Guidance for home care settings

- Home care organizations, which are a vital part of the health care system, play an important role in preventing unnecessary admissions to hospitals and long-term care facilities by providing care and support to people in their homes.
- People receiving home care are often elderly or have health problems, making them susceptible to serious illness if they contract COVID-19. Preventing COVID-19 in this vulnerable population is a priority.
- The Public Health Agency of Canada's (PHAC) infection prevention and control quidelines provide recommendations for home care organizations and suppliers to prevent transmission of COVID-19 to front-line workers and protect vulnerable clients.

- The PHAC's National Advisory Committee on Infection Prevention and Control, which comprises subject matter experts and front-line health care providers, worked with the Agency to develop these guidelines, which were also endorsed by the FPT Special Advisory Committee on COVID-19.
- The PHAC guidelines are not mandatory. They should be consulted in conjunction with provincial, territorial and local legislation, regulations and policies.

## Highlights of the guidelines

- To prevent the transmission of COVID-19 to clients, home care providers should monitor their health and take their temperature daily to detect signs and symptoms of illness. If they show signs of infection, they should be withdrawn from work until local public health authorities authorize their return.
- Home care providers should wear a mask during all visits to avoid transmitting COVID-19 to their clients before symptoms are detected.
- To protect themselves, front-line home care providers should contact their clients prior to visits to ask them if they or any members of their household have signs or symptoms of COVID-19. If so, home care organizations and providers can then determine if a visit can be delayed or otherwise arranged to ensure everyone's safety. The use of eye protection for the duration of home visits is strongly recommended to prevent potential transmission of COVID-19 to health care providers by clients in whom the infection has not yet been detected.

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

- Personal protective equipment (PPE) plays an important role in infection prevention and control measures to protect home care providers and their clients from COVID-19.
- Home care providers should refer to provincial, territorial and local guidelines and facility policies for specific recommendations on the use of masks, eye protection and other PPE, as well as PPE retention strategies.
- The Government of Canada is working to ensure that health care workers, including home care providers, have the PPE and medical supplies they need.
- This is being achieved through bulk procurement in collaboration with the provinces and territories, building national production capacity and researching alternatives and ways to extend product life.

### **Long-term care facilities**

 We are calling on all Canadians to help protect seniors and medically vulnerable people, who are at greater risk of serious complications from COVID-19.

- We must all work to stop the spread of the virus among residents of long-term care facilities and the workers who care for them.
- A no-visit policy should be strongly considered. If visits are permitted, they should be strictly limited to essential visits, i.e., those that are necessary to meet the basic personal medical or compassionate needs of residents. Essential visits should be limited to one person at a time for each resident.
- Like all Canadians, residents and employees of long-term care facilities should practise physical distancing whenever possible, including during meal times.
- Because they have direct contact with the most vulnerable people in our society, who are at the greatest risk of serious illness, health care workers should not report to work if they have symptoms.
- We understand that Canadians must make difficult decisions and personal sacrifices to stop the spread of COVID-19 and protect the most vulnerable.

#### 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 health care—associated infections.
- The Government of Canada has released *Infection prevention and control for COVID-19*: Interim guidance for care of residents in long-term care homes to assist staff and residents of long-term care facilities.
- This interim guidance is based on earlier guidance developed for the coronavirus pandemic, on lessons learned from the COVID-19 outbreak in China and other countries, as well as on interim guidance from other Canadian and international organizations.

### Public health guidelines for long-term care facilities

- Extreme vigilance is required in long-term care facilities to prevent employees from reporting to work if they have symptoms.
- Employees should be screened for COVID-19 symptoms before each shift, and those who start showing symptoms during their shift should be managed immediately.
- Where possible, employers should work with their employees to restrict work to a single facility and limit the number of areas within the facility where employees work.
- All employees and visitors must wear masks for the duration of their shift and visit to prevent transmission of the virus, even before they know they are sick.

- If visitors are expected, they should be screened for fever, cough or breathing difficulties, and they should not be admitted if they have symptoms related to COVID-19.
- Many facilities have already taken steps, such as barring visitors or other non-essential services on site.
- Long-term care facilities and assisted-living facilities should also follow the recommendations of their provincial or territorial health authorities to prevent the spread of infections, including COVID-19.

### Alberta long-term care homes

- The Government of Canada is committed to protecting all Canadians, including the vulnerable.
- All levels of government are working together to align public health measures to respond to the COVID-19 pandemic.
- Public health authorities are closely monitoring the development and stability of the pandemic's slowdown in Canada, while carefully considering ways to ease public health restrictions where possible.
- The epidemiological situation of COVID-19 varies between provinces and territories. Accordingly, not all approaches will be the same across Canada and will need to be tailored to the unique challenges and circumstances of the disease in each province and territory.
- Each Canadian province and territory is looking at different types of community settings, such as long-term care homes, and developing risk-based approaches and assessments based on developments within their borders.
- The Government of Canada is working with its provincial, territorial and international partners to ensure that our response to the COVID-19 pandemic is based on the most up-to-date scientific information and assessment of the situation.

On whether this approach is consistent with federal guidelines:

- Care in long-term care facilities is governed by provincial and territorial legislation.
- The Public Health Agency of Canada develops evidence-informed infection prevention and control guidance to complement provincial and territorial public health measures that address monitoring, prevention and control of nosocomial infections.
- Federal guidelines recognize that provinces and territories may choose to provide visitors with limited access to long-term care facilities in accordance with their legislation and policies.

- Last updated: May 2020
- Accordingly, we recommend that all staff and visitors, if access is permitted, wear masks for the duration of their shift and visit to prevent transmission of the virus, even if they are asymptomatic.
- If visits are permitted, visitors must be screened for symptoms such as cough, fever and breathing difficulties and should avoid entering a facility if they have COVID-19 symptoms.
- Visitors should be reminded to wash their hands and use an alcohol-based sanitizer, especially before putting on and taking off their masks.
- These facilities must also follow the recommendations of the relevant provincial or territorial health authorities to prevent the spread of infections, including COVID-19, in long-term care facilities and assisted-living facilities. Care in long-term care facilities is governed by provincial and territorial legislation.
- The Public Health Agency of Canada guidelines for infection prevention and control in long-term care facilities should be interpreted in conjunction with applicable provincial, territorial and local legislation, policies and regulations.
- As we enter the next phase of the pandemic, provinces and territories will begin to relax restrictions while emphasizing extreme caution.

## Guidance on death-care services and mass fatalities

- The Public Health Agency of Canada (PHAC) has developed guidelines on safely handling human remains during the COVID-19 pandemic. All information contained in the guidelines is based on the latest scientific evidence.
- We know that these types of guidelines can be difficult to hear about, especially for those who have lost a loved one. We extend our deepest condolences to all those who have lost a family member, friend or colleague to illness.
- However, these death-care services and mass fatality guidelines are an important part of pandemic planning and preparedness.
- Our understanding of the virus, and the risk of transmission of COVID-19 through human remains, is not yet known.
- In collaboration with public health, and infection prevention and control specialists and the Funeral Services Association of Canada, we have developed these guidelines to ensure safe service delivery to families and to protect the health of those providing these services to the public.

If pressed on the development of guidelines in response to recent outbreaks in long-term care facilities

These guidelines have been created to support proactive planning by the funeral services industry for a variety of possible scenarios during the pandemic.

# If pressed on funeral or burial practices for Indigenous people and members of various ethnic, religious or cultural groups

- Different religious, ethnic and cultural groups have specific guidelines for handling the bodies of deceased persons. It is important to respect and accommodate these practices to the extent possible, while protecting the health and safety of the community.
- We recommend that leaders of religious and cultural communities be involved in planning funeral services to ensure that funeral arrangements always respect cultural and religious values.
- Leaders may also be able to provide or facilitate the provision of cultural or religious support to the bereaved, including bereavement counselling.

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

- The remains of a person whose death is attributed to COVID-19 can be safely repatriated to Canada under certain conditions.
- In all cases, you must have the appropriate documentation, including a death certificate.
- There are two ways to repatriate the remains of a deceased person suspected or confirmed to be infected with COVID-19:
  - One for a cremated body
  - Another for a body transported in a hermetically sealed container
- We are aware that this may place some restrictions on families seeking to return home with the remains of a loved one. These restrictions are necessary for the protection of those who come into contact with the remains during the repatriation process.
- General information on what to do in the event of a death abroad can be obtained from funeral service providers in your community or by visiting https://travel.gc.ca/assistance/emergency-info/death-abroad on the Government of Canada's website.

### 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 deaths caused by COVID-19 in Canada, an increase that could exceed the normal capacity to provide funeral services.
- The PHAC has released guidelines to help local and regional planners, community leaders, funeral industry workers, medical examiners and coroners prepare for any sudden increase in the number of deaths associated with the pandemic.
- The guidelines are based on the latest scientific evidence and provide recommendations for body transport of bodies, planning, storage capacity and other technical factors.

## Reopening of dental clinics

- The Canadian Dental Association is supporting the provincial and territorial dental associations as they work with their government officials to gradually reopen dental clinics in accordance with infection prevention and control guidelines.
- Provinces and territories are responsible for regulating dentistry and decide when to allow their private dental clinics to reopen.
- Dental clinics in some provinces and territories are gradually reopening with enhanced safety measures.
- The Public Health Agency of Canada's (PHAC) infection prevention and control guidelines for acute health care settings applicable to dental practice complement provincial and territorial public health policies and procedures. The PHAC guidelines are not mandatory. They should be interpreted in conjunction with provincial, territorial and local legislation, regulations and policies.

## If pressed on enhanced safety measures

Each province and territory has the authority to decide what specific measures to adopt within its jurisdiction. Measures may include the following:

- Screening for COVID-19 symptoms and taking patient temperatures
- Booking fewer patients and staggering appointments
- Minimizing aerosol-generating procedures and allowing "settling periods" before thoroughly cleaning and disinfecting treatment rooms.

# PHAC infection prevention and control guidelines for acute health care settings

- These guidelines were updated to ensure they provide comprehensive recommendations based on the best available and current evidence.
- They emphasize the need for administrative measures and measures in patient care environments within facilities to protect health care workers and patients. They also

reiterate the fundamental importance of training in the use of personal protective equipment (PPE).

- Wearing a surgical mask for the full duration of the shift is an important measure that helps reduce the risk of transmission from health care workers to patients.
- Wearing a surgical mask, eye protection and a face shield for the full duration of the shift is an important measure that helps reduce the risk of transmission from patients to health care workers.
- This recommendation applies to health care workers who are in direct contact with patients as well as environmental services personnel who work in patient care areas.
- Any health care worker with symptoms associated with COVID-19 should immediately return home and return to work only on the recommendations of local public health authorities.
- Health care workers should refer to their provincial or territorial guidelines, along with the facility's policies on the use of masks, eye protection and other PPE, including any PPE retention strategies in place.

## Canada's supply of PPE and medical supplies

- The Government of Canada is working to ensure that health care workers have access to the PPE and medical supplies they need. This is being done through bulk procurement in collaboration with the provinces and territories, building national production capacity and identifying alternatives and ways to extend product life.
- Canada is working to allocate PPE and medical supplies to the provinces and territories in a timely manner based on an approach endorsed by the federal, provincial and territorial Ministers of Health.

#### Point-of-care risk assessment

Prior to any procedure or interaction with patients, all health care workers should assess the infectious risks posed to themselves, other workers and patients. This approach is referred to as point-of-care risk assessment and is the basis for selecting the appropriate PPE.

### Use of surgical masks instead of N95 respirators

The choice between a surgical mask and a N95 respirator should always be based on a point-of-care risk assessment.

### Isolation, quarantine (self-isolation) and physical distancing

Agence de la santé publique du Canada Public Health Agency of Canada Last updated: May 2020

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

#### Isolation

Isolation means staying home when you have COVID-19 symptoms and you may have been exposed to the virus. By avoiding contact with others, you help prevent the spread of the disease to others in your home and community.

#### You should:

- Go directly home and stay at home if:
  - You have been diagnosed with COVID-19 or are waiting for the results of a
  - You have any symptom of COVID-19, even if mild, and have:
    - been in contact with a suspected, probable or confirmed case of COVID-
    - been told by a public health official (either directly or through a public announcement or a self-assessment tool) that you may have been exposed to COVID-19
  - You have just returned from a trip outside of Canada and are showing COVID-19 symptoms (mandatory). Footnote\*
- Monitor your health for symptoms, as directed by your health care provider or public health authority, until an official informs you that you are no longer at risk of transmitting the virus to others
- Contact your health care provider or <u>public health authority</u> immediately if your symptoms get worse, and follow their instructions.

#### Limit contact with others

- Do not leave home unless you are seeking medical care
- Do not use public transportation (e.g., buses, taxis)
- Arrange to have groceries and supplies dropped off at your door to minimize
- Stay in a separate room and use a separate bathroom from others in your home, if possible
- o If you have to be in contact with others, practise physical distancing and keep at least two 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 unavailable, a non-medical mask or facial covering (i.e., constructed to completely cover the nose and mouth without gaping, secured by ear loops or ties behind the head and neck) when you need to be in the same room with others in the home, or when coughing or sneezing.
- o Follow the guidelines of your public health authority for the safe use and disposal or laundering of face masks.

o 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 warm water for at least 20 seconds, and dry with disposable paper towels or dry reusable towels, replacing it when it becomes wet.
- You can also remove dirt with a wet wipe and then use an alcohol-based hand sanitizer or a Health Canada—approved alcohol-free hand sanitizer.
- 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, close the container tightly 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 other facial covering may trap respiratory droplets and stop them from contaminating surfaces around you. Wearing a mask does not reduce the need for cleaning and disinfecting.

#### Care for yourself

- Monitor your symptoms as directed by your health care provider or public health authority.
- If your symptoms worsen, 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 those affected and the caregiver. If unavailable, a non-medical mask or facial covering (i.e., constructed to completely cover the nose and mouth without gaping, secured by ear loops or ties behind the head and neck).
- Eye protection (face shield or goggles) for use by caregivers
- Disposable gloves (do not re-use) for use by caregivers
- Disposable paper towels
- **Tissues**
- Waste container with a plastic liner
- Thermometer
- Over-the-counter medication to reduce fever (e.g., ibuprofen or acetaminophen)

- o Running water
- Hand soap
- Alcohol-based hand sanitizer containing at least 60% alcohol
- Dish soap
- Regular laundry soap
- Regular household cleaning products
- Hard-surface disinfectant; if unavailable, use concentrated (5%) liquid bleach and a separate container for dilution
- Approved cleaning products or alcohol prep wipes for high-touch electronics

### Quarantine (self-isolation)

- You need to quarantine for 14 days if you have no symptoms and one of the following situations applies to you:
  - You are returning from travel outside Canada (mandatory quarantine)
  - You had close contact with someone who has or is suspected to have COVID-19
  - You have been told by a 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 other people to help prevent transmission of the virus at the earliest stage of illness
  - Practise physical distancing at home and in the community
- If you develop symptoms, even if mild, stay home and isolate yourself immediately from others who live with you. Immediately call a public health care professional or a public health authority.

#### Physical distancing

- Canadians are advised to stay home, if possible. If you leave your home, practise physical distancing.
- We know that physical distancing is one of the most effective ways to reduce the spread of disease during an outbreak.
- We all need to follow the guidelines for physical distancing, even if you:
  - Don't have COVID-19 symptoms
  - Have no known risk of being exposed to the virus
  - Have not travelled outside of Canada in the last 14 days
- You can physically distance by making changes in your everyday routines in order to minimize close contact with others, including:
  - Avoiding crowded places and gatherings
  - Avoiding common greetings, such as handshakes
  - Limiting contact with people at higher risk (e.g., seniors and those in poor
  - Keep a distance of at least two arm lengths (approximately two metres) from others, if possible.

- Last updated: May 2020
- The most effective ways to stay healthy and prevent the spread of any respiratory infection are as follows:
  - Wash your hands often with running water and soap for at least 20 seconds
  - Cough and sneeze into the bend of your arm, not your hands
  - Avoid touching your eyes, nose and mouth, especially if you haven't washed your hands
  - Avoid close contact with sick people
  - Stay home if you are sick to avoid spreading the virus to others
- While keeping a physical distance of two metres between you and others, you can:
  - Greet people with a wave instead of a handshake, kiss or hug
  - Have food delivered or shop online
  - Ask a family member, neighbour or friend to help you with essential errands
  - Exercise at home
  - Go outside to get some fresh air, run, bike or walk your dog
  - Eat and play with family and friends online
  - Use technology, such as video calls, to stay in touch with friends and family
  - Work from home
  - Get creative by making chalk art or organizing games and backyard obstacle courses

## 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
  - 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 the 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 symptoms, from mild to severe. Some people may not recognize the signs of illness when the first symptoms appear because they are similar to cold or flu-like symptoms.
- 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.

- Last updated: May 2020
- Do not report to a health care provider's office before calling so that the 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 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;
  - provincial, territorial and municipal government websites and social media accounts.

# **Enforcement of mandatory 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 practise 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 recent 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.
  - There are some very powerful measures under the Quarantine Act 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 selfisolation 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 were 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 the onset of illness/symptoms. When these same people were tested using a different test (polymerase chain reaction [PCR]), several of them still tested 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 guideline replaces the current, stricter one requiring more resources, whereby individuals were required to obtain two negative tests before ending their home isolation.

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

- Canadian public health guidance related to COVID-19 has been changing as evidence and our understanding of COVID-19 rapidly evolve. 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.
- The following measures are the best way to prevent the spread of COVID-19:
  - Stay home when you are sick, away from others
  - Wash your hands often
  - Cough into a tissue or sleeve
  - Practise physical distancing
  - Clean and disinfect all surfaces and objects
  - Protect those most at risk of contracting the virus.
- It is important that we continue to apply these measures, even as we move through the next stages of the pandemic and slowly resume our daily activities.

- Last updated: May 2020
- If used properly, a non-medical mask can play an important role in situations where physical distancing is impossible or unpredictable.
- Considering that scientific research shows that the virus can be transmitted before you are symptomatic, when you are sick, and even asymptomatic, wearing a non-medical mask—even if you have no symptoms—is another step you can take to protect those around you when physical distancing is not possible.
- Public health authorities in your area will make recommendations based on several factors including rates of infection or transmission in the community. Recommendations will vary from place to place and depending on the local epidemiological situation.
- The use of a non-medical mask or cloth facial covering is recommended for limited periods of time, especially in high-traffic areas where keeping two metres away from other people is not possible:
  - Public spaces where there are no physical barriers or measures to ensure distancing (e.g., certain stores or work areas)
  - Enclosed environments (e.g., public or commercial transportation)
  - o High-risk areas where outbreaks can spread rapidly (e.g., group living areas, correctional facilities)
- Wearing a non-medical mask in the community does not mean that you can forego proven public health measures that provide effective protection.
- Go to Canada.ca/coronavirus for information on proper use of masks and non-medical facial coverings, including how to make your own. Non-medical masks can be made at home with readily available materials, ensuring that they are accessible to anyone who needs them. Discussions are ongoing about the best materials and manufacturing methods for non-medical masks or cloth facial coverings.

### 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 covering your cough with tissues or your sleeve can reduce that chance.

#### Considerations when wearing a non-medical mask

- 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 by:
  - avoiding to move them around or to adjust them often
  - avoiding to share them with others
  - adjusting them properly so that they fit snugly against the face

- Last updated: May 2020
- If wearing a non-medical mask makes you feel safer and stops you from touching your nose and mouth, that is also good. However, remember not to touch or rub your eyes as it is another route of infection.
- Your hands should be clean when putting on and taking off non-medical masks, and wash your hands or use a Health Canada-approved hand sanitizer if you touch your face.
- Non-medical masks should be replaced as soon as they become wet or soiled, washed in hot water and completely dry before being used again.
- You should also be aware that you can contaminate masks by touching them. The outside of the mask may also become contaminated.
- Non-medical masks and facial coverings are not recommended for children under the age of two or those who have difficulty breathing, are unconscious or are unable to remove the mask by themselves.
- Remember that non-medical masks will not prevent the spread of COVID-19 if public health and hygiene guidelines, including frequent handwashing and physical distancing, are not strictly followed at all times. The canada.ca/coronavirus website is updated regularly and provides information on measures such as handwashing when putting on or taking off masks. The site also includes information on washing cloth masks and safely discarding other non-medical masks (including anti-dust masks).

### Workplace/for employers

- Medical masks may be appropriate in some situations. For example, medical masks may be a suitable choice for some service providers, depending on their workplace and clientele.
- In some non-medical settings, medical masks may be a better option than non-medical masks. Masks are not suitable for all types of jobs. Employers should consult with their company's occupational health and safety team and local public health authorities before implementing policies requiring the use of face masks in the workplace.

#### Modelling and surveillance

#### Surveillance for COVID-19

- For several weeks now, the Canadian health care system has been on alert and has been working to detect possible cases of COVID-19.
- Canada continues to focus on containment to delay and slow the spread of COVID-19. We are doing this through early identification of cases, careful tracing of close contacts and the use of proven public health measures such as isolation. We also recommend that Canadians practise physical distancing.

- Last updated: May 2020
- Canada has a highly integrated federal, provincial and territorial approach to surveillance, involving front-line health care 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.

# Data modelling (April 28)

- The Government of Canada is continuing to work with its provincial, territorial and international partners to ensure that the response to the COVID-19 outbreak is based on the latest science and assessment of the situation.
- We are constantly analyzing data and results from clinical and epidemiological studies as they become available to determine when public health measures are working and when we need to take further action to control the outbreak.
- We are also working with provincial and territorial governments and universities to predict how COVID-19 could spread in Canada in the future and to estimate a range of possible cases, hospitalizations and deaths that could occur in the coming months.
- Using these models, we can prepare our health care system to provide care for the predicted number of patients and determine what public health measures may be needed to change the course of the pandemic in Canada.
- Our actions have a profound impact on the models. We can all help reduce the impact of COVID-19 in Canada by continuing our physical distancing efforts.
- Since infection rates vary across the country, projections of the effects also vary from one province or territory to another.

- Last updated: May 2020
- Models cannot predict what will happen, but they can help us understand what might happen and thus help us plan and take action to ensure the best possible outcome.
- Modelling the path of COVID-19 requires us to make assumptions based on incomplete data and scientific knowledge that is still evolving. These assumptions are changing as new information about the virus and more data about the outbreak in Canada become available.
- We are constantly improving the models to provide Canadians with the most accurate information about possible outcomes.

#### Case and death rates in Quebec

- Several factors are contributing to the higher number of reported cases and deaths in Quebec compared to other provinces and territories.
- First, Ontario and Quebec have reported several outbreaks in long-term care facilities and seniors' residences. These settings drive transmission and death rates among older people. In Quebec, residents in these facilities account for over 80% of deaths.
- Long-term care facilities continue to experience outbreaks, which affect the number of cases and deaths in some provinces. According to provincial and territorial websites and media reports, over 63% (1,157/1,834) of cases have occurred in long-term care facilities.
- The timing of **spring break** is another factor that may have contributed to the higher numbers. In Quebec, spring break occurs earlier than in other provinces, so people may have travelled to countries and regions where the outbreak had not yet been reported.
  - The way cases are reported in Quebec may also contribute to the higher number of reported cases and deaths. In Quebec, the figures include cases with COVID symptoms who have been in contact with a person with a laboratory-confirmed diagnosis, without having received laboratory confirmation themselves. These cases and deaths are included in Quebec's figures, but they are not in other provinces and territories. Quebec's public health authority is able to provide more details on how the province reports its confirmed cases.
- Quebec was able to expand its testing capacity very early in the outbreak through targeted testing, including testing for health care staff, long-term care facility residents and respiratory hospitalization cases, allowing it to identify cases.

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

- Other provinces and territories publicly report the number of individuals with a laboratory-confirmed diagnosis.
- We realize that laboratory-confirmed cases do not provide the true picture of infected people where the virus is circulating. This is because sick people may not necessarily be tested for laboratory confirmation.
- People with mild symptoms may go unnoticed or unreported, and some people may have no symptoms at all. This is why public health measures, such as social distancing, are critical.

## Government of Canada support for La Loche, Saskatchewan

- The Government of Canada is working 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 (PHAC) has provided Health Canada—authorized point-of-care screening devices in La Loche, Saskatchewan, to help municipal authorities respond to the COVID-19 outbreak in that community.
- Indigenous Services Canada has also provided resources to on-reserve First Nations affected by COVID-19 to help them meet their surge capacity needs.

### Support for Saskatchewan

- The National Microbiology Laboratory (NML) has provided the community of La Loche with Genexpert's Xpert Xpress SARS-CoV-2 point-of-care testing devices and 46 test kits (each kit contains 10 tests).
- The NML has also provided GeneXpert's Xpert Xpress SARS-CoV-2 point-of-care testing devices and point-of-care test kits to other remote Saskatchewan communities:
  - o The All Nations' Healing Hospital in Fort Qu'Appelle has received point-of-care testing equipment and eight test kits.
  - Île-à-la-Crosse and La Ronge each received point-of-care testing devices and three test kits.
  - Hatchet Lake received point-of-care testing devices and two testing kits.
  - Stony Rapids in the Athabasca region received ten testing kits.
- The NML is prepared to ship at least 70 additional test kits to Saskatchewan once the province confirms which communities will benefit the most from these kits.

# If pressed

- The Public Health Agency of Canada (PHAC) is working to allocate personal protective equipment (PPE) and medical supplies to the provinces and territories in a timely manner based on an approach endorsed by the federal, provincial and territorial Ministers of Health.
- Provinces and territories may also request assistance from the National Emergency Strategic Stockpile (NESS) to meet their essential needs. To date, the NESS has responded to over 40 requests for assistance related to COVID-19.
- Provinces and territories are providing PPE to Indigenous communities according to the allocation provisions and guidelines in place in their jurisdictions.
- The PHAC does not comment on the total amounts of PPE that a 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 better understand this disease and how the outbreak may progress.
- Canada is following the guidance of the WHO, which recommends a guarantine 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 that individual develops 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.
- The Public Health Agency of Canada (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 PHAC continues to liaise with international partners, including the WHO, to better understand the epidemiology of this disease.

### Multisystem inflammatory syndrome in children

- We continue to learn more about COVID-19 and its clinical manifestations, some of which are quite rare.
- A better understanding of multisystem inflammatory syndrome in children is needed. This syndrome appears to have a higher incidence in areas with high numbers of COVID-19.
- To date, there have been fewer cases of COVID-19 in children than adults. However, the disease can have serious consequences for children. It is therefore important for everyone to take precautions to prevent infection.
- Parents and caregivers should contact a health care professional if a child develops symptoms such as fever, lethargy, gastrointestinal problems and rash.
- The Public Health Agency of Canada is working with Canada's paediatricians to monitor the situation closely.
- Health care providers in Canada are aware of this potential syndrome and are being vigilant to detect cases.

# **Monitoring**

- The Public Health Agency of Canada (PHAC) continues to monitor, collect data and collaborate with other countries to inform public health actions in Canada.
- The PHAC has several systems in place to monitor community transmission and serious consequences of COVID-19 in children.
- A number of methods are being used to monitor the syndrome as part of PHAC's COVID-19 surveillance:
  - 1. A national system for reporting cases to provincial and territorial authorities and then to PHAC
  - 2. A network of children's hospital emergency department physicians who report cases of COVID-19
  - 3. The Canadian Paediatric Surveillance Program (CPSC), a collaboration between PHAC and the Canadian Paediatric Society.
- The CPSP's COVID-19 monitoring protocol will be modified to include cases of multisystemic inflammatory syndrome, even in the absence of a positive COVID-19 test result, in order to generate more data on this new disorder.

### COVID-19: On the way to becoming endemic

- The virus responsible for COVID-19 is a new virus. Although we are ramping up efforts to make a future treatment or vaccine accessible and affordable to all, developing new therapies and vaccines to treat or prevent the disease will take time.
- The COVID-19 pandemic has led to a global search for therapies that could be used to treat or prevent the disease. But as with many other viral respiratory infections, COVID-19 is not going away, and a vaccine that will provide long-term protection against the virus will be needed.
- Scientists in Canada and around the world are working hard to develop a COVID-19 vaccine, in addition to working on treatments for people who get sick, including early supportive therapies, symptom management and prevention of complications.
- Once a vaccine is available, it is expected that it will offer protection similar to other vaccines that exist today.
- Canada's participation in the World Health Organization's multi-country "Solidarity Trial." which is looking at potential drug treatments for COVID-19, is an example of Canada's contribution to global efforts to find a treatment for people with the disease.
- This unprecedented multi-country trial to test potential COVID-19 treatments is a new model for global collaboration, whose goal is to quickly find treatments with the potential to reduce the number of COVID-19 victims. Patient recruitment for the Canadian component of this trial has already begun, and approximately 20 sites will be selected across Canada.
- At the same time, we are moving quickly to develop a vaccine to prevent the spread of COVID-19 and prevent people from becoming infected. Through the Canadian Institutes of Health Research's (CIHR) Rapid Research program, the Government of Canada has invested a total of \$54.2 million to support 99 teams of researchers across the country.
- These teams are working to develop and implement measures to rapidly detect, control and reduce the transmission of COVID-19. Their activities include vaccine research and the development of strategies to combat stigma, misinformation and fear.
- As we await the development of a vaccine and continue to make progress with treating COVID-19, people need to do everything they can to prevent transmission:
  - Stay home and away from others if you are sick
  - Wash hands often
  - Cough into a tissue or sleeve to cover your cough
  - Practise physical distancing
  - Clean and disinfect all surfaces and objects
- The goal of these public health measures is to control the virus and reduce its spread to a point where communities and begin to reopen slowly.

# If pressed

On May 15, 2020, Health Canada approved an application for a clinical trial of CanSino Biologics' COVID-19 vaccine. This is the first clinical trial application in Canada for a vaccine specifically developed to prevent COVID-19.

### **COVID-19 screening in Canada**

- We continue to perform extensive screening tests in Canada—at some of the highest rates in the world.
- To date, priority for screening has been given to individuals exhibiting symptoms and those in high-risk situations.
- This includes people working in care settings, long-term care facilities and correctional facilities or who are in situations where a positive case is associated with a high-risk environment that could lead to an outbreak.
- As we move into the next phase, i.e., relaxing certain public health measures and reopening some sectors of the economy, there will continue to be cases of COVID-19 until the population has developed herd immunity or until a vaccine is available.
- COVID-19 will be part of our lives, and screening will continue to be an important tool to detect and isolate new cases, to perform contact tracing to halt the spread of the virus and to prevent outbreaks in the community.
- Cases and outbreaks continue to be reported at an alarming rate in high-risk settings, such as long-term care facilities. During the next phase, screening groups at highest risk of complications from COVID-19 will be critical. This screening will serve as an early warning system for our health care system.
- Increased screening does not equate to a quicker return to normal activities or a return to daily life as it was before COVID-19. Screening is not a substitute for public health measures.
- No specific number of daily tests would allow us to relax public health measures consistently across Canada. The outbreak is occurring differently from one province and territory to another, even from one region to another.
- We also need to be smart about testing. Individuals can be contagious before exhibiting symptoms, while they have symptoms and even if they have no symptoms at all. It doesn't make sense to use all of our resources and supplies for testing where there are few cases and no indications of community spread.

- The timing of screening is crucial. A negative test can give people a false sense of security because it doesn't mean that the person has not been exposed to the virus. The person can become contagious within days of being tested, so screening is recommended at least five days after potential exposure.
- Since May 5, we have been carrying out an average of 20,000 tests a day in Canada, almost double what we were doing a month ago. This number continues to grow.
- Canada is maintaining a positivity rate of 6 to 7%, which is within the range required to **accurately detect** where the disease is circulating.
- If the positivity rate were to drop below 3% in Canada (to 1%, for example), it would mean that we are casting too wide a net and testing people who don't need to be tested, such as:
  - People outside of areas of Canada where the disease is circulating
  - People who are tested too early
- The number of tests and the positivity rate show that our current screening system is highly sensitive. We continue to expand our laboratory capacity to keep it that way.
- Health Canada is working with manufacturers to allow commercial diagnostic devices to reach the market to increase the diagnostic capacity 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. This order makes new diagnostic tests available in Canada. They are listed on Health Canada's web site.
- New diagnostic tests will provide faster and more convenient screening for Canadian patients.
- We must stay the course and stick with what has been shown to work. Regardless of the level of screening where they live, all Canadians must to the following to prevent the spread of COVID-19:
  - Stay home and away from others when sick
  - Wash hands often
  - Clean common surfaces with a suitable disinfectant
  - Protect vulnerable individuals
  - Practise physical distancing

 Wearing a non-medical mask or facial covering is also recommended in crowded public spaces and when it is not possible to consistently maintain a physical distance of 2 metres between oneself and others.

### Reagents and tests for COVID-19

- There are several commercial reagents approved by Health Canada that can be used to test for COVID-19. There is a worldwide shortage of many of these reagents, which affects laboratory capacity. We need homegrown solutions to address this problem.
- The shortage of reagents required for COVID-19 testing is affecting Canada's testing capacity. The Public Health Agency of Canada's (PHAC) National Microbiology Laboratory has developed a reagent to address this shortage. The reagent is being mass produced by Luminultra Technologies, a New Brunswick-based company.
- The PHAC has also signed a temporary licensing agreement with bioMérieux Canada for the rights and formulation of its reagent used to diagnose COVID-19.
- The Government of Canada's testing priorities include access to test reagents, assessment of commercial testing technologies and access to licensed test kits to enable provinces and territories to expand their testing capacity.

#### On Luminultra

- Scientists at Canada's National Microbiology Laboratory (NML) have replicated and validated a commercial reagent for COVID-19 using open source information. This reagent is similar to those used in diagnostic laboratories across the country.
- Luminultra Technologies purchases the raw materials required for the development of reagent batches formulated by the NML, and coordinates the shipment of the reagent to public health laboratories across the country.
- Luminultra shipped its first batch of reagent on April 10, 2020.
- When operating at full capacity, Luminultra will be able to manufacturer reagents for up to 500,000 tests per week.
- It is anticipated that as its production capacity increases, Luminultra will be able to produce enough reagents to help meet domestic demand.

### On the bioMérieux agreement

- bioMérieux is a French company that produces reagents in COVID-19 diagnostic tests. The company is having trouble obtaining some of the ingredients needed to manufacture its product and to meet global demand.
- Through an innovative public-private partnership, PHAC has signed a temporary licensing agreement with bioMérieux Canada, at no cost, for the rights and formulation of

their reagents that are used for diagnosing COVID-19. The systems for producing these reagents are at various stages of development and testing, in an effort to alleviate some of the reagent shortages in the near future.

#### What are reagents?

- A reagent is a chemical formulation used to process samples for laboratory testing.
- The specific reagents produced for COVID-19 tests are extraction reagents.
- They extract the virus from a sample in order to detect genetic material and determine whether a patient's test for COVID-19 is positive or negative.

### Screening tests for individuals

- Laboratory testing for the novel coronavirus in symptomatic individuals has clear clinical and public health value, but the same is not true for testing asymptomatic individuals.
- Canada has and will continue testing for all symptomatic individuals as part of our evidence-based approach, while taking into account 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.
- We must realize that this is not a simple and straightforward issue, and that some of the science is unclear.

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

- We need to focus on the testing the right people at the right time.
- In Canada, testing focuses on individuals exhibiting symptoms consistent with COVID-19.
- Testing asymptomatic individuals is not considered an effective way to detect and prevent the spread of the virus and could 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. That is why we have taken the precaution of placing people in guarantine 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 swabs

- The Government of Canada is aware of issues with some swabs received in early April.
- These swabs were delivered as part of a bulk order of 8.85 million swabs expected by Canada in April and May.
- The manufacturer (ESBE Scientific) is a reputable, Health Canada–licensed company. We have been informed that the company has suspended production to address manufacturing issues. As a result, future deliveries of swabs will likely be delayed as the company resolves its quality issues.
- The issue could affect future orders. The Public Health Agency of Canada continues to work directly with the provinces and territories to determine their medical supply needs and place bulk orders. Public Services and Procurement Canada will continue to identify all suppliers capable of meeting Canada's needs.

### Changes to authorization of the Spartan test kit

- On March 26, 2020, Health Canada issued an authorization with terms and conditions to Spartan Bioscience Inc. for use of the Spartan Cube for research purposes only.
- This authorization was issued under the interim order respecting medical devices for use in relation to COVID-19, which allows Health Canada to authorize the use of devices after an expedited scientific review process, based on minimum requirements.
- On April 11, 2020, Health Canada completed its scientific review to ensure that the kit met safety and effectiveness requirements. The authorization conditions were amended, and restrictions on the sale of the product for non-research purposes were lifted.
- Health Canada's regulatory decision was based on laboratory testing of the product and not on clinical efficacy data. The review took into consideration the fact that further clinical validation would be conducted by public health laboratories to determine its performance in a clinical setting. This approach is consistent with that of other reputable regulatory agencies.
- On May 1, 2020, the National Microbiology Laboratory (NML) submitted its final report to Health Canada on clinical trials conducted in three provinces (Alberta, Ontario and Manitoba) with Spartan swabs to collect samples directly from patients under clinical conditions.
- According to the report, although the Cube performed well in the laboratory as per the manufacturer's specifications, there were performance issues in the clinical trial. These problems appear to be related to proprietary swabs that would not collect enough

mucosal material for testing.

- Based on the clinical results, on May 2, 2020, Health Canada placed conditions on the product's authorization to limit its sale for research purposes until the company could provide data demonstrating acceptable clinical performance.
- Health Canada is not revoking the authorization based on evidence that the kit works well in the laboratory. The Spartan kit can therefore continue to be sold for research purposes alone until the company can provide data demonstrating acceptable clinical performance.
- Health Canada will continue working with as the company moves to meet the regulatory requirements to allow for use point-of-care test.

# If pressed on the number of tests that have been distributed after the test kits were authorized

- Spartan Bioscience forwarded its distribution record to Health Canada on May 2 and confirmed that it had 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
  - Public Health Ontario
  - Public Health Agency of Canada
- These organizations are aware of the new authorization conditions issued by Health Canada.
- Health Canada has asked the company to voluntarily recall the products so they aren't used for testing at this time. The company complied.
- On May 2, Health Canada issued a regulatory letter to the company outlining the new conditions of authorization in accordance with section 6 of the interim order. The letter also outlined the steps for the voluntary recall of the kits.
- Health Canada has limited the sale of test kits to research purposes until sufficient evidence of clinical performance can be provided and assessed.

# If pressed on details of the recall

- The recall includes the following:
  - Issue a notice informing clients of the risks associated with using the product for diagnostics and steps to mitigate these risks.
  - Request the return of all unused single-use devices and components (e.g., reagents and swabs) from non-laboratory settings and from laboratories using the product for diagnostics.

Request the return of swabs only from laboratories that will continue to use the device for research.

# If pressed on Health Canada's review of Spartan

- On March 26, 2020, Health Canada issued an authorization to Spartan Bioscience Inc. for use of the Spartan Cube with the condition that sale of the product be limited to research purposes. This authorization was issued under the Interim Order respecting medical devices for use in relation to COVID-19, which allows Health Canada to authorize the use of medical devices after an expedited scientific review process, based on minimum requirements.
- On April 11, Health Canada completed its scientific review to ensure that the kit met safety and effectiveness requirements. The authorization conditions were amended, and restrictions on the sale of the product for non-research purposes were lifted.
- Health Canada's regulatory decision was based on laboratory testing of the product and not on clinical efficacy data. The review took into consideration the fact that further clinical validation would be conducted by public health laboratories to determine its performance in a clinical setting. This approach is consistent with that of other reputable regulatory agencies.
- On May 1, 2020, the NML submitted its final report to Health Canada on clinical trials conducted in three provinces (Alberta, Ontario and Manitoba) with Spartan swabs to collect samples directly from patients under clinic conditions. These clinical trials are crucial because they reveal performance issues that would not show up in the laboratory. According to the report, although the Cube performed well in the laboratory as per the manufacturer's specifications, there were performance issues in the clinical trial. These problems appear to be related to proprietary swabs that would not collect enough mucosal material for testing. Based on the clinical results, Health Canada amended its conditions of authorization to restrict sales of the Spartan Cube to research purposes until the company can resolve performance issues with the kit and provide sales data.

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

- The Public Health Agency of Canada's NML performs scientific review of new medical devices as part of its research efforts.
- Given the urgency of the situation, the NML is validating tests and evaluating the performance of diagnostic equipment such as COVID-19 test kits.
- This validation role is part of the scientific research and is separate from Health Canada's regulatory approval process. Although the validation process is separate from the Health Canada approval process, the NML works closely with Health Canada to share insights gained through the review process.

The NML tests laboratory supplies for the clinical diagnosis of COVID-19 to ensure that they conform to the gold standard used in public health laboratories. The validation

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process is designed to assess whether the product can be used to provide reliable and accurate results for the diagnosis of COVID-19.

# If pressed on the purchase of the Spartan kit by the government

The Government of Canada has entered a supply contract with Spartan to secure delivery of these kits. The contract is conditional on Health Canada's approval of the kit for sale in Canada.

### Home test

- Rapid diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada.
- Health Canada is against home testing for COVID-19 because it has not evaluated and approved any home test kits, which means that the results could be inaccurate.
- These kits interfere with the health system to collect accurate and timely data on the spread of infection, which is key to managing a pandemic.
- Health Canada has only authorized the sale and import of COVID-19 diagnostic tests for the exclusive use of qualified health care professions or technicians.
- Health Canada has not authorized diagnostic tests or sample collection kits for use by the general public to detect or self-diagnose COVID-19.
- The Government of Canada continues to work with Canadian and international companies to provide Canadians and health care workers with the tools they need to care for Canadians and reduce the spread of COVID-19.

#### On the interim order respecting medical devices

- As an emergency public health measure, the <u>Interim order respecting the importation</u> and sale of medical devices for use in relation to COVID-19 provides expedited access to medical devices to combat COVID-19.
- This interim order makes new diagnostic tests readily available in Canada. They are listed on Health Canada's website.
- The interim order will help ensure the availability of medical devices relating to COVID-19 to treat, mitigate or prevent the disease, if necessary.

#### Serology and immunity certificates

- Canada's Chief Medical Officers of Health do not support immunization certificates. We still lack sufficient data to determine what the immune response would be to infection with SARS-CoV-2, the virus that causes COVID-19.
- Research is underway to determine whether individuals who recover from COVID-19 have immunity and, if so, for how long.
- On May 12, 2020, Health Canada authorized the first COVID-19 serological test in the country, followed by a second test on May 14. However, the tests are not authorized for diagnostic use of COVID-19. For an up-to-date list of authorized tests, go to the Health Canada website.
- Serological tests are blood tests that detect antibodies to the virus that causes COVID-19. These tests indicate whether a person has previously been infected with the virus.
- As scientists work to better understand immunity to COVID-19, we are focusing our efforts on proven and effective public health measures.
- We continue to recommend that Canadians stay home when they are sick, wash their hands well and practise physical distancing if they need to go outside. These are proven public health measures.

# If concerns are raised about immunity certificates

- The World Health Organization (WHO) recently warned that there is insufficient evidence at this time on the efficacy of humoral immunity to guarantee the accuracy of immunity certificates and that the use of these certificates could increase the risk of sustained transmission.
- False positives could cause individuals to modify their behaviours, thereby exposing themselves to the virus or unknowingly affecting others.
- Ethical and legal issues related to sharing information about the results of serological tests must also be addressed to protect the confidentiality of personal health information and prevent the stigmatization of low-income Canadians and people with precarious employment. Immunity certificates may increase the risk of discrimination against employees without COVID-19 antibodies. Return-to-work pressures may lead some individuals to voluntarily expose themselves and their families to infection in the community if immunity certificates are used to confirm a return to work.
- Creating a registry of immunity certificate holders could lead to confidentiality or data security issues that would need to be addressed.

# If asked about serology

- On May 12, after a review of scientific priorities, Health Canada authorized the sale of the first COVID-19 serological test. For an up-to-date list of authorized tests, go to the Health Canada website.
- In addition, the Public Health Agency of Canada's National Microbiology Laboratory is developing a number of in-house serological tests and is also evaluating a range of commercial tests related to COVID-19.
- Serological tests provide proof of previous exposure to the virus responsible for COVID-19 through antibody testing.
- Serological tests will help us understand the immune status of people who have been infected.
- The use of validated and effective COVID-19 serological tests will be an important part of Canada's health response.
- Once we have a clear understanding of the scientific basis for COVID-19 immunity and immunity in this country, we will be able to better monitor COVID-19 and immunity and return-to-work policies, especially in health care settings.
- Serological surveys can also help inform important health decisions once a vaccine is available.

#### The first COVID-19 serological tests

- Following a scientific review, Health Canada authorized the sale of two serological tests: DiaSorin's LIAISON® (authorized on May 12) and Abbott's ARCHITECT SARS-CoV-2 IgG Assay (authorized on May 14).
- Both tests are approved to detect virus-specific antibodies. Serological tests detect the antibodies, indicating previous exposure to the virus that causes COVID-19.
- Health Canada authorized the tests after conducting evidence-based scientific analysis to ensure that the tests will provide accurate and reliable results.
- Go to Health Canada's website for a full list of authorized COVID-19 testing devices: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19industry/medical-devices/authorized/list.html
- Serological tests will help us understand the immune status of infected individuals.

- The use of validated and effective COVID-19 serological tests will be an important part of
- Serological tests can also be used to inform important public health decisions once a vaccine is available.
- Health Canada will continue focusing on the health and safety of Canadians and distributing safe and effective health products relating to COVID-19 as quickly as possible.

### Additional messages

Canada's health response.

- These tests must be carried out in the laboratory.
- Serological tests are critical to understanding the immune response to viral infection and will play a key role in determining the extent of exposure to the virus through serological surveillance studies.
- Further research is needed to fully understand the relationship between a positive antibody test result and protection against re-infection.
- In accordance with Health Canada's guidance on serological tests, a condition is placed on the authorization of serological test to monitor their ability to perform as intended once they are used in the Canadian health care system.
- Serological tests should be used in combination with testing strategies set out by municipal, provincial or territorial public health authorities.
- Nucleic acid-based testing is also authorized for COVID-19 testing in Canada to diagnose active infection.

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

- As a public health emergency measure, the Minister of Health has signed an interim order to provide expedited access to medical devices for uses related to COVID-19, including testing devices.
- Only testing devices authorized by Health Canada can be imported or sold in Canada. Unauthorized tests may not produce accurate results and may lead to misdiagnosis.
- Health Canada has confirmed that tests authorized to diagnose COVID-19 are adequately backed by evidence that indicates they will provide accurate and reliable results. Over a dozen testing devices for diagnosing COVID-19 are now available in Canada. They are listed on Health Canada's website.
- Canada has continued a science-based approach to pandemic management, including maintaining pre-market approval requirements for testing technologies.

Last updated: May 2020



- Providing Canadians with accurate information on the status of infection is a key element of Canada's pandemic response.
- Health Canada's position on the use of serological testing is consistent with the World Health Organization's view that it will play a key role in research and surveillance.
- The Public Health Agency of Canada's National Microbiology Laboratory and its partners are working to evaluate several commercial serological tests for detecting the SARS-CoV-2 virus. Collaborators across the country include members of the Canadian Public Health Laboratory Network, clinical researchers in front-line health care settings and Canadian Blood Services. All are working to develop the equipment needed to evaluate and implement serological testing in Canada.
- Health Canada continues to review other serological testing technologies in accordance with its serological testing guidelines. Health Canada will authorize other high-sensitivity and high-specificity serological tests. For more information, go to the Testing devices for COVID-19: Serological testing devices web page.

# If pressed on validation of test kits by the NML

The Public Health Agency of Canada's National Microbiology Laboratory does not validate medical devices, such as swabs or test kits, under its usual mandate. However, it is evaluating whether they can be used for testing as part of its research activities.

Given the urgency of the situation, at the request of companies the NML is evaluating the effectiveness of diagnostic supplies such as virus testing kits and 3D swabs. It tests laboratory supplies for the clinical diagnosis of COVID-19 to ensure that they conform to the gold standard used in public health laboratories.

The NML's validation process is designed to assess whether the product yields reliable and accurate results for the diagnosis of COVID-19. Although the process is separate from Health Canada's scientific review process, the NML is working with the Department's Medical Devices Directorate to share insights gained through the review process.

Health Canada regulates the sale and importation of medical devices in Canada. Unauthorized medical devices can give inaccurate results, which can lead to misdiagnosis. The accuracy and reliability of COVID-19 tests approved by Health Canada are well established.

# If pressed on the scientific review of DiaSorin's LIAISON® test and Abbott's ARCHITECT SARS-CoV-2 lgG Assav test

- Health Canada has completed its scientific review of the DiaSorin LIAISON® test and Abbott's ARCHITECT SARS-CoV-2 IgG Assay test under the interim order authorization process.
- Both tests are authorized under the interim order and are subject to certain conditions:

Last updated: May 2020

 Submission of a plan to Health Canada to evaluate the effectiveness of the test when administered in designated facilities, including at least two Canadian facilities

Last updated: May 2020

- Submission of a summary of other cross-reactivity studies
- Submission of a report on reagent stability studies
- Abbott's ARCHITECT SARS-CoV-2 IgG Assay has been validated by an evaluation using samples from 31 infected individuals and 1,070 negative samples.
  - Additional validation results from the University of Washington confirming the data provided by the company were found in published literature.
- DiaSorin's LIAISON® test has been validated by an evaluation using samples from several facilities in Italy and France.
  - Additional validation results confirming the data provided by the company were provided by British Columbia's provincial laboratory.
- Health Canada will continue working with the NML and other public health laboratories across Canada to review relevant results from their validation and use of testing devices.

# If pressed on what serological testing means for Canadians

#### What are serological tests used for?

Serological tests are critical to understanding the immune response to viral infection. They will play a key role in determining the extent of exposure to the virus through serological monitoring studies.

Serological tests are not authorized to diagnose COVID-19 because they detect antibodies produced in an individual by immune response. These antibodies are unlikely to develop until the later stages of infection, which will often give false-negative results if used too early. For diagnostic tests, testing directly for the presence of virus characteristics while infections are present is best done using molecular tests from swab samples.

#### How will the results of the serological tests be used?

The use of validated and effective COVID-19 serological tests will be an important part of Canada's health response.

On April 23, the Government of Canada established the COVID-19 Immunity Task Force to lead the collaborative work to test blood samples across the country for the presence of COVID-19. Rapid and representative national surveys will provide a snapshot of where we are now and what to expect in the event of a second wave. They can also shed light on the possible immune status of vulnerable populations and individuals, including Aboriginal communities and residents of nursing homes and long-term care facilities.

Serological tests can also be used to inform important public health decisions once a vaccine is available.

Is the government considering issuing passports or certificates of immunity or negative serological tests to permit freedom of movement?

Efforts are underway around the world to assess whether people who have recovered from the disease can safely resume their daily activities.

More research is needed before Canada makes any decisions.

Most people do not develop full immunity to other respiratory viruses after recovery.

At this time, we simply do not know if people who have recovered from COVID-19 will be immune, how long they will remain immune, or whether people may experience less severe or potentially more severe symptoms if they contract COVID-19 a second time.

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

- As a public health emergency measure, the Minister of Health has signed an interim order to provide expedited access to medical devices for uses related to COVID-19, including testing devices.
- Only testing devices authorized by Health Canada can be imported or sold in Canada. Unauthorized tests may not produce accurate results and may lead to misdiagnosis.
- Health Canada has confirmed that tests authorized to diagnose COVID-19 are adequately backed by evidence that indicates they will provide accurate and reliable results. Over a dozen testing devices for diagnosing COVID-19 are now available in Canada. They are listed on Health Canada's website.
- Canada has continued a science-based approach to pandemic management, including maintaining pre-market approval requirements for testing technologies.
- Providing Canadians with accurate information on the status of infection is a key part of Canada's pandemic response.
- Health Canada's position on the use of serological testing is consistent with the World Health Organization's view that it will play a key role in research and surveillance.
- The Public Health Agency of Canada's National Microbiology Laboratory and its partners are working to evaluate several commercial serological tests for detecting the SARS-CoV-2 virus. Collaborators across the country include members of the Canadian Public Health Laboratory Network, clinical researchers in front-line health care settings and Canadian Blood Services. All are working to develop the equipment needed to evaluate and implement serological testing in Canada.
- Health Canada continues to review other serological testing technologies in accordance with its serological testing guidelines. Health Canada will authorize other high-sensitivity and high-specificity serological tests. For more information, go to the Testing devices for COVID-19: Serological testing devices web page.

#### Pan-Canadian study to monitor COVID-19

Every day we are learning more about COVID-19 and keeping abreast of new scientific data as it becomes available. The scientific data collected through the work of the

COVID-19 Immunity Task Force will provide crucial knowledge to inform decisionmaking.

- Extensive serological surveys (blood tests) of the Canadian population will be conducted to measure the scope and scale of COVID-19 cases across the country.
- These efforts need to be well coordinated and executive to achieve optimal results to guide policy decisions on how to bring the country back to normal or a "new normal."
- We are creating a task force of organizations to work under the guidance of a Board of Directors to set priorities and recommend projects for funding to the Government of Canada. The leadership team comprises three individuals recognized for their contributions to research, academic and innovation in public health and health care, both in Canada and abroad.
- The co-chair of the Board of Directors will be
  - Dr. David Naylor, renowned for his scientific and academic leadership and successful management of large and complex organizations.
  - Dr. Catherine Hawkins, who will contribute her national and international experience in leading large-scale and complex research projects and building partnerships to advance public health priorities.
  - Dr. Tim Evans, Director of McGill University's School of Population and Global Health, will lead the secretariat to successfully implement this complex initiative.
- The task force will initiate, support and coordinate the rapid design and implementation of population-based studies to produce the first reliable estimates of SARS-CoV-2 immunity in the general population and in priority populations in Canada.
- The task force will include the Public Health Agency of Canada's National Microbiology Laboratory (NML). It will be responsible for standardizing tests and helping acquire commercial test kits (once approved) to help the task force conduct its operations effectively and consistently.
- Rapid and representative national surveys will provide a snapshot of the current situation and what to expect if there is a second wave. They can also shed light on the possible immune status of vulnerable populations and individuals, including members of Aboriginal communities and residents of nursing homes and long-term care facilities.
- Serological surveys can also be used to inform important public health decisions once a vaccine is developed.

# Presymptomatic and asymptomatic transmission

Now that more countries have recorded high numbers and modes of transmission, recent studies have confirmed that infected people can transmit the virus before even showing symptoms. This is known presymptomatic transmission.

- Data also shows that some infected people can transmit the virus without ever showing symptoms. This is known as asymptomatic transmission.
- At present, we don't know the extent to which presymptomatic and asymptomatic transmission plays a role in the spread of the pandemic, but we do know that this type of transmission occurs in people who have close contact or share a small physical environment with infected individuals.
- The main vectors of the global COVID-19 pandemic are individuals with visible symptoms, since coughing and respiratory droplets are the primary ways the virus spreads. However, because asymptomatic transmission has now been demonstrated, everyone—even those who do not feel sick—needs to follow proven methods to prevent 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:
  - o 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 lifethreatening conditions when conventional therapies have failed or are unavailable
  - o 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

#### Canadian hospitals join global drug trials

- COVID-19 is a global pandemic that requires a global solution.
- The involvement of various countries, including Canada, in this unprecedented mega trial of potential COVID-19 treatments is truly a new model for global collaboration.
- This global trial, coordinated by the World Health Organization, will test several potential drugs to treat COVID-19. Since all countries will use the same experimental design, it will be possible to obtain more reliable results faster.

- As with all unproven treatments, there are risks and benefits. Consequently, candidate treatments are best used as part of a clinical trial.
- The Government of Canada has invested approximately \$1 million in the Canadian portion of this global trials through the Canadian Institutes of Health Research. This investment is part of the government's \$275 million commitment to support medical research on the COVID-19 pandemic.
- Canada is home to some of the world's brightest and most qualified researchers, who are working hard to support the international response to the ongoing pandemic. As many as 20 institutions across the country are expected to be invited to participate in the Canadian component of this global trial.
- To advance research and development of a COVID-19 vaccine, the World Health Organization, together with the Coalition for Epidemic Preparedness Innovations, is coordinating an international collaboration in which Canada is participating.

#### Experimental therapies

- Any drug or health product with a therapeutic claim may not be sold or marketed in Canada without prior approval by Health Canada as a safe, effective and quality product. This approval process is initiated when the manufacturer of the drug or health product files an application for approval with Health Canada.
- Health Canada is accelerating the review of all submissions related to COVID-19 to ensure that Canadians have timely access to health products that are effective against COVID-19.
- Currently, no drugs to treat or prevent COVID-19 specifically have been approved. For drugs that show promise in treating COVID-19, the best way to access them is through clinical trials.
- Health Canada is inviting health care professionals who prescribe or offer investigational therapies to patients with COVID-19 to contact Health Canada to initiate a clinical trial.
- Health Canada continues to monitor the post-market safety and effectiveness of drugs and health products.

### In pressed on fast tracking access to treatments

- Health Canada recognizes that Canadians want timely access to promising new drugs and health products, especially when treatment options are limited.
- The Minister of Health, as a public health emergency measure, has signed interim orders to allow accelerated access to medical devices and drugs related to COVID-19.
- Health Canada will continue to use all available means to expedite the supply of safe and effective health products relating to COVID-19.

### If pressed on off-label use

Additional background: Some health care providers prescribe "off-label" drugs to treat COVID-19 symptoms. In other words, they are prescribing drugs to treat COVID-19 that are authorized and indicated to treat other health conditions.

- In Canada, a health care professional's decision to prescribe or use a particular drug for an approved or off-label indication falls within the routine practice of medicine, which falls under the jurisdiction of provincial and territorial professional regulatory authorities.
- While Health Canada regulates drugs in Canada, health care professionals are responsible for taking into account information provided in the Canadian product monograph, on the labels of approved products and from other reliable sources such as medical journals, reports and peer-reviewed studies, to ensure that the potential benefits of the drug outweigh its risks to individual patients.
- Off-label use may not be supported by the same level of scientific evidence as authorized use. An off-label prescription may be justified by a range of data, from data from rigorous clinical studies to anecdotal evidence without substantial scientific validation.
- Drug labels are designed to indicate authorized use and, therefore, may not provide all the information necessary for safe and effective off-label use. For drugs used off-label, this means that there may be less information about possible interactions with other drugs and other possible adverse effects associated with off-label use of the drug.
- It is illegal to directly or indirectly promote experimental therapies or off-label use of experimental drugs.
- Health Canada encourages health care professionals to consider the use of off-label drugs to treat COVID-19 when conducting a clinical trial so that data can be collected and used to inform future prescribing practices.

### If pressed on clinical trials

- Clinical trials play a critical role in advancing research and evaluating investigational products to help address emerging health issues.
- The purpose of clinical trials is to determine whether the use of a drug or medical device is effective and safe for humans.
- Clinical trials require informed consent from patients and monitoring and safeguards to ensure the safety of participants.
- Clinical trials enable the health care community to systematically collect data on the efficacy of treatments and their potential risks to inform treatment decisions for other patients.

#### Hydroxychloroquine and azithromycin for the treatment of COVID-19

- Canadians and their families who have COVID-19 need access to safe and effective drugs and health products for diagnosis and treatment.
- There has been some preliminary evidence from studies suggesting that hydroxychloroquine alone or a combination of hydroxychloroquine and 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 hydroxychloroguine 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 health care 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.
  - Hydroxychloroguine is approved to treat lupus, rheumatoid arthritis and malaria.
  - Azithromycin is an antibiotic used to treat pneumonia and other bacterial infections.
- Ensuring access to these drugs for patients who need them for approved uses is important.
- Since these drugs are just beginning to be used in scientific experiments to treat COVID-19, Health Canada recommends that health care professionals who wish to prescribe them to treat COVID-19 do so in a clinical trial.
- A clinical trial requires the informed consent of patients and allows the medical community to systematically collect data on the risks and benefits of treatment.
- All clinical trials on COVID-19 treatment are given priority review. Corporations, health care practitioners and researchers who want to conduct a clinical trial should contact health Canada.

### If pressed on the National Emergency Strategic Stockpile

- The Government of Canada has added hydroxychloroguine to the National Emergency Strategic Stockpile (NESS). The stockpile will be prioritized for its approved applications, and then used in clinical trials for the treatment of COVID-19.
- Hydroxychloroguine will be added to the NESS over several months to minimize impacts on availability for approved applications.

- Last updated: May 2020
- Provinces and territories may draw on the NESS for emergencies, such as responding to an infectious disease outbreak, natural disaster or other public health incident when their own resources are insufficient.
- The stockpile contains a variety of items, including medical devices, medications, beds and blankets.
- The NESS is designed to supplement provincial and territorial stockpiles in the event of a rare or high-impact public health incident.
- The NESS is not meant to replace provincial or territorial stocks or procurement. Provinces and territories are responsible for preparing and maintaining their own supply capabilities.
- Immediately following the coronavirus outbreak in China in January, the Public Health Agency of Canada closely monitored the situation and assessed NESS inventories to acquire the necessary supplies to prepare for a possible outbreak in the country.
- Supply is tightening across the world. The federal government continues to work hard to get everything it needs as quickly as possible, working directly with all province and territories.

# If pressed on the availability of hydroxychloroquine and azithromycin

- Health Canada is closely monitoring stockpiles of potential treatment candidates for COVID-19 in Canada, including hydroxychloroquine and azithromycin.
- Four companies market hydroxychloroquine in Canada: Apotex Inc., JAMP Pharma Corporation, Mint Pharmaceuticals and Sanofi-Aventis Canada. Health Canada has been informed that all four companies are seeing increased demand.
- Sixteen companies market azithromycin in Canada: Altamed Pharma, Angita Pharma, Apotex, Auro Pharma, Dominion Pharmacal, JAMP Pharma Corporation, Laboratoire Riva, Marcan Pharmaceuticals, Pharmascience, Pro Doc, Sandoz Canada, Sanis Health, Sivem Pharmaceuticals ULC, Sterimax, Teva Canada Incorporated and Pfizer Canada. None of these companies has reported a shortage of azithromycin in Canada.

# If pressed on Health Canada's actions to mitigate shortages associated with COVID-19

- Health Canada is closely monitoring the impact of the COVID-19 pandemic on Canada's drug supply, including targeting the weakest links in supply chains to bridge gaps and avoid shortages.
- Health Canada has also stepped up its surveillance efforts and is consulting with the provinces and territories, the pharmaceutical industry, the health sector, and patient

groups on a regular, sometimes daily, basis. Health Canada is also working with other international regulatory bodies, including the European Medicines Agency, the U.S. Food and Drug Administration, Australia's Therapeutic Goods Administration and the World Health Organization to share information on any global supply disruptions. This ongoing dialogue helps us to better detect shortages, develop mitigation strategies and respond in a coordinated manner.

- As part of the government-wide response to the COVID-19 pandemic, the government passed the COVID-19 Emergency Response Act on March 25, 2020, and the Food and Drugs Act was amended to enable Health Canada to implement more robust ways to reduce and prevent shortages.
- On March 30, the Minister of Health signed an interim order authorizing exceptions on the importation and sale of drugs, medical devices and foods for special dietary use that are required to prevent or alleviate the effects of shortages that are directly or indirectly related to COVID-19.
- The interim order exceptionally authorizes the importation of certain drugs that do not necessarily meet all the requirements of Canadian regulations, such as bilingual labelling, but are manufactured to standards equivalent to those applied in Canada in order to maintain the supply of drugs in Canada and to protect the health of Canadians during this period.
- Only drugs on the List of drugs for exceptional importation and sale will be subject to the exceptional importation and sale provisions of the interim order. For the time being, the only drugs that will be eligible for inclusion on this list will be those for which a Tier 3 shortage has been reported, such as hydroxychloroquine.
- Although no drugs have been listed yet, Health Canada will evaluate proposals from companies wishing to access Tier 3 shortage drugs under this new process, including hydroxychloroguine, and will update the list as required.
- Health Canada will continue to work with other federal government departments, provinces and territories, international partners and industry to ensure that Canadians have continued 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, especially children, who are ill with COVID-19 need access to safe and effective drugs and to health products for diagnosis and treatment.
- Hydroxychloroquine is approved in Canada for the treatment of lupus, rheumatoid arthritis and malaria.

- Since this drug just starting to be used in scientific experiments to treat COVID-19, Health Canada recommends that health care professionals who wish to prescribe it to patients to treat COVID-19 do so in a clinical trial.
- On May 2, 2020, Health Canada authorized the Research Institute of the McGill University Health Centre to conduct a clinical trial to study the safety and efficacy of hydroxychloroquine as a treatment for COVID-19 in hospitalized children.
- There has been some preliminary evidence from international studies suggesting that hydroxychloroguine may be effective in reducing the viral load in some groups of patients with COVID-19, as well as in treating respiratory tract infections related to COVID-19. However, as results vary, further studies are needed, especially in children.
- Like all drugs, hydroxychloroquine has known risks, which can be limited and carefully monitored during a clinical trial.
- A clinical trial requires the informed consent of the patient (and parent or guardian, if applicable) and would allow the health care community to systematically collect information on the risks and benefits of treatment.

# **Regulatory flexibilities for COVID-19 treatments**

- Health Canada's top priority is to ensure that all Canadians have access to the drugs and medical devices they need during the COVID-19 pandemic.
- Health Canada is prepared to consider certain rarely used regulatory relaxations to allow early filing of submissions for drugs that show promise to treat or prevent COVID-19.
- Health Canada may accept new evidence from ongoing clinical trials as it becomes available, while ensuring that the review is always subject to the same levels of safety, efficacy and quality. This process can lead to a more efficient review by Health Canada and reduce the overall review time for a new drug, while upholding high standards of scientific review.
- The evidence provided must still demonstrate that the drug is safe, effective and high quality before Health Canada approves it for use by Canadians.
- A similar approach was previously adopted for the approval of the H1N1 vaccine.

#### On the use of this approach for remdesivir

- Potentially promising treatments such as remdesivir could be reviewed under this model.
- Health Canada is in discussions with Gilead Sciences Canada regarding a drug submission for remdesivir.
- Remdesivir is an antiviral drug that was originally developed to treat Ebola.

# Remdesivir for the treatment of COVID-19

- Canadians and their family members who are ill with COVID-19 need access to safe drugs for diagnosis and treatment.
- Right now in Canada there are no drugs specifically authorized to treat or prevent COVID-19. Health Canada has been closely monitoring developments in potential treatments for COVID-19, including remdesivir.
- Remdesivir is an experimental drug that has been used to treat some hospitalized patients with COVID-19 in clinical trials. While there is evidence from preliminary clinical trials suggesting that remdesivir may help patients recover more quickly, its efficacy in treating COVID-19 remains to be determined, and it will require a review of the clinical data once it is submitted to Health Canada.
- Health Canada is aware that the U.S. Food and Drug Administration (FDA) has granted emergency use authorization for the experimental drug remdesivir based on initial clinical trial data from the U.S. National Institute of Allergy and Infectious Disease (NIAID). The preliminary data show that remdesivir can help patients recover faster. For the FDA, authorization is temporary and does not replace the formal process for submitting, reviewing and approving new drugs.
- Health Canada has not yet received a submission for approval to use remdesivir to treat COVID-19. If the company files an application for remdesivir, Health Canada will use the relaxed regulation available only for public health emergencies to allow the company to file a submission earlier and continue to submit data on the safety, efficacy and quality of the drug. Health Canada will assess the data on an ongoing basis.
- Health Canada is working with its international counterparts and will leverage available knowledge wherever possible to expedite the review of any remdesivir application filed with the Department. Health Canada is in discussions with Gilead Sciences Canada, the manufacturer of remdesivir, to discuss an expedited regulatory track, including relaxing the ongoing review recently made available by Health Canada, and to provide guidance on how to best file for access to the Canadian market.
- Remdesivir is still considered an experimental treatment, and the best way to access it is through a clinical trial. So far, Health Canada has approved two clinical trials involving remdesivir for COVID-19 in Canada. Clinical trials give Canadians access to new therapies to treat COVID-19 and are an opportunity for the health care community to systematically collect information on the effectiveness of treatments and associated risks. Go to our website for more information about trials.
- To date, remdesivir has also been used on a case-by-base basis under Health Canada's Special Access Programme (SAP), which provides emergency access to drugs for serious or life-threatening illnesses.

- Last updated: May 2020
- If remdesivir is authorized for use in Canada, Health Canada will work with the company to ensure access to the drug for Canadians, while recognizing international demand for the product.
- The evidence provided must still demonstrate that the drug is safe, effective and high quality before Health Canada approves it for use by Canadians.

### If there are questions about promising results for remdesivir:

- Remdesivir is an experimental drug that has yet to be approved in any country. It was originally developed as a potential treatment for Ebola infection and has shown promise in the treatment of SRAS-2.
- The best way to access experimental treatments that may help treat COVID-19 is to conduct a clinical trial. Clinical trials give Canadians access to new treatments for COVID-19 and are an opportunity for the medical community to systematically collect information on the effectiveness of treatments and associated risks.
- The U.S. National Institute of Health (NIH) has published data on a randomized, placebo-controlled clinical trial suggesting that remdesivir may have a positive effect on COVID-19 outcomes. Specifically, early results from a trial conducted by the U.S. National Institute of Allergy and Infectious Diseases (NIAID) showed that hospitalized patients receiving remdesivir had a faster cure rate than those receiving a placebo. However, the full trial data have not yet been released to Health Canada for critical review.
- According to data released by the NIH, patients who received remdesivir had a 31% faster recovery time than patients who received a placebo. The median recovery time was 11 days for patients treated with remdesivir, compared to 15 days for those who received a placebo.
- Health Canada recognizes the urgent need for COVID-19 treatments and the suggested results of the NIAID trial. However, all available evidence must first be reviewed by Health Canada to ensure that the drug is safe, effective and high quality for Canadians.
- Health Canada is in discussions with Gilead Sciences Canada, the manufacturer of remdesivir, to discuss an expedited regulatory track, including relaxing the ongoing review recently made available by Health Canada, and to provide guidance on how to best file for access to the Canadian market.

### If there are questions about the availability of remdesivir

- Remdesivir is not currently an approved product and can only be accessed through a clinical trial or Health Canada's Special Access Programme (SAP).
- If remdesivir is authorized for use in Canada, Health Canada will work with the company to ensure access to the drug for Canadians.

- Currently, very few patients in Canada have been treated with remdesivir under special access programs or compassionate care.
- Due to high global demand for remdesivir, access for Canadians will be primarily through clinical trials. Access through the SAP will be possible for certain groups, such as pregnant women or children with a confirmed case of COVID-19 and serious illness.
- Health Canada is in discussions with Gilead Sciences Canada, the maker of remdesivir, to discuss an expedited regulatory track and to provide guidance on how to best file for access to the Canadian market. The company has been advice of the possibility of an open submission, which is only available in the event of a public health emergency.

# Medical supplies and devices

### Canada's supply of PPE and medical supplies

- We are aware of the shortage of personal protective equipment (PPE) and medical supplies in Canada and are committed to doing whatever it takes to protect the health of Canadians, especially front-line workers, from COVID-19.
- The Government of Canada is working with provincial and territorial governments to rapidly assess needs in terms of PPE (N95 masks, surgical masks, face shields, nitrile gloves, gowns and other protective clothing) and medical supplies (disinfectant, respirators, swaps and test kits).
- To meet these needs, we are purchasing large quantities of equipment and supplies, investing in COVID-19 testing and working with Canadian companies to increase their manufacturing capacity.
- We have also received donations from national and international organizations.
- Canada is working to allocate PPE and medical supplies to the provinces and territories in a timely manner based on an approach agreed to by the federal, provincial and territorial Ministers of Health.
- The Public Health Agency of Canada (PHAC) is also sending PPE and respirators from the National Emergency Strategic Stockpile (NESS) to provinces and territories upon request.
- Canada's NESS contains supplies that provinces and territories can request in emergency situations, e.g., an infectious disease outbreak. Its role is to help provide back-up support in times of crisis that complements provincial and territorial resources.

Provinces and territories are responsible for preparing and maintaining their own supply capacity.

# Regulatory measures to improve access to medical devices, including PPE

- In recent weeks, we have taken the following steps to support the government-wide response to COVID-19.
  - Expediting access to medical devices relating to COVID-19, e.g., test kits.
  - Expediting issuance of establishment and manufacturing licenses.
  - Allowing the importation into Canada and sale of unapproved medical devices, subject to certain requirements, to address shortages.
  - Simplifying access to products that may not meet all current regulatory requirements, such as bilingual labels, including personal protective equipment (masks, gowns), swabs, and hand and surface disinfectant.
  - o Amending the Food and Drugs Act and the Patent Act to bolster efforts to prevent and respond to shortages.

Health Canada will monitor and evaluate the safety, quality and efficacy of any product that is permitted to be imported and sold under these special measures.

#### Gown shortages

- Gowns play a key role in protecting health care workers during the COVID-19 pandemic. However, growing global demand for gowns has caused a temporary shortage in Canada and around the world.
- To help health care facilities develop strategies to continue ensuring the safety of health care workers when providing patient care, the Public Health Agency of Canada and Health Canada have made recommendations on preserving inventory, prioritizing use, finding alternatives and managing outdated gowns.
- The Government of Canada is making every effort to ensure that health care workers have the personal protective equipment (PPE) and medical supplies they need through bulk procurement in collaboration with the provinces and territories, building national production capacity and identifying alternatives and ways to extend product life.
- The Government of Canada has ordered gowns and has begun receiving shipments from international and domestic suppliers. The Public Health Agency of Canada is working to distribute the items to provinces and territories following an approach endorsed by the federal, provincial and territorial (FPT) Ministers of Health.

## Preservation strategies for supplies

- To preserve supplies of gowns that provide protection against droplets and fluids, health care facilities must implement environmental and administrative measures to minimize restrictions on their use.
- These measures may include the following:
  - Installing physical barriers between health care workers and potentially contagious individuals in control areas
  - Limiting, postponing or cancelling non-essential activities that may require a gown
  - Exploring ways to expedite washing and return of reusable gowns
  - Limiting the number of visitors to patient rooms where gowns are normally required
  - Using a type of gown normally reserved for other uses (e.g., surgical gowns), if inventory and the workload of operating-area staff permit.

### Alternatives to protective gowns

- Alternatives or additions to gowns (e.g., coveralls, lab coats, aprons) may be more difficult to put on and take off than protective gowns, which my increase the risk of contamination.
- It should also be noted that the level of droplet and fluid protection provided by alternative or gown additions varies.
- To extend the life of gowns, health care workers can wear an apron on their gown that they can change between patients.
- When protective gowns are not available, coveralls may be considered to provide adequate protection where there is a risk of exposure to body fluids.

#### Expired and reusable gowns

- Health Canada does not recommend the use of disposable gowns that have expired without first confirming that they are still resistant to fluid.
- Reusable (i.e., washable) gowns may be washed after each use, following the manufacturer's instructions regarding sterilization and bleaching requirements for health care facilities, including the number of times the gowns may be washed without affecting performance, safety and effectiveness.
- Reusable gowns may be used beyond their recommended shelf life, provided they are not damaged. Expired gowns must be visually inspected for damage prior to use.

## Orders and domestic production of medical gowns

- Due to global demand for PPE, some materials normally used in the manufacture of gowns are being reallocated to mask production. This makes it difficult for manufacturers around the world to fulfill their orders, resulting in production and shipping delays.
- To meet domestic need, Canada has strengthened its domestic production capacity. Innovation, Science and Economic Development Canada and Public Services and Procurement Canada have been reaching out to Canadian industries, and thanks to several Canadian companies that have switched to the production of blouses, domestic deliveries have already begun.
- To date, Public Services and Procurement Canada has ordered over 130 million gowns. Over 200,000 gowns have been delivered to the PHAC, with more deliveries scheduled in the coming weeks.

#### Procurement contracts to increase supplies in Canada

- Innovation, Science and Economic Development Canada and Public Services and Procurement Canada continue to engage Canadian industries to increase domestic production capacity, including transforming plants to produce equipment and supplies such as portable respirators, surgical masks and rapid test kits.
- Thanks to these efforts, the Government of Canada has signed supply contracts with Canadian companies including Thornhill Medical, Medicom and Spartan Bioscience.
- The government has also signed letters of intent with businesses, including Precision Biomonitoring, Fluid Energy Group, Irving Oil, Calko Group and Stanfield's, for the production of test kits, disinfectant and protective clothing, including masks and gowns.
- Canada Goose has received its Medical Device Establishment Licence from Health Canada. This will allow the company to retool its manufacturing facility to produce gowns.
- Throughout this process, the PHAC and Health Canada are playing a leading role in conducting technical reviews to ensure that products meet the Government of Canada's technical specifications for COVID-19, which are outlined Public Services and Procurement Canada's Buy and Sell website.
- The Government of Canada has also awarded a contract to Amazon, which will manage the logistics of distributing PPE and supplies to support the fight against COVID-19.
- Amazon will work directly with Canada Post to provide warehousing services and will use its existing delivery service providers, Canada Post and Purolator to ship the

products to health authorities in all provinces and territories for use by front-line health care workers.

### Relabelling PRI-MED surgical masks

- The Public Health Agency of Canada conducts quality audits of personal protective equipment and medical supplies from Canadian or foreign sources received by the Government of Canada to confirm that they meet the Government of Canada's technical specifications for COVID-19 response in health care facilities.
- PRI-MED, Canada's preferred partner in the fight against COVID-19, distributes medical products to virtually every hospital in the country.
- PRI-MED has manufacturing facilities in China and is working to meet the licensing requirements for the export of its products. In the meantime, PRI-MED is complying with China's requirements by labelling masks manufactured in China for export as "nonmedical use" to support the fight against COVID-19 in Canada.
- Meeting the needs of front-line workers remains the Government of Canada's top priority. For this reason, the PHAC assesses surgical masks and PRI-MED labelling upon receipt against the Government of Canada's technical specifications for COVID-19 intervention in health care facilities.
- When the PHAC confirms that PRI-MED's surgical masks meet the technical specifications for use in health care facilities, PRI-MED replaces the labelling of the masks to indicate that they are suitable for medical purposes to support the fight against COVID-19 in Canada.
- If the PHAC determines that the quality of the product is inadequate for medical purposes, it conducts a subsequent evaluation for non-medical purposes outside of health care facilities.

#### Invitation to submit an expression of interest for logistics services

- The Government of Canada is working to obtain personal protective equipment (PPE) for front-line health care workers across the country.
- In support of these efforts, the Government of Canada is soliciting expressions of interest from logistics service providers to facilitate the timely receipt and distribution of an exceptional volume of PPE orders across Canada.
- This new expression of interest is for an end-to-end logistics solution that differs from the solution from the current agreement with Amazon. It includes warehousing, customer and brokerage documentation and inventory management.

The PHAC will continue to monitor the quantities of PPE and supplies available, provinces and territories that request it and locations where the equipment is shipped.

#### Purchasing and donating PPE

- The PHAC screens medical supplies and personal protective equipment received by the Government of Canada, whether donated or purchased, to ensure that they meet technical specifications for COVID-19 set out on the Public Works and Government Services Canada Buyandsell.ca website.
- The screening process varies depending on the medical device. For example, acceptable alternatives to N95 masks, such as KN95 respirators, undergo a visual inspection for design and manufacturing defects and are tested to ensure that the flow, pressure drop and penetration meet the requirements for filtration masks. Gowns are visually inspected and tested for liquid resistance.
- Since our health care providers may not be familiar with some of the supplies, those that meet the technical specifications will be distributed to the provinces and territories, along with documentation confirming that the products meet specifications and instructions for use.
- For example, supplies received from China may be labelled in Mandarin. To ensure timely distribution, the PHAC is unable to replace labels on all items. Accordingly, provinces and territories are encouraged to follow PHAC instructions that accompany the supplies, with appropriate training for front-line health care workers.
- KN95 masks are another example. The standard procedure for an N95 mask is to perform a fit test, but KN95 masks cannot be tested this way, which is why the PHAC is asking the provinces and territories to perform a fit test. Health care workers may not be familiar with this process, so instructions will be provided.
- The Government of Canada is pleased to accept generous PPE donations from international and domestic organizations, including the Jack Ma Foundation/Alibaba, Home Depot, Apple, CBC/Radio-Canada, Shell, AstraZeneca and many others.
- We are happy to see so many Canadians stepping up to help those who need it most.

# The Government of Canada's coordinated response to purchasing equipment and supplies

The Government of Canada has taken a coordinated approach to distribute the necessary supplies and equipment across the country.

Public Services and Procurement Canada: PSPC is leveraging existing supply agreements and is contacting domestic and international supply communities to identify and purchase needed products.

The Department is asking all suppliers to come forward with products or services they can offer to support Canada's response.

- Public Health Agency of Canada: PHAC is working with federal partners, provinces and territories to identify the needs and requirements for responding to COVID-19. The Agency also oversees Canada's National Emergency Strategic Stockpile, which contains supplies that provinces and territories can request in emergency situations.
- **Health Canada:** As the regulatory body for health products, Health Canada is working to expedite access to products that 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 has also adopted an interim measure to facilitate access to certain products, including PPE.

Under the Interim Order, a medical device licence or authorization is required to sell or import high-risk medical devices into Canada.

Health Canada will review all submissions and applications related to COVID-19 as quickly as possible, while upholding patient safety standards.

- Innovation, Science and Economic Development Canada: ISED is responsible for Canada's Plan to Mobilize Industry to fight COVID-19, which includes new measures to directly support businesses so they can rapidly scale up their manufacturing capacity or retool their production lines to develop made-in-Canada products that will help fight COVID-19. On March 20, ISED issued a call to action for manufacturers and businesses.
- National Research Council of Canada: The NRC's Industrial Research Assistance Program builds on its existing relationships with thousands of the most innovative small and medium-sized businesses to bring innovative solutions to the market to combat COVID-19.

#### Reusing single-use medical devices

- Like other hospital practises, the purchase and use of reprocessed medical devices by health care facilities is the responsibility of provincial and territorial governments.
- Given the COVID-19-related shortage of certain medical devices, Health Canada is working on guidelines for cleaning and sterilizing single-use devices.

The Government of Canada has taken additional emergency measures in recent weeks to facilitate access to new COVID-19 diagnostic tests and to disinfectants, hand sanitizer, personal protective equipment and testing swabs.

#### Decontaminating and reusing N95 masks

- N95 masks used by health care workers are labelled as single-use products.
- The Government of Canada, like many other countries, is exploring ways to extend the use of personal protective equipment (PPE), including N95 masks, through decontamination to help Canada meet its supply needs.
- The Government of Canada has asked the provinces and territories, as well as health care providers, to keep N95 masks and store them in accordance with local biosafety standards and guidelines while it reviews the effectiveness of decontamination processes.
- Health Canada has already authorized certain devices for the decontamination of N95 masks under the Interim Order respecting medical devices. Products and manufacturing processes must meet safety, quality and efficacy requirements to protect the health and safety of Canadians.
- The Government of Canada has acquired decontamination equipment to increase provincial and territorial capacity to reprocess N95 masks as needed.
- Other countries, including the United States, have adopted this approach.
- The Government of Canada is working hard to provide PPE and medical supplies to health care workers through bulk procurement in collaboration with the provinces and territories, building domestic production capacity and researching alternatives and ways to extend product life.

# On the Public Health Agency of Canada's purchase of decontamination equipment for reprocessing single-use N95 masks during the fight against COVID-19.

- On April 15, 2020, the Government of Canada signed a contract with Stryker Canada for the purchase of 82 decontamination devices.
- These devices will provide a total additional reprocessing capacity of approximately 275,500 N95 masks per week.
- These devices were developed through Canadian research and development efforts and are manufactured in Canada.
- The Government of Canada continues to work closely with all provinces and territories to address their potential needs for additional decontamination and reprocessing capacity.
- The National Research Council of Canada has purchased 20 Clean Flow Mini health care devices to share with hospitals to study mask decontamination.

# On Health Canada's considerations regarding the reprocessing of single-use N95 masks during the fight against COVID-19.

- The Government of Canada recognizes that reprocessing masks is one possible solution that would provide an additional supply of masks for health care workers who need them to protect themselves.
- Due to the risk of PPE shortages during the fight against COVID-19, the Government of Canada continues to work with manufacturers to identify alternative technologies to effectively decontaminate single-use N95 masks for safe reuse by front-line health care workers.
- Decontamination is an acceptable way to make masks safe for reuse. Companies are required to provide evidence that their processes sufficiently decontaminate masks for reuse.
- Health Canada has issued a notice advising manufacturers of important regulatory requirements that they must follow to demonstrate that their decontamination methods for single-use N95 masks meet key safety and effectiveness requirements.
- The Department has also issued a notice containing important considerations for health care professionals, which provides additional details on Health Canada's requirements relating to evidence to ensure that products and manufacturing processes meet mandatory safety, quality and effectiveness standards.
- Manufacturers that wish to reprocess medical devices for use against COVID-19 can apply for an expedited authorization review under the Interim Order issued on March 18, 2020. This is a streamlined regulatory process to tackle the health crisis.
- Two approaches are possible:
  - o Companies can supply instruments and sterilization or decontamination systems to health care facilities for the reprocessing of single-use N95 masks.
  - Companies can reprocess single-use N95 masks themselves and redistribute them to health care facilities.
- Health care facilities that have sterilizers that allow them to reprocess N95 masks internally may do so without authorization from Health Canada. However, the Department strongly recommends that they use only technologies that have been authorized by Health Canada.
- The Government of Canada continues to engage with the health care community and the provinces and territories to monitor the quantity of PPE and learn about possible ways to reprocess N95 masks.
- Our goal is to find solutions quickly and respond appropriately to the pressing need for safe and effective PPE in health care settings.

#### Authorizations granted under the Interim Order respecting medical devices

- Health Canada has invited medical device companies with extensive experience manufacturing decontamination and reprocessing equipment to submit applications to authorize these technologies for the safe and effective reprocessing of N95 masks and other PPE. As with all products intended for COVID-19-related use, Health Canada is expediting the application process for these products as a top priority.
- Under the Interim Order respecting medical devices (link), Health Canada has authorized expanding the intended use of sterilizers and new devices for reprocessing N95 masks.
- A list of authorized devices can be found here (search for "sterilizer" or "decontamination" in the "Technology" column). This list will be updated regularly as new devices are authorized under the Interim Order.
- Health Canada will continue to monitor current global trends and evaluate the evidence behind various decontamination and sterilization methods and strategies for reprocessing other PPE, including single-use surgical masks, during the COVID-19 pandemic.

#### On our existing guidelines

- In May 2016, Health Canada issued a notice to industry regarding the reuse of singleuse medical devices.
- Health Canada applies the same requirements to companies that reprocess medical devices originally licensed and labelled for single use and distribute them to health care facilities in Canada as it does to manufacturers of new devices.
- Manufacturers of licensed sterilizers or decontamination devices each have their own quidelines that tell users how to use the device to decontaminate masks, including the following:
  - Instructions for health care facilities
  - Instructions for health care personnel
  - A fact sheet on N95 mask decontamination
- In addition, Health Canada also issued a notice with important considerations for health care professionals, which provides more information on Health Canada's evidence requirements to ensure that products and manufacturing processes meet mandatory safety, quality and effectiveness standards.

# On the report to Canada's Chief Science Advisor: Task Force on Reprocessing of Respirators/N95 Masks

Experts from PHAC and Health Canada were among the member of the Task Force that reviewed the available evidence on reprocessing and reuse of N95 face masks (also

referred to as respirators or N95 respirators) in light of potential shortages of these devices.

- The Task Force conducted an accelerated review of mask reprocessing options using ultraviolet light, heat and microwaves, and chemicals such as carbon hydrogen peroxide.
- The recommendations in this report are consistent with current practices and plans supported by PHAC and Health Canada.
- Since the report was submitted, Health Canada has approved additional reprocessing technologies. The Department continues to evaluate all COVID-19-related technologies in a timely manner.

#### Legislative amendments

## Key messages regarding 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 that help prevent or alleviate shortages of drugs and medical devices
  - Request additional information from companies that produce food, drugs, cosmetics or medical devices to assess the risks and benefits of new products and to confirm that they are safe for Canadians
  - Obtain authorization from third-party manufacturers to provide necessary patented inventions, such as a medication or medical equipment, as may be required to combat the pandemic
- These measures received Royal Assent on March 25, 2020, and came into effect immediately.
- 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 the necessary steps to continue protecting the health and safety of Canadians during this pandemic and will take appropriate action, in collaboration with the provinces, territories and other stakeholders, to protect the supply of essential drugs and medical devices in Canada.

# Consistency of these amendments with the Protecting Canadians from Unsafe **Drugs Act (Vanessa's Law)**

- These amendments complement the powers granted by *Vanessa's Act*.
  - By granting the authority to collect additional safety information to guide decisions about new products entering the Canadian market or products already on the market

By broadening powers to include other potential new products, including cosmetics and foods for special dietary use that may be required to address shortages during the pandemic

### Temporary exemption for medical treatment under the Controlled Drugs and Substances Act

- Many people with substance use disorder or who live with chronic pain may find it challenging to effectively practise 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 practise, this exemption will:
  - Permit pharmacists to extend and renew prescriptions
  - Permit pharmacists to transfer prescriptions to other pharmacists
  - 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 health care 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 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 ongoing COVID-19 pandemic is having a significant impact on Canadians and the health care system. The Government of Canada must ensure that it can effectively respond to the needs of those affected.
- In response to the COVID-19 pandemic, the Minister of Health signed an Interim Order to help prevent and address shortages of drugs, medical devices and foods for special dietary use resulting directly or indirectly from the COVID-19 pandemic.
- Once it comes into force, the Order will allow the importation and sale of products that are not registered in Canada, 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 that may be imported and sold under the Interim Order. Manufacturers of drugs and medical devices will be required to meet strict monitoring requirements.
- The Interim Order will also require companies that manufacture and import medical devices deemed essential during the COVID-19 pandemic to report existing or anticipated shortages, as is currently the case with drugs. This will allow the health systems to better prepare and redistribute materials as needed to provide Canadians with ongoing access to these products.
- The Interim Order will also enable faster market access for certain hard-surface disinfectants and hand sanitizers on the market.
- Together, these measures will improve access to the drugs, medical devices and foods for special dietary use that Canadians need to stay healthy and safe, and help patients 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:
  - o the Roche Molecular Systems Inc. cobas SARS-CoV-2 diagnostic device
  - 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 U.S. directive to allow unauthorized health products

- Health Canada will continue to use every tool 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.

#### Unilingual product labelling for COVID-19

- Health Canada's top priority is the health and safety of Canadians. Accordingly, the Department is doing everything possible to facilitate access to products required to slow the spread of COVID-19.
- Health Canada is committed to meeting the requirements of the Official Languages Act and promoting linguistic duality.
- Typically, bilingual labelling, instructions and safety information is required for all products sold in Canada.
- In light of the exceptional demand and urgent need for products to limit the spread of COVID-19, Health Canada has decided to facilitate interim access to certain imported products that may be labelled in only one official language to increase access to highdemand products.
- Many global suppliers have indicated that they label products in English only to expedite production and will only ship to countries that accept English-only labels.
- These products include household cleaners, cleaning products used in the workplace, hand and body soaps, hard-surface disinfectants and hand sanitizer.
- Effective immediately, all new importers of these products under the Interim Order must make a bilingual label available to consumers. Pre-authorized importers will be required to provide a bilingual label on their website and provide sellers with a way 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-licensed manufacturers of hand sanitizers that currently use unilingual labelling under the interim measures must move to bilingual labelling by June 8, 2020.

- Last updated: May 2020
- To mitigate the risks associated with unilingual labelling, importers are required to post a bilingual label on their website. They must also provide sellers with a way to inform consumers of the website where the bilingual information can be found at the time of sale. This could be done by placing a sticker directly on the products, putting up posters or distributing pamphlets at the point of sale.
- Health Canada continues to strongly encourage companies importing products into Canada to use bilingual labels.
- Health Canada will lift these interim measures once the normal supply of these products becomes more stable.

# If pressed on interim measures aimed at facilitating market access to certain hard surface disinfectants and hand sanitizer:

- Health Canada is allowing the importation of hand sanitizers and disinfectants from countries with similar regulatory frameworks and quality assurance requirements to Canada's as an interim measure to address the shortage of these products.
- Although Health Canada is making it easier to access imported products labelled in only one official language during the shortage, the use of bilingual labels is still strongly encouraged.
- To mitigate the risks associated with unilingual labelling, importers of affected products are required to post a bilingual label on their website. They must also provide sellers with a way to inform consumers of the website where the bilingual information can be found at the time of sale. This could be done by placing a sticker directly on the products, putting up posters or distributing pamphlets at the point of sale.
- Effective immediately, all new importers of these products under the Interim Order must make a bilingual label available to consumers. Pre-authorized importers will be required to provide a bilingual label on their website and provide sellers with a way 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-licensed manufacturers of hand sanitizers that currently use unilingual labels as part of the interim measure must use bilingual labels by June 8, 2020.
- Health Canada will take a risk-based approach to address reported non-compliance.

#### If pressed on the expected duration of these measures:

Health Canada's priority is to ensure that Canadians have access to products required to slow the spread of COVID-19.

Health Canada will lift these interim measures once the normal supply of these products becomes more stable.

# If pressed on interim policies aimed at facilitating market access to household cleaners, commercial cleaning products, 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, material safety data sheets be in both official languages. One of the permitted flexibilities under 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 address a current or potential shortage in the supply of cleaning products and hand and body soaps that can be used to combat the COVID-19 pandemic. The flexibility will make it easier to import these products from the United States, where product labelling may not be available in both official languages.
- Although Health Canada is making it easier to access imported products labelled in only one official language during the shortage, the use of bilingual labels is still strongly encouraged.
- To take advantage of interim policies, importers of affected products are required to post a bilingual label and, where applicable, bilingual safety information on their website. They must also provide sellers with a way to inform consumers and employers of the website where the bilingual information can be found at the time of sale. This could be done by placing a sticker directly on the products, putting up posters or distributing pamphlets at the point of sale or use. This requirement is effective immediately for all new importers of these products under the interim policies. Importers that have already provided a form must meet the requirements by June 8, 2020.
- Canadian manufacturers of cleaning products and hand and body soaps are not included in these interim policies because they are able to provide bilingual labelling and material safety data sheets (if applicable) for their products. As a result, Canadian companies that manufacture these products must continue making products with labels and material safety data sheets, where applicable, in both official languages.
- Health Canada is also working to communicate with Canadians in both official languages through our Recalls and Safety Alerts database and social media to keep them informed about these products. Canadians are also encouraged to visit Health Canada's website, which provides links to information in both official languages from industry websites.
- Health Canada will take a risk-based approach to address reported non-compliance.
- Health Canada will lift these interim policies once the normal supply of these products becomes more stable.

# **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 front-line 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 0 purposes
  - Foreign nationals entering Canada if they arrive from a foreign country other 0 than the United States, with some exceptions, including temporary foreign workers and international students
  - Foreign nationals entering from the U.S. with signs or symptoms of 0 respiratory illness

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

- Canada and the U.S. 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 U.S. 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 app

- Under the emergency orders issued under the Quarantine Act, any person entering Canada must quarantine (self-isolate) or isolate for 14 days.
- To ensure compliance with the order, all travellers entering Canada are required upon entry to provide the Government of Canada with essential contact information, report their symptoms and confirm that a quarantine plan has been prepared.
- Currently, this information is collected using a paper or web form upon entry into Canada.
- The ArriveCAN app, rolled out during the week of April 29, is an alternative to paper forms that can expedite the entry process at the Canadian border. Travellers are encouraged to use it.
- With ArriveCAN, travellers can enter their information quickly, easily and safely into a digital version of the Coronavirus Form as soon as they arrive in Canada.
- Electronic declarations add additional protection to travellers and border and quarantine officers by reducing physical contact.
- The application collects exactly the same information that is required on the paper and online Coronavirus Form.
- Additional information is now requested from travellers, such as flight or border crossing information, whether they have COVID-19 symptoms and whether they have a quarantine plan in place.
- The personal information collected on the paper or online form or the application created by border and guarantine officers will allow the Public Health Agency of Canada to verify that travellers are complying with the Quarantine Act. The information will be shared with the provinces and territories and law enforcement agencies to ensure compliance with the order.
- Protecting the privacy of Canadians' personal information is a priority of the Government of Canada. Any tool used to collect personal information is subject to 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 under the Quarantine Act and the Department of Health Act. Personal information may be used or disclosed for the following purposes: (1) monitoring or verifying compliance with the mandatory isolation order and penalizing violations; (2) providing information to help travellers comply with the isolation order; and (3) for public health follow-up.

- Under the Privacy Act and the Privacy Regulations, CBSA and PHAC are required to retain personal information under their control. Personal information used for administrative purposes, such as that collected through the app, is kept for a minimum of two years from the date it was last used.
- The ArriveCAN app supports Canada's digital strategy for service delivery to Canadians and enhances efforts to go green.

#### Non-essential travel restriction (Canada–U.S.)

- 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 a temporary 30-day restriction on all nonessential travel at the Canada-U.S. border. This initial period of 30 days may be renewed.
- All travel of an optional or discretionary nature, including but not limited to 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 or study
  - o 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
  - Other activities at the discretion of the border services officer.
- 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.

# The Government of Alberta introduces enhanced screening measures at border crossings and ports of entry

- Federal officials are responsible for screening all travellers entering Canada. In the course of their duties, they follow the latest guidelines, which include the requirement for travellers with COVID-19 symptoms to report them.
- The Government of Canada is aware of Alberta's new health screening measures at points of entry, which include temperature checks.
- To prevent the spread of COVID-19 from international points of entry, the Government of Canada is working closely with all levels of government to ensure consistent public health measures across all provinces and territories.
- To prepare its response to the COVID-19 pandemic, the Government of Canada is working with its provincial, territorial and international partners to develop risk-based approaches based on the latest science and assessments of the situation in Canada's provinces and territories.
- Public health authorities are closely monitoring the outbreak in Canada to see when there will be a stable and sustained downturn, while carefully considering options for easing public health restrictions when and where possible.
- Because the epidemiology of COVID-19 differs in each province and territory, public health measures will vary from one province or territory to another, and even from one region to another.

### Order in Council 10 - Mandatory Isolation

- The Government of Canada's top priority is to ensure the health and safety of Canadians. We are taking unprecedented action to address the COVID-19 outbreak. This includes continually assessing the risks so that we can adapt our response accordingly.
- The emergency order put in place by the Government of Canada under the Quarantine Act already requires people entering Canada by air, land or sea to isolate for 14 days if they have COVID-19 or to be guarantined for 14 days if they are asymptomatic in order to limit the spread of the disease.

- An updated order will be issued to clarify the terminology. It is based on new scientific evidence that asymptomatic individuals can spread the virus.
- Under the updated order, travellers arriving in Canada, symptomatic or asymptomatic, may not isolate or quarantine (as appropriate) in a place where they could encounter vulnerable people, such as adults 65 years of age or older or those with pre-existing medical conditions.
- Each traveller will also need to confirm that they can isolate or quarantine in a suitable location where they will have access to basic necessities such as food and medication. Travellers will need to make isolation or quarantine arrangements before arriving in Canada. Those who do not have a suitable place to isolate or quarantine will have to go to a location specified by the Chief Public Health Officer of Canada. These are new criteria for asymptomatic travellers.
- Compliance with this order is mandatory of anyone arriving in Canada on or after April 15, 2020.
- If a traveller is symptomatic and does not have private transportation or a suitable location to isolate, they will be required to isolate for 14 days in a location specified by the Chief Public Health Officer of Canada.
- Asymptomatic travellers are still at risk of infecting others and must wear a non-medical mask or facial covering (e.g. constructed to completely cover the nose and mouth without gaping, secured to the head by ties or ear loops) while en route to their destination where they will be quarantined for 14 days. They will be required to follow the directions of the public health authority identified by the screening officer or quarantine officer if they develop signs and symptoms of COVID-19. Masks will be provided to travellers who do not have one.
- Symptomatic travellers are also required to wear a non-medical mask or facial covering while en route to their final destination where they will be required to isolate, or when they cannot physically stand more than two metres away from others.
- Asymptomatic travellers who do not have a suitable location to quarantine are subject to the same requirements as symptomatic travellers and are required to go to a location specified by the Chief Public Health Officer of Canada.
- https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirusinfection/latest-travel-health-advice.html#a3. Various individuals 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 needing to quarantine as long as they are asymptomatic (do not have symptoms of COVID-19).
- These individuals are required to wear a non-medical mask or facial covering while en route to their final destination. On arrival at their destination, exempted individuals should practise physical distancing, consider wearing a mask or other facial covering when unable to practise physical distancing and stay more than 2 metres away from

others, monitor their symptoms, stay home when possible and follow the instructions of the local public health authority if they feel ill.

- We have based this decision on the latest science and our discussions with the provinces and territories.
- These additional measures will help contain the outbreak and stop the spread of COVID-19 in Canada.
- They will also help protect the elderly and those with pre-existing health conditions, who are at greater risk of developing serious complications from COVID-19.
- The Government of Canada will continue to work closely with its regional, provincial, territorial and international partners to limit the spread of COVID-19.

#### On enforcement

- The Government of Canada will conduct spot checks to verify compliance.
- Penalties for failure to comply with this order include a fine up to \$750,000, six months' imprisonment, or both.
- Anyone who causes a risk of imminent death or serious harm to another person through a wilful or negligent violation of the Quarantine Act is liable to a fine of up to \$1,000,000, three years' imprisonment, or both.
- Amendments to Quarantine Act offences under the Contraventions Regulations are ongoing. They will be designated as contraventions subject to fines.
- Amounts could range from \$75 to \$1,000. The fine for a young person is \$100.

#### Designated quarantine facilities:

- The Chief Public Health Officer has designated quarantine facilities, such as hotels, across the country, including Vancouver, Calgary, Toronto and Montreal.
- Under section 7 of the Quarantine Act, the Chief Public Health Officer may designate any place in Canada as a quarantine facility to protect the health of Canadians, if she considers it necessary.

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

 Foreign nationals who may enter Canada include temporary foreign workers, certain students, individuals delivering emergency medical supplies and certain types of refugee claimants, including those who arrive in Canada at land ports of entry and are able to make a claim for refugee protection under the Safe Third Country Agreement (STCA).

- Last updated: May 2020
- All foreign nationals authorized to enter Canada must meet the requirements of the emergency orders made under the Quarantine Act, including a mandatory 14-day quarantine after entry into Canada, unless they have been granted a specific exemption. They must also comply with provincial and territorial emergency orders and local health guidelines.
- Foreign nationals are generally not allowed to enter Canada for optional or discretionary reasons or if they have COVID-19 symptoms.
- Temporary foreign workers are necessary to our food industry and supply resilience so that all Canadians have access to essential food and supplies during the pandemic.
- The Minimizing the Risk of Exposure to COVID-19 in Canada Order (Prohibition of Entry into Canada from the United States) is in effect from April 22, 2020, to May 11, 2020.
- Amendments to this Order will ensure that Canada continues to meet its international obligations with respect to refugees and refugee claimants.
- These measures will help prevent the spread of the disease in Canada, while ensuring that essential travel and supply chains are not disrupted.

# On foreign nationals who wish to apply for refugee protection

- Foreign nationals entering Canada between official ports of entry to file a refugee claim will still be returned to the United States, a designated safe third country.
- The entry ban will not apply to any foreign national from the United States who arrives in Canada at an official land port of entry and meets the criteria for an exemption from the STCA—whether or not they are symptomatic. The foreign national will then be able to make a refugee claim.
- Claimants who are unable to meet Canada's quarantine/isolation requirements will be directed to a federal facility.

#### On the 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, six months' imprisonment, or both. In addition, anyone who intentionally or recklessly contravenes the Act or its regulations and exposes another person to an imminent danger of death or serious bodily harm may be liable to a fine of up to \$1,000,000 or imprisonment for up to three years, or both.
- Amendments have also been made to the Contraventions Regulations, making failure to comply with specific requirements under the Quarantine Act a contravention that may result in a ticket being issued.
- These tickets carry a fine ranging from \$275 to \$1,000. For young offenders, the fine is \$100.

# On essential travel to Canada by foreign nationals via the United States

Essential travel will continue without restriction. Both governments recognize the importance of sustaining vital supply chains between both countries. These supply chains ensure that people on both sides of the border have access to food, fuel and essential medicines.

## If pressed

Foreign nationals who are permitted to enter into Canada include:

- Individuals who arrive in Canada at an official land port of entry and may request refugee protection under the Safe Third Country Agreement.
- Persons registered as Indians under the Indian Act.
- Protected persons.

In addition, as long as they are seeking entry into Canada for a purpose that is not discretionary or optional and do not exhibit COVID-19 symptoms, foreign nationals in the following categories may also enter Canada.

Foreign nationals in these categories must still prove that they are travelling to Canada for essential reasons 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-Miguelon, 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;

- Last updated: May 2020
- 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:
  - o Fever
  - o 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 arrival 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 determine whether the visit is essential.
- 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 whom 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.

- Last updated: May 2020
- 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.

# **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 recommendations will continue to change because the situation is rapidly evolving and we are learning more about the COVID-19 every day.
- Based on the available evidence, we are asking Canadians to avoid non-essential travel to limit the spread of COVID-19, especially in small and rural communities where health care systems could be easily overwhelmed.
- That is why we are asking everyone to stay away from cottages, campgrounds and vacation properties during the COVID-19 pandemic.
  - Unless the property is your primary residence or is in the same community as your primary residence, you should wait until the situation in Canada changes before going there.
  - If you get sick, you may not be able to get the help you need. If you stop on the way to get gas or groceries, your risk of exposure increases and, if you are asymptomatic, you could spread the virus to others.
  - An influx of people into a small community can also strain the supply of food and other essential supplies for residents.

- If you need to go to your cottage for insurance reasons, you should only make a day trip and return directly to your 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 on the issue of human exposure to radiofrequency electromagnetic energy is to conduct research on possible health effects, review the relevant scientific literature and develop exposure guidelines commonly referred to as Safety Code 6.
- Safety Code 6, which covers the frequency range used by 5G technology, meets or exceeds internationally accepted standards and is based on a thorough review of the scientific literature. The health of Canadians is protected when exposure limits outlined in Safety Code 6 are met.
- There is no scientific basis for the recent suggestion linking the roll out of 5G networks with the COVID-19 outbreak. The World Health Organization and the International Commission on Non-Ionizing Radiation Protection have also recently shared this message on their websites. Go to Canada.ca/coronavirus for details on transmission of COVID-19.