COVID-19
EVERGREEN QUESTIONS AND ANSWERS

Questions and Answers

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Q252. Is there an estimate in terms of how many ICU beds Canada will require as the epidemic reaches its peak? And how many ICU beds are available now? 1

Q253. How many ventilators does Canada have now, and how many would be needed when the epidemic reaches its peak? 1

Q254. What is the federal government doing in terms of increasing the supply of ventilators and masks? 1

Q255. Is Health Canada reaching out to the three RCMP forensic labs to provide personal protective equipment to health care workers? 1

Q256. Will the federal government consider to have a plan in place to increase the speed of donated medical supplies to fulfil the medical equipment shortage? 1

Q257. Does Canada have a stockpile of syringes/needles or other vaccination-related equipment for a pandemic immunization campaign? 1

Q258. Will Health Canada ensure there is an adequate supply of immunization supplies for when a COVID-19 vaccine is eventually available? 1

Q259. What is the current wait time for Canadian PPE manufacturers (not importers) to receive approval to sell and distribute their products to healthcare facilities? How many firms are currently waiting for these certificates? 1

Q260. What has the response been to the call by the federal government for medical devices that we are low on (http://www.ic.gc.ca/eic/site/080.nsf/eng/00048.html)? 1

Q261. How has Canada resolved the mask shortage when the U.S has yet to do so? 1

Q262. What are PHAC's forecasts for how much PPE will be needed across industries for when the economy fully reopens? Is there a breakdown by sector and by region? 1

24. ***Distribution and quality control*** ***1***

Q263. When did Canada start to procure personal protective equipment and supplies to prepare for COVID-19? 1

Q264. How much PPE was exported to China from mid-January through March 31, through all known channels (institutional, retail, community)? 1

Q265. Where will medical supplies be stored before they are distributed by Canada Post or Purolator to hospitals? 1

Q266. How many shipments have been sent using Amazon Canada to send PPE to the provinces as of May 1st? 1

Q267. Do you ever have concerns about the quality/standard of medical equipment donated to Canada? 1

Q268. Has the Public Health Agency of Canada rejected any donated supplies that it has quality controlled? Has any equipment failed quality control tests in the last two months? 1

Q269. What happens to those items that fail inspection? Are they destroyed? Shipped back to donor country? 1

Q270. How many shipments of N95 masks have been inspected and a) accepted and b) rejected? 1

Q271. Does the government have any requirements on the standards of medical supplies used by local health agencies? If so, what are they? 1

Q272. How many swabs did Canada receive to date and how many have been distributed? 1

Q273. Recent media coverage has highlighted that during the week of April 6, Canada received 320,000 swabs from China that were contaminated with mould. What measures are being taken to ensure that this does not happen again? Is there other medical equipment coming from China that could not be used because it does not meet Health Canada's criteria? 1

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Q368. Can you explain why the number of warehouses stocking supplies from the National Emergency Strategic Stockpile was reduced, and whether that led to a reduction in the amount of PPE that was stockpiled by the federal government? 1

Q369. In the early 2000s, NESS had 165 completely equipped portable hospitals. It had 33,000 beds (hospitals beds/cots) during 9/11 19,000 of them were deployed to NS and Nfld. What happened to those stocks? 1

Q370. In the early 2000s, there were 10 regional warehouses, there are now five. On what basis was the decision made to rationalize the number of locations? 1

Q371. Has the NESS stockpile changed in the last 10 years? Has it diminished or deteriorated since 2015 and has there been any specific policy/funding changes through governments? 1

Q372. The rationalization of the NESS stockpile put more emphasis on pharmaceuticals than nuts and bolts medical equipment. Can you confirm that and explain the rationale? 1

VACCINE AND TREATMENT 1

Q373. Is there a vaccine that protects against coronaviruses in humans? If none are currently approved, are there any that are in development or being tested? 1

Q374. Canada is spending millions to fund vaccine research. If a Canadian group successfully develops a vaccine, will early doses go to Canadians first? Is that an explicit condition of any Canadian funding? 1

Q375. Would Canada impose any exports limits on vaccine doses to ensure material manufactured in Canada is available to Canadians? 1

Q376. Has Canada made a commitment to donate 10% of the stockpile to the WHO? What is Canada doing to ensure vaccines are accessible where they are needed most? 1

Q377. Does Canada already have in place a contract for a pandemic vaccine from a supplier able to produce large quantities when the time comes? 1

Q378. How long will it take to develop a vaccine? 1

Q379. How will Canada secure a Canadian supply of an eventual COVID-19 vaccine in an open market against other countries also seeking to secure their own supplies? 1

Q380. Once a COVID-19 vaccine is available, how will Canada produce or obtain enough doses required for Canada? 1

Q381. Is the PVC13 vaccine, used against pneumonia, useful as a therapy against COVID-19? 1

Q382. How are people being treated for this illness? 1

Q383. Is Health Canada investigating these reports and is there any current direction regarding the use of Vitamin C as a defence or treatment against the coronavirus? 1

Q384. Are there safety issues with the use of ibuprofen in COVID-19 cases? 1

Q385. Can Hydroxychloroquine and azithromycin be used to treat any patient who is infected with COVID-19? Will they be effective for everyone? 1

Q386. Does Health Canada have an official position on Hydroxychloroquine and chloroquine for treating COVID-19? 1

Q387. What is Health Canada doing about products claiming to prevent, treat or cure COVID-19? 1

Q388. What actions will Health Canada take in case of non-compliance related to health products claiming they can cure, treat or prevent COVID-19? 1

Q389. Are there any natural health products, including traditional Chinese medicines, Ayurvedic medicines and homeopathic products to protect against or treat this virus? 1

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CANADA'S SITUATION

Q1. What is Canada doing in response to the current pandemic situation?

Our top priority is the health and safety of Canadians. The Public Health Agency of Canada is actively monitoring the situation regarding the novel coronavirus (COVID-19) and continuously assessing the risks to adapt our response, accordingly.

The Government of Canada has created the infrastructure to respond to the public health threats of the virus, and is well prepared to act—in collaboration with provincial and territorial governments and international partners—to minimize the health, economic, and social impacts of this rapidly evolving public health issue.

Canada's response is based on plans and guidance related to pandemic preparedness, with the following guiding principles:

- **Collaboration** - all levels of government and stakeholders need to work in partnership to produce an effective and coordinated response.
- **Evidence-informed decision-making** - decisions should be based on the best available evidence.
- **Proportionality** - the response to a pandemic should be appropriate to the level of the threat.
- **Flexibility** - actions taken should be tailored to the situation and evolve as new information becomes available.
- **A precautionary approach** - timely and reasonable preventive action should be proportional to the threat and informed by evidence to the extent possible.
- **Use of established practices and systems** - well-practised strategies and processes can be rapidly ramped up to manage a pandemic.
- **Ethical decision-making** - ethical principles and societal values should be explicit and embedded in all decision-making.

These principles build on lessons learned from past events, particularly the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003, which led to dedicated legislation, plans, infrastructure, and resources to help ensure that the country would be well prepared to detect and respond to a pandemic outbreak. Some examples include:

- The creation of the Public Health Agency of Canada, which monitors and responds to disease outbreaks that could endanger the health of Canadians.
- The appointment of a Chief Public Health Officer, who advises the Government of Canada and Canadians on the steps they should take to protect their health, working in close collaboration with the chief medical officers of health in provinces and territories.
- The development of the Canadian Pandemic Influenza Preparedness: Planning Guidance for the Health Sector, which sets out guidance to prepare for and respond to a pandemic.
- The enhancement of diagnostic capacity in the National Microbiology Laboratory.
- The strengthening of working relationships with the World Health Organization and other international partners, such as the United States Centers for Disease Control and Prevention.

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While the Government of Canada has been focusing on containing the spread of COVID-19, it has also been undertaking coordinated planning to prepare for possible broader transmission of the virus, and to mitigate the impacts of this pandemic.

To support these efforts, the Prime Minister convened an **Incident Response Group on coronavirus**, which has been meeting since the end of January, and, on March 5, he created a **Cabinet Committee on the federal response to the coronavirus disease (COVID-19)**. Chaired by the Deputy Prime Minister and vice-chaired by the President of the Treasury Board, the committee meets regularly to ensure whole-of-government leadership, coordination, and preparedness to limit the health, economic and social impacts of the virus.

Q2. When did the Public Health Agency of Canada first learn about COVID-19?

The Public Health Agency of Canada (PHAC) first learned about an "undiagnosed pneumonia" in China on **December 31, 2019**, following information picked up overnight and shared through its Global Public Health Information Network (GPHIN).

On **January 2, 2020**, a written message about the situation was sent by Canada's Chief Public Health Officer to provincial and territorial colleagues across the country. Similarly, PHAC's National Microbiology Laboratory (NML) sent an alert to a network of federal and provincial public health laboratories on January 2, 2020.

With respect to laboratory preparedness, PHAC's NML convened a meeting on **January 7, 2020** with directors of the provincial public health laboratories across Canada to discuss pandemic preparedness and review guidance documents in light of the unfolding situation in Wuhan, China.

Initial discussion included preparations needed to establish federal, provincial and territorial testing capabilities and the process for submitting samples to the NML if the virus were to be imported into Canada through returning travellers.

PHAC officially activated the Health Portfolio Operations Centre in **mid-January** to ensure effective planning and coordination of the Agency's response efforts, in collaboration with international and federal, provincial and territorial partners. The Federal/Provincial/Territorial Response Plan for Biological Events and the Federal/Provincial/Territorial Special Advisory Committee on COVID-19 was activated on **January 28, 2020** to ensure a coordinated response across Canada.

On **January 26, 2020** the NML received the first "presumptive positive" specimen from our partners at Public Health Ontario from a returning traveller suspected of having COVID-19. Scientists from the NML tested the specimen and confirmed Canada's first case of COVID-19 on **January 27, 2020**.

Usually laboratories already have highly characterized samples of the virus they are trying to detect so that they are confident that their tests can accurately detect cases. Although it is possible to rapidly develop new tests based upon the genome sequence of the virus—given that this was a novel virus—we did not yet have samples of SARS-CoV-2 when these first cases arrived in Canada. Therefore, the lab instead gained confidence in the results by using a multitude of tests to investigate these early specimens, including tests designed in both Canada and Germany. We also performed genetic sequencing on the early specimens to provide the final confirmation that these early cases were truly positive for COVID-19.

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Once the first few cases were confirmed, laboratory extractions from the specimens were sent to provincial public health laboratories across Canada so that they too could offer testing in their labs with high confidence that the results were accurate. It was during these early days that the NML confirmed that all cases and presumptive positives underwent additional testing at NML. Soon after, by working with the Vaccine and Infectious Disease Organization and the Sunnybrook Hospital (where the first case was admitted), the SARS-CoV-2 virus was cultured from patient specimens in appropriate biocontainment settings (containment level 3 labs) so that labs had ample material to study the virus, and importantly, to proceed with quality assurance processes. Using these materials or by studying local cases, provincial laboratories conducted extensive studies on how well their tests were performing, and they then started issuing confirmed cases directly, without needing further tests done at the NML.

With the availability of tests to detect cases of COVID-19, and with testing capacity expanding across Canada, it was important that a national testing strategy be developed in collaboration with provincial and territorial health authorities. This strategy continues to be refined today, not only as more testing capacity is brought forward, but as the pandemic continues to evolve in response to Canada's public health efforts. Beyond detecting new cases of COVID-19, this testing strategy will aim to identify and end chains of transmission, as well as prevent transmission in and among high-risk settings and populations.

Q3. Is Canada planning to use WHO guidelines for reopening the economy and the borders to base its plan?

Canada has a strong history of pandemic planning and has been a leader internationally on this front. The 2006 pandemic plan was released after SARS and leveraged for our response to the previous H1N1 pandemic. Since H1N1, we've been continuously updating our plan. One of the key lessons we learned from H1N1 is that we need a flexible and scalable approach to planning.

We are carefully reviewing the World Health Organization's COVID-19 Strategy Update, in consultation with our partners. In the meantime, our public health efforts will continue to focus on reducing the spread of the virus by rapidly identifying cases, finding close contacts and using tried and true public health measures such as isolation and physical distancing.

We are continually evaluating the impact of our public health measures on the number of cases reported and we are adjusting them as needed in collaboration with our provincial and territorial partners. Our response must be based on evidence because our understanding of the science of COVID-19 continues to grow.

Q4. What was Dr. Tam's role in co-authoring the Interim Report on the WHO's Response to COVID-19 from January-April 2020? Does she represent the Government of Canada?

- Dr. Tam is a member of the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme. The Committee provides advice to the WHO Director General and reports its findings through the WHO Executive Board to the World Health Assembly. Members serve in their personal capacity and exercise their responsibilities with full regard for the paramount importance of independence. The Committee has provided recommendations to strengthen the WHO Emergencies Programme in terms of human resource practices, use of innovative technologies in outbreak response and application of lessons learned from previous responses.

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- Dr. Tam does not represent the Government of Canada in her role on the IOAC.

- This position is voluntary and is not remunerated by the WHO.

Q5. Is Dr. Tam on any other WHO committees on COVID-19?

- At this time, Dr. Tam is not a member or an advisor on any other WHO committees.

- Dr. Tam served as an Advisor to the International Health Regulations (IHR) Emergency Committee for Pneumonia due to the Novel Coronavirus 2019-nCoV for its first and second meetings. The members of an IHR Committee are drawn from the IHR Expert Roster established under Article 47, which includes experts in all relevant fields of expertise, and from the members of the WHO Expert Advisory Panels. Members and advisors are selected on the basis of expertise required for any particular session. As the situation concerning the COVID-19 pandemic has evolved significantly since January, the Director-General made adjustments to the members and advisors to the committee, and Dr. Tam is no longer an advisor to the Committee.

- This position was voluntary and was not remunerated by the WHO.

Q6. The review recommends that Member States review WHO financing for its Health Emergencies Programme. What are Canada's contributions to the WHO? Will Canada increase its contributions?

- Canada provides both assessed (mandatory) and voluntary contributions to the WHO each year.

- The level of assessed contributions is agreed to by Member States at the World Health Assembly, and has stayed relatively steady over the past several years. Canada provided $17.5 million for its assessed contributions for 2020, in full and on time.

- The vast majority of Canada's voluntary contributions to the WHO are provided by Global Affairs Canada (GAC). Over the past ten years, on average, Canada has provided more than $70 million annually in assessed and voluntary contributions to support the work of the WHO.

Q7. Has Canada provided funding to the WHO for the COVID-19 response?

- Canada has and will continue to support WHO's leadership to help address the current outbreak of COVID-19.

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- Since February 11, Canada has provided $15.5 million to the WHO, and a further $1.5 million to the Pan American Health Organization (PAHO)—the WHO regional office for the Americas—to help vulnerable countries prepare and respond to COVID-19.

- On April 5, 2020, Canada announced the allocation of $159.5 million in funding to support international efforts to fight the COVID-19 pandemic. The allocation includes additional contributions to the WHO.

Q8. The interim report provides recommendations to the WHO to improve its response in a number of areas. Is Canada confident in the ability of the WHO to lead this global response to COVID-19? Does Canada agree with the recommendations?

- Canada is confident that the WHO is taking an evidence-based approach in its response to the pandemic and ensuring that the technical advice it provides is based on the best available science and evidence.

- Canada values the WHO's leadership and coordination role in the COVID-19 response, including its role overseeing the International Health Regulations, driving collaborative global research efforts towards new vaccines and effective treatments, working with all actors to address shortages of critical medical supplies and personal protective equipment, and supporting the most vulnerable countries in their preparedness and response efforts.

- Canada also values the important work of the IOAC, which serves an invaluable role in independently assessing the performance of the WHO Health Emergencies Programme. The recommendations of the IOAC will provide a good evidence-based, objective foundation for further post-crisis discussions as to how global responses to health emergencies can be improved.

- The IOAC recommendations are aligned with many of the actions being put forward by Member States in the COVID-19 resolution adopted by the World Health Assembly (WHA) this week. This includes the calls for an independent assessment of the COVID-19 response, examining both Member States and the WHO Secretariat, undertaken "at an appropriate time," to assess performance during the response and to identify lessons for the future. Canada has made it clear for many weeks now that it would support a comprehensive review of the global response post-crisis and is pleased to be a co-sponsor of this WHA resolution.

INFORMING CANADIANS

Q9. Where can Canadians find the most up-to-date information about this coronavirus?

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For the latest and most up-to-date information, visit canada.ca/coronavirus. You can also follow Canada's Chief Public Health Officer, Dr. Theresa Tam, on Twitter at @CPHO_Canada.

A new toll-free phone number (1-833-784-4397) has been established to answer questions from Canadians about the 2019 novel coronavirus. Service is available from 7 a.m. to midnight.

Canadians travelling abroad are encouraged to consult the Travel Health Notice on travel.gc.ca.

Q10. Why is the Government of Canada running an ad campaign about COVID-19?

The Government of Canada is implementing a comprehensive national public education campaign for COVID-19 that will provide Canadians with credible information on behaviours that will protect individuals and overall public health. The campaign will include advertising, social marketing, the development of information resources, the establishment of partnerships and targeted outreach to at-risk populations. This work will complement current Public Health Agency of Canada outreach and communications activities such as the website for information on COVID-19 with a virtual assistant to help Canadians get to the information they need more efficiently, a toll-free information line, a self-assessment tool, digital advertising, social media posts, and regular updates to media.

Public education plays a critical role in our response to COVID-19 as it helps to:

- increase awareness and understanding about symptoms and treatment;
- provide information on preventive measures such as self-isolation; and
- address misinformation and public concerns.

Ads are planned for a number of ethnic radio and print paper by the end of April 2020. However, given the current situation where certain print outlets are closed and we need to find alternatives, we are unable to provide a list of specific media outlets and timelines.

Virtual Health Tools Announcement

On Sunday, May 3, 2020, the Prime Minister announced $240.5 million in funding to develop and launch virtual health tools to support Canadians.

Q11. What, specifically, will the money be spent on?

This funding will further enable the development and reach of:

- The **Canada-COVID-19 mobile app**, which provides Canadians with access to a symptom tracker, credible sources of information and resources, and a **self-assessment tool**;

- The **Wellness Together Canada** portal, which makes it easy for Canadians to access self-directed tools and find credible information on mental health and substance use. It also connects Canadians to peer support workers, social workers, psychologists and other professionals for confidential chat sessions, phone calls and online counselling; and,

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- **Artificial Intelligence capacity**, which will help gain further insights and understanding in to the emergence, spread and public health risks of COVID-19: Health Canada and the Public Health Agency of Canada have put in place contracts with BlueDot to enhance and expand upon existing expertise in this field.

In addition, the Government of Canada is working with provinces and territories, and in collaboration with Canada Health Infoway, to support the use and adoption of virtual care services. This means that Canadians can continue to have their regular health needs met in a safe and secure manner, via telephone, text, or video-conferencing, in addition to face-to-face visits.

Q12. Do you have a breakdown of the how the money will be spent?

Our government is committed to working collaboratively with provinces and territories to determine priorities for this investment. Health Canada is already engaging with provinces and territories, as well as with Canada Health Infoway to identify where additional support is needed in terms of virtual care technology and infrastructure.

The majority of this funding ($200 million) will be used to support Canadians having improved access to needed health services through virtual tools and approaches. We are working with provinces and territories to map out where virtual tools are needed most so that Canadians can continue to receive the high-quality care they expect from Canada's health systems.

The remaining balance of this funding ($40.5 million) is supporting a growing suite of digital solutions and tools, including Wellness Together Canada and the Canada COVID-19 app.

Q13. Will a contact tracing app be part of this funding announcement? If so, how will the Government of Canada ensure Canadians' data is protected?

Rigorous contact tracing by provincial and territorial public health authorities continues to be an important part of Canada's COVID-19 response. Recognizing the importance of tracking the virus and preventing future flare-ups, the Government of Canada's National Volunteer Recruitment Campaign included a call-out for volunteers to help provincial and territorial authorities with case tracking and contact tracing for COVID-19.

Our government is aware that many contact tracing tools are being developed to help digitize the contact tracing process, including through mobile apps, and is monitoring these developments closely. It is important that such apps protect the privacy and security of users. Privacy considerations will continue to be front and centre at every stage of any initiative undertaken by the Government of Canada.

Q14. There vulnerable populations in Canada who are being affected by COVID-19. Will any of this funding address their unique needs?

Health Canada is exploring ways to support a variety of populations in the deployment of virtual health services. Community partners could potentially use virtual technologies, particularly secure messaging and videoconferencing, in a way that addresses unique needs of vulnerable populations. However, important discussions are needed with provincial and territorial partners on the implementation of these tools.

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Canada COVID-19 App

Q15. How do I access the Canada COVID-19 app?

The app is accessible as a free mobile app for modern Apple iOS and Android smartphones and tablets, but is also available as a web application that can be accessed through any modern laptop or desktop computer browser.

Q16. How does it work?

The app is simple to use and designed to provide users with information and recommendations based on their personal risk. It also provides users with the ability to track their symptoms.

It includes educational information related to COVID-19 on subjects like physical distancing, handwashing, food safety, pets and other common questions, as well as links to reliable and up-to-date public health information sources.

The Canada COVID-19 app will help Canadians access the information they need, whether through email, app or online service. In addition, we are putting in place other tools to further enhance the ability of Canadians to easily receive reliable and up-to-date information on COVID-19.

Q17. How does this app relate to resources already available in some provinces?

This app builds on what provinces and territories are doing and provides another valuable resource for Canadians. This mobile platform was based on a mobile app launched by BC and developed by Thrive Health.

On the national platform, where a province or territory opts in to this mobile app, users will be directed to a province-specific module that will contain jurisdiction-specific information.

Q18. What have been the results of these types of self-assessment tools?

Canadians using the tool are able to get the information and guidance they need, and this is resulting in a reduction calls to 811 and telehealth lines, as well as in-person services such as family doctor visits, walk-in visits, and urgent care centres.

The additional functionality of the new Canada COVID-19 app will further support Canadians to ensure they have evidence based recommendations, up-to-date information and resources.

EXPERT ADVICE AND RESEARCH

Q19. Do we have a Scientific Advisory Group for Emergencies like the UK's Sage committee that advices ministers/cabinet on the coronavirus? Or do we get all our scientific advice from the Public Health Agency of Canada?

In January, a federal-provincial-territorial Special Advisory Committee on the Novel Coronavirus (SAC) was established to advise Deputy Ministers of Health across Canada on the coordination, public health policy, and technical content related to the COVID-19 outbreak. SAC comprises

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representatives from several Government of Canada departments and agencies as well as members of the Pan-Canadian Public Health Network Council and the Council of Chief Medical Officers of Health of Canada.

It is supported by three expert groups that bring together senior federal-provincial-territorial officials and public health experts: a Technical Advisory Committee, a Logistics Advisory Committee and the Public Health Network Communications Group.

Since January, the Minister of Health has held near-daily calls with her provincial and territorial counterparts, as has the Deputy Minister of Health Canada, to understand the situation in each jurisdiction and accelerate collaboration to meet common needs.

In March, as part of the Government of Canada's more than $1 billion COVID-19 Response Fund, the Prime Minister announced $275 million in support for coronavirus research and medical countermeasures, to combat COVID-19, including potential vaccines and treatments.

The Chief Science Advisor of Canada (CSA) has assembled multidisciplinary a science expert panel to advise her on the latest scientific developments relevant to COVID-19, with sub-committees focused on health systems and modelling approaches. This information will assist the CSA in providing current and cross-disciplinary advice to the Prime Minister and government. The expert groups are composed of distinguished Canadian scientists and will be meeting on a regular basis to discuss available science and evidence from disease modelling, risk perception, diagnostic, and clinical research. The first expert panel meetings began in March.

As announced by the Prime Minister April 23, 2020, the Government of Canada is investing in new medical countermeasures to better understand COVID-19, and develop the infrastructure needed to fight the virus here in Canada. This includes:

The establishment of the COVID-19 Immunity Task Force that will operate under the direction of a leadership group, which will include Dr. David Naylor (co-chair), Dr. Catherine Hankins (co-chair), Dr. Tim Evans, Dr. Theresa Tam, and Dr. Mona Nemer. The task force will establish priorities and oversee the coordination of a series of country-wide blood test surveys that will tell us how widely the virus has spread in Canada and provide reliable estimates of potential immunity and vulnerabilities in Canadian populations.

Q20. What is CanCOVID?

Canada's Chief Science Advisor has collaborated with the Government of Canada's departmental science advisors, the U15 Group of Canadian Research Universities, Compute Ontario and the University of Toronto to launch CanCOVID, a new Canada-wide network of health, science and policy researchers to facilitate COVID-19 research collaboration.

Q21. Could you explain the importance of Dr. Francesco Marchetti, response to the revision of an OECD Test Guideline (TG) -488?

The revisions of the OECD TG 488 are focused on updating the recommended protocols for germ cell mutagenicity testing. The original guideline included some protocols that have been demonstrated to be ineffective at detecting mutagenicity in germ cells and, if used for testing

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agents for regulatory submission, could have resulted in erroneous conclusions. Mutations in germ cells are associated with a variety of heritable diseases and proper classification of chemicals as germ cell mutagens is important under the Globally Harmonized System of classification and labelling. The revised guideline provides recommendations that are expected to generate more robust data on the ability of chemicals to induce mutations in germ cells. Also, it provides a common sampling time for simultaneously assessing mutagenicity in somatic tissues and germ cells, thus, significantly reducing the number of animals needed for testing.

Health Canada led the OECD Expert Workgroup to revise the germ cell portion of the TG 488 guideline. These revisions were ratified after extensive deliberation among several member countries. This consensus was reached based largely on two publications from the Germ Cell Workgroup of the Genetic Toxicology Technical Committee of the Health and Environmental Sciences Institute, chaired by Health Canada.

FUNDING

Q22. How much money has the Public Health Agency of Canada received for COVID-19? How much of that money was for supporting COVID-19 testing across the country? How much for public health surveillance? How much for contact tracing?

Approximately $230M of the identified funding has been allocated to the Public Health Agency of Canada (PHAC).

Of this amount, the following has been specifically earmarked for the following purposes:

a) $25.7M for COVID-19 testing (this is funding to support lab testing at PHAC's National Microbiology Laboratory), and
b) $23.1M for public health surveillance.

Funding for contact tracing was not included in this envelope as it is conducted locally by the provinces and territories.

Q23. What will the $240.5 M for mental health tools during COVID-19 entail?

More than ever, Canadians need to have tools and resources to support their health and wellbeing, including readily available information, mental health supports, alerts, and screening tools. Today's announcement of $240.5 million will help Canadians access reliable health information and support access to health services through virtual tools and approaches.

This funding will further enable the development and reach of:

- The Canada-COVID-19 mobile app, which provides Canadians with access to a symptom tracker, credible sources of information and resources, and a self-assessment tool;

- The Wellness Together Canada portal, which makes it easy for Canadians to access self-directed tools and find credible information on mental health and substance use. It also connects Canadians to peer support workers, social workers, psychologists and

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other professionals for confidential chat sessions, phone calls and online counselling; and,

- Enhanced analytics capacity, which will help gain further insights and understanding in to the emergence, spread and public health risks of COVID-19: Health Canada and the Public Health Agency of Canada have put in place contracts with BlueDot Inc. to enhance and expand upon existing expertise in this field.

In addition, the Government of Canada is working with provinces and territories, and in collaboration with organizations like Canada Health Infoway, to support initiatives to expand virtual health services to help Canadians continue to have their regular health needs met in a safe and secure manner, via telephone, text, or videoconferencing, in addition to face-to-face visits. The Government is committed to working collaboratively with all jurisdictions to determine priorities for this investment, and to identify where additional support is needed in terms of virtual care technology and infrastructure.

The majority of this funding ($200 million) will be used to help support Canadians having improved access to needed health services through virtual tools and approaches. The remaining balance of this funding ($40.5 million) is supporting a growing suite of digital solutions and tools, including Wellness Together Canada and the Canada COVID-19 app.

Health Canada is exploring ways to support a variety of populations in the deployment of virtual health services. Community partners could potentially use virtual technologies, particularly secure messaging and videoconferencing, in a way that addresses unique needs of vulnerable populations. However, important discussions are needed with provincial and territorial partners on the implementation of these tools.

Q24. How much money has the government committed to mental health services?

The Government of Canada is investing $5 billion over ten years to improve Canadians' access to mental health services. This targeted investment is being provided directly to provinces and territories to help them expand access to community-based mental health and addiction services for children and youth, integrated services for people with complex needs, and spread proven models of community mental health care and culturally appropriate interventions linked to primary health services. This is in addition to federal health funding provided through the Canada Health Transfer valued at $41.9 billion in 2020-21, which supports provincial and territorial health systems.

On May 3, the Prime Minister announced an investment of $240.5M to increase access to virtual services and digital tools to support Canadians' health and wellbeing. The Government of Canada recognizes that Canadians require access to credible tools and resources that provide reliable information, screening tools, and health supports. The funding has been allocated as follows:

- $25M has been allocated for Wellness Together Canada. A contract of $16M was signed for Wellness Together Canada, an online mental health and substance use portal that provides Canadians with free resources, tools, and professional support services to help with wellness and resilience, as well as their mental health and substance use issues.
- $15M has been allocated to support the growing family of digital products that includes the Canada COVID-19 app, which helps people track their symptoms, receive the latest updates, and access trusted resources.

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- $200M has been allocated to expand virtual care services across Canada in partnership with provinces, territories and other federal partners, such as Canada Health Infoway. Discussions are taking place with provinces and territories on how best to allocate these resources to meet the needs of Canadians.

Q25. Is the $16M Wellness Together contract the total committed so far, with an extra $9M of breathing room?

Health Canada signed a contract with the Wellness Together Canada consortium for $16M; $2M is for the portal design and continual quality improvement, and $14M is for direct services (e.g., text, voice, chat). The remaining $9M is in reserve to respond to emerging needs and to make any necessary enhancements to the portal (e.g., services for health care providers, first-line responders and essential service workers).

Q26. Can you confirm what the Public Health Agency will do with the $50 million allocated for COVID-19 public health information work?

Since the start of the COVID-19 pandemic, the Government of Canada has been working hard to provide Canadians with the information they need to protect themselves, their families, their communities and businesses.

On March 11, 2020, the Government of Canada announced funding of $50 million to support communications and public education efforts to keep Canadians informed with timely, trusted, accessible, evidence-informed information they need.

The national public education campaign includes advertising, social marketing, the development of information resources, the establishment of partnerships and targeted outreach to at-risk populations. This work will complement current Public Health Agency of Canada's outreach and communications activities such as:

- Canada.ca/coronavirus, a Government of Canada website dedicated to providing the latest information on COVID-19;
- a toll-free information line (1-833-784-4397);
- sustained social media campaigns to provide information and updates to Canadians as well as general awareness and prevention messaging;
- digital advertising to promote infection prevention tips and travel advice, which directs readers to Canada.ca/coronavirus;
- regular updates to the media;
- airport and border signage and handouts for travellers; and,
- coordinated public health messaging with provincial and territorial partners and intermediaries.

Thirty million dollars of the overall public education campaign budget is allocated for advertising efforts. To date, this includes three 30-second national TV ads; two 30-second nation radio ads; print advertising in daily, weekly, indigenous and ethic newspapers; and digital advertising across a wide variety of platforms. Almost all ad placements are in Canadian media outlets.

These advertising efforts include communicating information to Canadians in multiple languages. In addition to English and French, the first radio ad ran in Farsi, Italian and Mandarin. The language selection for these radio spots was based on the need to urgently

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share information in communities with links to countries where Travel Health Notices were in place at the time of production.

In April, print advertisements were published in newspapers in the following languages: Tagalog, Punjabi, Spanish, Arabic, Tamil, Urdu, Korean, Hindi, Inuktitut and Cree. The languages for our print advertisements were selected based on the top ethnic languages spoken in Canada, as per Statistics Canada, in addition to English and French. We also considered the availability and reach of the outlets in these languages.

We can't provide a breakdown of advertising expenses at this time as the Government of Canada's Agency of Record (AOR) works with publishers to get ads in market and then subsequently invoices the Government of Canada. For the next phases of public education, we continue to work with the AOR to determine advertising space available for purchase across a wide variety of platforms and channels.
For more information please access the English TV and radio advertisements at:
First series of TV ads (ran from March 24 to April 12)
https://www.youtube.com/watch?v=sscyXpYQ6Dk
https://www.youtube.com/watch?v=k7ns6t9NzXs
First radio ad (ran from March 18 to April 12)
https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/awareness-resources/covid-19-radio-public-service-announcement.html
Second series of TV ads (ran from April 18 to May 3)
https://www.canada.ca/en/public-health/services/video/covid-19-stay-home.html

Q27. Which organizations funded through the $30 million COVID advertising campaign were not Canadian outlets? How much money was given to non-Canadian businesses for that advertising?

Various media outlets and platforms are being considered, including print, TV, radio and digital platforms to reach a range of audiences. The majority of platforms are Canadian based; however, exceptions were made for some digital platforms that effectively reach some of our specific target audiences within Canada, including Facebook and YouTube. We do not yet have final costs for the media buy, as the campaign is ongoing and final invoices have not been received yet.

Q28. How much will be spent on digital ads through Google and Facebook?

Digital advertising on platforms such as Google and Facebook are important tools for reaching Canadians. The Agency of Record is still planning and the campaign is still underway. PHAC is unable to provide a total amount spent at this time because we are still waiting on final invoices digital ad buys.

Q29. When will the newspaper component of the Public Health Agency of Canada's ad campaign roll out? Why has the government been slow to place ads and make ad buys in newspapers?

The situation in Canada is changing rapidly and we are learning more about COVID-19 every day. Canadians need easy access to resources to help them get the information they need about COVID-19.
The Public Health Agency of Canada (PHAC) launched a comprehensive public education campaign to help ensure Canadians have access to the most up-to-date information on COVID-

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19. This plan includes the use of both digital and print platforms. The first phase of the campaign included a national print buy and our ad appeared in approximately 950 daily, weekly, Indigenous and ethnic newspapers across Canada in late March and throughout April 2020. Due to the rapidly changing response to COVID-19, media planning by the Agency of Record took longer than expected. The Agency of Record continues to plan the next phases as the situation in Canada evolves.

Q30. Are the ads to raise awareness about COVID-19 on Spotify included in that $30 million?

The Government of Canada ads featured on Spotify are part of the $30 million campaign. As final invoices have not been received, we are unable to provide information related to expenditures.

Q31. What is the cost of the contract between the government (PSPC) and Cossette? How much is Cossette being paid to do this work?

The total value of Cossette's contract with the Government of Canada (Public Services and Procurement Canada) for ongoing services is currently $813,600 (including tax) for a period of three years.

Other services are provided upon request and paid for based on work completed (task authorizations), in accordance with the Basis of Payment of the Contract, including the Contractor's fees and rates. Cossette's fees and rates are business confidential.

MENTAL HEALTH SUPPORT FOR CANADIANS

Launch Of Wellness Together Canada Portal

Q32. How do I access the Wellness Together Canada portal?

The portal can be found on Canada.ca/coronavirus and the Canada COVID-19 app, along with the other COVID-19 virtual tools offered by Health Canada.

Q33. Is the government planning to make other COVID-19 digital tools and resources available to Canadians?

This portal is part of a suite of virtual products supported or funded by Health Canada to provide Canadians with information and support during the COVID-19 pandemic. The self-assessment tool and Canada COVID-19 app have already been launched.

We will continue to work with all of our partners to ensure that Canadians have access to up-to-date information, tools, and resources on COVID-19.

Q34. New funding was announced for virtual services and digital tools to support Canadians health and wellbeing. Will any of the money go toward private firms that already have virtual health care platforms or is the government planning on spending it all on the existing Wellness Together Canada platform?

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The Government of Canada recognizes that Canadians need access to virtual services and digital tools and resources to support their health and wellbeing, including readily available information, mental health supports, alerts, and screening tools. That is why last Sunday the Prime Minister announced an investment of $240.5M to help Canadian health systems accelerate access to virtual services and digital tools and resources to support Canadians health and wellbeing.

Of the $240.5M announced, $40.5M is intended help provide Canadians with readily available access to the information and resources they need, including through a growing suite of digital solutions and tools, including Wellness Together, an online portal that provides Canadians with free resources, tools, and professional support services to help with wellness and resilience, as well as mental health and substance use. It will also support a growing family of digital products that includes the Canada COVID-19 app, which helps people track their symptoms, receive the latest updates, and access trusted resources.

However the bulk of the funding -- $200M – will be used to improve access to needed health services by supporting provinces and territories in the rapid deployment of virtual tools and approaches.

Health Canada is already engaging with provinces and territories, as well as with health system experts and organizations like Canada Health Infoway to identify where additional support is most needed in terms of virtual care technology and infrastructure. These discussions will provide a clearer understanding about how best to support health systems in the implementation of virtual care and will be critical in informing next steps over the coming weeks and months.

Q35. How does it work?

The portal will provide much-needed support to Canadians with respect to mental health and substance use challenges in the context of the current COVID-19 pandemic. It will offer Canadians different levels of support depending on their need, ranging from information and self-assessment tools, to the opportunity to chat with peer support workers and other professionals. The chats can include a limited number of live telephone sessions.

The portal is being offered by a consortium of organizations who specialize in mental health and substance use. It is led by Stepped Care Solutions. Partner organizations include Kids Help Phone and Homewood Health, along with contributions from Bell Canada Enterprises, the Mental Health Commission of Canada, the Canadian Psychological Association, and Facebook Canada.

Q36. Is the information I share in this portal safe?

Crisis support links and a number of resources can be accessed directly through the portal without registration. There is the option to register for additional support and resources. The resources and services available on the portal are provided by accredited professionals. Any information provided will be kept in the strictest confidence.

Q37. What is the projected number for Canadians using the Wellness Together Canada app? What is the capacity for the portal right now?

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The portal provides 24/7 access to free evidence-based tools and resources to Canadians in all provinces and territories to help meet their needs for mental health and substance supports. In addition, there are more than 6000 service providers employed with Homewood Health and Kids Help Phone who will deliver the psycho-social support services to which Canadians are referred through the portal.

Following the SARS outbreak, it was reported that more than 40% of the population reported increased levels of stress in family and work settings during the outbreak, with 16% showing signs of traumatic stress levels. Based on these estimates and other considerations unique to the COVID-19 pandemic, it is anticipated that approximately 11 million Canadians will experience high levels of stress in family and work settings, and close to 2 million will show signs of traumatic stress. That's why access to the portal will be closely monitored to adjust services to align with the demands of Canadians.

Q38. How many psychologists, social workers, peer supporter workers and other professionals have been retained so far and how many is the government seeking to retain? How many of these staff are available full time?

The suite of tools on Wellness Together Canada will offer Canadians different levels of support depending on their needs, ranging from information and self-assessment tools, to the opportunity to chat with peer support workers and other mental health professionals. There are more than 6000 service providers employed with Homewood Health and Kids Help Phone who will deliver the psycho-social support services via text and call.

While the exact provider mix is not available at this time, the service providers cover a range of health professions, including social work and psychology, with diverse backgrounds: counselling psychology, clinical social work, rehabilitation, crisis management, child psychology/neuropsychology, sexuality, adolescence issues, marital/family therapy, and substance use. The vast majority of these service providers are licensed mental health and substance use professionals.

Q39. I understand staff through Homewood / Kids Help Phone are handling the calls - but are government employees triaging at intake to get people to the right services, and if so, how many new people have been hired, or is this a matter of redeployment?

Federal public service employees are not providing health services through the portal. This service connects those in need with specialized consultants and trained counsellors. The Wellness Together Canada portal provides access to immediate text support and a wide variety of psycho-educational resources appropriate to youth and adults to address common mental health and substance use issues. People also have the choice of creating an account and completing a self-assessment that will help them decide on other resources that would be a good fit for them. If they are not sure what resources to use, they can also connect with a live counselor by phone or text to help them navigate the resources on the portal and find what's right for them. These options include self-guided therapy, moderated peer-to-peer support and coached therapy, and one-to-one counseling by phone or text.

Q40. Will the federal government pay for the psychologists the Mental wellness portal refers people to?

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The Wellness Together Canada portal is part of a suite of virtual products that are supported or funded by Health Canada to provide Canadians with information and support during the COVID-19 pandemic. Funding for the portal is provided to a consortium of organizations, including Stepped Care Solutions, Kids Help Phone and Homewood Health. The psycho-social support services that Canadians are referred to through the portal are delivered by trained mental health professionals employed by Kids Help Phone and Homewood Health. These services are paid by Health Canada through the same funding that pays for the portal.

Q41. Will the Government of Canada be making additional mental health and suicide prevention investments?

As a result of school closures and reduced access to community resources, Kids Help Phone is experiencing increased demand for its confidential 24/7 crisis support services, which are available online, by telephone, and through text messaging. In response, the Government of Canada has provided $7.5 million to Kids Help Phone to meet this increased demand and provide young people with the mental health support they need during this difficult time.

This additional support will provide English and French e-mental health services to children and youth across Canada who are feeling the social and financial impacts of the COVID-19 pandemic. It will ensure that vulnerable Canadian youth and children can find the help they need when they need it most.

Q42. Were the particular needs of Indigenous people taken in to consideration in this portal?

In the process of funding this initiative, Health Canada requested that the portal take cultural safety into account. The Department also requested that the portal be trauma-informed. This portal is for all Canadians.

Q43. Is the portal accessible for people without internet access?

The portal is a digital tool and can only be accessed via the internet. If you need mental health or substance use support and do not have access to the internet, we encourage you to contact your local health authority or crisis line. There are many services available, with more organizations stepping up every day, to support Canadians during this difficult time.

Q44. Do you have any early statistics on uptake for the Wellness Together Canada portal? Can you also share a breakdown by province.

150,000 Canadians have accessed the portal to date (as of May 8th). Here is the provincial breakdown:

Eastern Canada	7.04%
Quebec	12.75%
Ontario	51.87%
Western Canada	28.00%
Nunavut/Yukon/NWT	0.33%

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Q45. Now that it's up and running, is the uptake for the Wellness Together Canada portal larger than expected? Is the projection still that 11M Canadians are feeling stressed?

We know that Canadians are feeling stressed and worried because of the pandemic, and we anticipate that an increasing number of Canadians will begin to use the service in the coming weeks. Since its launch three weeks ago, the usage continues to grow on a daily basis. For example, from April 22 to May 6, the number of Canadians who accessed the portal grew by 87%.

Q46. What is the status of the pan-Canadian suicide prevention service?

Budget 2019 announced $25 million over 5 years, and $5 million per year ongoing, to implement and sustain a fully operational pan-Canadian suicide prevention service. This will provide people across Canada with access to bilingual, 24/7 crisis support from trained responders, using the technology of their choice: voice, text or online chat.

In July 2019, the Public Health Agency of Canada launched a call for applications for funding for organizations interested in leading a pan-Canadian suicide prevention service. This solicitation ended on October 31, 2019. A decision is expected soon.

Q47. What is the government doing to help avoid an increase in overdose deaths in the context of COVID-19?

The Government of Canada is taking action to assist community health services providers and all levels of governments as they respond to the COVID-19 pandemic. The Government supports harm reduction, treatment, housing and other services for people who use drugs. We are committed to ensuring provinces and territories have the tools they need to manage the compounding effects of the opioids overdose crisis and the COVID-19 pandemic on their communities.

- On March 19, 2020, Health Canada issued a six-month exemption for prescriptions of controlled substances (such as narcotics) under the *Controlled Drugs and Substances Act* and its regulations. This exemption temporarily authorizes practitioners to issue, verbally, prescriptions with controlled substances, allows pharmacists to refill and renew prescriptions more easily, allows prescriptions to be transferred to other pharmacies, and allows medications to be delivered or picked up by other individuals.

  This will help people with substance use disorder in treatment with opioid agonist therapy maintain access to their medication, while physically distancing.

- On April 6, 2020, Health Canada issued class exemptions allowing provinces and territories to establish new temporary Urgent Public Health Need sites (also known as overdose prevention sites) within existing supervised consumption sites, shelters or other temporary sites, as needed, to help people stay safe from overdose and respect physical distancing and self-isolation measures.

  The Department will also permit community health service providers to ensure existing supervised consumption sites can quickly adapt their operations to respect public health guidelines in the context of COVID-19. This can be done without the need to advise or seek additional approval from Health Canada. These changes to operations could

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include new measures on how people move through the space, changes to hours of operation, changes to the number of booths, or other measures.

Q48. What are the updated statistics on downloads/clicks of the COVID-19 app and the Mental Health Portal? How many Canadians have accessed health services through it?

As of April 26, there have been 471,015 downloads of the Canada COVID-19 app. As of April 21, 70,000 Canadians have visited the mental health portal.

Q49. What other resources are available for Canadians?

The COVID-19 pandemic is new and unexpected. This situation can be unsettling and can cause a sense of loss of control. It is normal for people and communities to feel sad, stressed, confused, scared or worried.

The Government of Canada is working with provinces and territories to spread and scale digital platforms that can help governments in their response to COVID-19, including education, information, mental health supports, alerts, and screening tools.

We will continue to work with all of our partners to ensure that Canadians have access to up-to-date information, tools and resources on COVID-19.

There are a number of resources for people in crisis, including:

Kids Help Phone
1-800-668-6868 or Text CONNECT to 686868 (Available to young Canadians between 5-29 years old who are seeking 24-hour confidential and anonymous care with professional counsellors).

Hope for Wellness Help Line
Call the toll-free Help Line at 1-855-242-3310 or connect to the online chat. (Available to all Indigenous peoples across Canada who are seeking immediate crisis intervention)

Crisis Services Canada
1-833-456-4566 (Available to all Canadians seeking support).

GUIDANCE

Long Term Care Facilities

Q50. Why do you recommend that personal support workers and essential visitors and volunteers wear personal protective equipment when there is a shortage?

Personal support workers are an integral and important part of the health care system. Personal support workers provide close, direct care to patients. Every person entering a long-term care home, including essential visitors and volunteers, has a responsibility to prevent infections

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among residents of these facilities, who are at high risk of severe illness and death from COVID-19.

The Government of Canada is working to ensure health care workers have the personal protective equipment and medical supplies they need. We are doing this through collaborative bulk procurement with the provinces and territories, building domestic production capacity, and identifying potential alternatives and ways to extend product life.

Q51. Why are you telling workers to not to have multiple jobs when they may need to have multiple jobs to survive?

We know that seniors are more at risk of developing severe complications from COVID-19 because of their underlying medical conditions and age.

For seniors living in long-term care homes or assisted-living facilities, there is an even greater risk of infection and transmission of the virus owing to proximity. The movement of workers from one facility to another increases the risk of spread of infection, which ultimately puts seniors more at risk of contracting the virus. We need to protect seniors in these challenging times.

Therefore, the guidelines recommend identifying staff who work in more than one location and ensuring efforts are made to prevent this where possible.

Q52. How would residents' needs be met if there is a further restriction on the availability of personal support workers?

The administration of long-term care is the responsibility of provincial and territorial governments. They have put in place a number of measures to support continued quality care to residents during this crisis. For example, actions undertaken have included introducing flexibility in staffing policies and approaches, and working with third-party providers to deliver short-term care support.

The Government of Canada is working with provincial and territorial governments to respond to COVID-19. A national recruitment campaign has been developed, seeking volunteers, including individuals with health care experience, to help conduct case tracking functions and support health system surge capacity. An inventory of volunteers is being maintained from which provincial and territorial governments can draw as needed.

More information is available at: https://emploisfp-psjobs.cfp-psc.gc.ca/psrs-srfp/applicant/page1800?toggleLanguage=en&poster=1437722

Q53. What is the Government doing to support low wage workers?

The Government of Canada is taking strong and quick action to protect our economy, and the health, safety, and jobs of all Canadians during the global COVID-19 outbreak.

The new Canada Emergency Response Benefit (CERB) will support Canadian workers, whether employed or self-employed, who have stopped working and lost their income because of COVID-19. It will provide eligible workers $2,000 a month for up to 4 months to help them pay the bills.

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The Government of Canada's priority is to ensure that Canadians receive the money they are entitled to as quickly as possible. We have launched a portal to provide information and to help workers apply for the new benefit.

Q54. What is the Government of Canada doing to protect seniors' financial security?

The Government of Canada is taking measures to ensure that the Canada Pension Plan and Old Age Security benefits that seniors rely on will continue to be paid without delay, and that new applications for these benefits will be processed in a timely fashion.

The Old Age Security pension is intended to provide a minimum income guarantee to all seniors. Therefore, the Old Age Security pension is based on age and residence and not on employment history or investment income, and it continues to be paid to seniors monthly.

The income-tested Guaranteed Income Supplement is provided to all low-income seniors. Old Age Security pensioners who experience a drop in income as a result of the pandemic may be eligible to receive this additional support.

To further protect seniors' financial security, we are introducing several new measures. For low- and modest-income Canadians, including seniors, starting April 9, 2020, the Government began providing a one-time special payment through the Goods and Services Tax (GST) credit. This will provide close to $400 to low-income single individuals and close to $600 to low-income couples.

We are also reducing required minimum withdrawals from Registered Retirement Income Funds (RRIFs) by 25% for 2020. This will provide flexibility to seniors and help preserve RRIF assets during a volatile market.

Further, we are extending the deadline to file your income taxes to June 1, 2020, and allowing any new balances due, or instalments, to be deferred until September 1, 2020, without incurring interest or penalties.

Q55. What is the Government doing to protect seniors' pensions?

Budget 2019 introduced new measures to enhance the security of workplace pensions in the event of corporate insolvency.

Measures to make insolvency proceedings fairer, more transparent and more accessible for pensioners and workers are now in force.

Higher expectations and better oversight have also been set for corporate behaviour:

- federally incorporated businesses are now explicitly permitted to consider pensioner and worker interests when acting in the best interests of the corporation; and
- publicly traded, federally incorporated firms will be required to disclose their policies pertaining to workers and pensioners well-being and executive compensation, or explain why such policies are not in place.

Finally, measures protect Canadians' hard-earned benefits by clarifying in federal pension law that pension plan members are entitled to the same pension benefits when a plan is wound up as when it was ongoing.

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Q56. What is the Government doing to protect seniors from elder abuse?

The Government of Canada is committed to protecting the safety and well-being of seniors in Canada and recognizes the devastating impact of elder abuse on seniors and their families.

We continue to provide information, resources and tools to help seniors, caregivers, service providers and the general public identify elder abuse and respond appropriately.

We will continue to work collaboratively with provinces and territories, as well as community organizations, to implement measures to help improve the lives of seniors and their families.

Q57. What is the Government doing to protect seniors from COVID-19 related fraud and scams?

The Government of Canada is working to implement measures to help improve the lives of seniors and their families and is taking the issue of financial exploitation of seniors very seriously. Indeed, fraud and theft are offences under the *Criminal Code*.

Employment and Social Development Canada has been sharing anti-fraud content from other government departments in real time on its Seniors Facebook page, as well as other departmental channels.

In the longer term, the Government will move forward with a national definition of elder abuse, invest in better data collection and law enforcement, and establish new penalties in the *Criminal Code* relating to elder abuse.

This builds on work underway, such as the National Seniors Council's examination of the issue of financial abuse of seniors and funding under the New Horizons for Seniors Program to community groups to help reduce elder abuse.

Q58. Why did it take PHAC so much longer to release its guidelines for long-term care?

Protecting long-term care residents and staff is a priority and the Public Health Agency of Canada (PHAC) is working with provinces and territories on all aspects of their response to COVID-19 for this population. Developing the Infection Prevention and Control for COVID-19: Interim Guidance for Long Term Care Homes required consultation with jurisdictions and additional experts from across Canada to develop the information needed to protect residents and staff. The science on transmission of COVID-19 continues to evolve rapidly, and this guidance reflects the considered synthesis of the most recent findings on COVID-19 transmission.

This document reflects the carefully considered and evidence-based development needed to provide the greatest protection to residents and staff of long-term care facilities in Canada.

Q59. How many deaths have there been in long term care facilities?

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As of May 8, it is estimated that 81% of the 4,569 COVID-19 deaths in Canada are linked to long-term care residences. Information on deaths in long-term care facilities is based on reporting from provincial and territorial public health authorities.

Note that these figures are based on provincial and territorial public reporting.

Q60. Is the Public Health Agency of Canada compiling data relating to COVID-19 outbreaks in long-term care facilities?

The Public Health Agency of Canada (PHAC) is monitoring the impact of COVID-19 on our most vulnerable populations, including residents in long-term care homes. Data collection occurs through daily contact among federal/provincial/territorial epidemiologists who work together to collect and share information. Case report data are collected from provinces and territories (PTs) via a reporting form that includes a field for indicating residence in a long-term care facility. We supplement this information with publicly available data sources. Data on outbreaks in long-term care facilities are reported through local public health authorities to their PT public health counterparts, who synthesize this information, report publicly, and implement controls measures. Work is underway on a standardized dataset for long-term care facilities. PHAC also makes information about possible exposure to the virus in settings such as long-term care facilities publicly available on its website.

Q61. Which provinces or territories adopted the long-term care guidelines?

The Infection Prevention and Control for COVID-19: Interim Guidance for Long-Term Care Homes advises that long-term care home (LTCH) operators identify staff who work in more than one location (e.g., other LTCHs or health care settings), and efforts are made to prevent this where possible, to limit spread between facilities and to inform investigations during an outbreak. “Where possible” was included so that unintended harm to residents would not result from unsafe staffing levels due to facility-level human resource limitations. In order to further mitigate the risk of harms, this guidance also recommends that all staff and visitors wear a mask at entry to the LTCH to prevent asymptomatic or pre-symptomatic transmission of COVID-19. Staff are to be carefully monitored with, at minimum, twice-daily screening of symptoms. If staff develop fever or symptoms, they are to be removed from duty and should be tested for COVID-19. Additional safeguarding measures in this guidance include recommending that staff who are ill or who are exposed to COVID-19 cases not enter the LTCH for at least 14 days from last exposure, unless otherwise directed by local public health authorities.

This guidance has been developed for Canadian LTCHs and staff. Long-term facilities-based care is governed by provincial and territorial legislation and this guidance should be read in conjunction with relevant provincial, territorial and local legislation, regulations, and policies. Please connect with the provinces and territories for information on the adoption of this guidance.

Additional guidance for people with disabilities in Canada

Q62. What factors may make a person with a disability at risk of acquiring COVID-19?

Some factors that may make a person with a disability more at risk of acquiring COVID-19, or progressing to more severe COVID-19 infection, other than age and underlying chronic conditions, include:

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- The nature of their disabilities, such as those who have difficulty washing their hands or those with vision impairment, who must touch objects for support or to obtain information;
- People with disabilities living in communal living spaces, due to the proximity of others;
- Individuals with disabilities who interact with multiple care providers and supports, which increases the risk of exposure;
- Barriers to accessing public communications related to COVID-19, response services and programs;
- Individuals with disabilities currently seeking treatment for unrelated health conditions in the health care system;
- Loss of services and supports in the community, such as employment, therapy and schools, which can lead to regression in positive development in some persons with disabilities.

Q63. What specifically should person with disabilities to do protect themselves?

To protect and prevent transmission of COVID-19 to people with disabilities and those who care for them, it is advised that they should:

- Stay home and only go outside for necessary activities (i.e. medical appointments or getting groceries);
- Ask family, a neighbour or friend to help with essential errands;
- Wash their hands and/or support the handwashing for the person with disabilities frequently;
- Immediately notify or have others notify their family/care providers/friends if they become ill.

Q64. What should healthcare providers do to accommodate persons with disabilities?

Health care providers should consider accommodations for people with disabilities and those who support them to access their services.
People with disabilities must have the right to have any essential support person with them at all times. These essential supports may be paid staff, friends or family.

There are special considerations for health care workers with disabilities, and essential support for people with disabilities, such as work options, financial and mental health resources and other policies and procedures.

Personal protective equipment, such as face shields, are an effective alternative to face masks for those people with hearing and/or visual impairment, and people with cognitive and/or intellectual disabilities, conditional that their support person does not have COVID-19 .

Q65. What should assessment centres do to accommodate persons with disabilities?

It is important that designated COVID-19 assessment centres services are available to people with disabilities. This includes accessibility (i.e. ramps, accessible parking), and accommodations for people with anxiety, and/or cognitive/intellectual disabilities. These accommodations may also include skipping the lineup, private rooms, noise and light sensitivity

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considerations, and/or alternatives to swabs in vehicles.

COVID-19 assessment centres should also consider that essential care/support/sighted guide/interpreter/friends remain with a person during their time at the assessment centre, and that information is provided in a functionally, multi-lingual and culturally appropriate way.

The assessment centres should ensure that test results are communicated to the person with the disability, and/or their support systems. Any results should be communicated in a functionally, multi-lingual, plain-language and culturally appropriate way.

ISOLATION, QUARANTINE (SELF-ISOLATION), AND PHYSICAL DISTANCING

Q66. In order to loosen restrictions around physical distancing is there a certain percentage of the population that would need to be tested?

We continue to test at a very high rate in Canada—one of the highest in the world. We know that testing is key to finding new cases and to identifying and stopping new lines of transmission. We are now reaching 20,000 tests daily, almost double where we were earlier this month, and this number continues to grow.

There is no definite number for how many tests need to be done each day to relax physical distancing measures. This will vary across jurisdictions. However, increasing testing helps in detecting new cases and their associated contacts early in order to prevent or reduce the spread of COVID-19.

Canada has been maintaining a rate of positive tests of about 6% to 7%, which is within a good range to accurately detect where the disease is circulating. We want to have the most accurate picture possible of what is happening in our communities. This shows that we have a highly sensitive testing system. We are continuing to increase our laboratory capacity to make sure that this continues to be the case.
The primary focus is testing people who present with symptoms and those in high-risk situations. This includes long-term care facilities, health care workers, correctional facilities and to support outbreak control in any setting.

Our priorities continue to be accessing testing reagents, evaluating rapid point-of-care tests, and accessing authorized test kits to help ensure that provinces and territories are equipped to ramp up testing according to their requirements.

Q67. Can asymptomatic people go outside for walks, as long as they maintain physical distancing?

For all Canadians, you can go for a walk if you:

- Have not been diagnosed with COVID-9
- Do not have symptoms of COVID-19
- Have not travelled outside of Canada in the past 14 days.

If you go out for a walk, do not congregate and always practise physical (social) distancing by keeping at least two metres from others at all times.

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For travellers entering Canada, during their 14-day period of isolation or quarantine:

- For those in mandatory isolation, stay inside your home.
- For those in quarantine (self-isolation), you may go outside for fresh air in a private place like your yard or on a balcony; however, you must stay on your property and not go into community settings.

BORDER MEASURES

ArriveCAN mobile application

Q68. How do I access the ArriveCAN app?

The mobile app is currently available in the Google Play Store or the Apple App Store.
It is accessible and can be downloaded and installed for free on:

- iPhones running iOS 12 or above; and
- Android phones and tablets running OS 6 and above.

It is also available as a web application that can be accessed through any laptop or desktop computer browser.

Q69. How does it work?

The App is simple to use and is designed to collect basic contact and travel information from travellers, as well as their location for mandatory isolation. The App also asks yes or no questions related to symptoms and self-isolation plans.

Q70. Is the Government planning to make other COVID-19 digital tools and resources available to Canadians?

The Government of Canada is working with provinces and territories to make available additional digital platforms that can help with the response to COVID-19, including education, information, mental health and substance use supports, alerts, and screening tools.
On March 31, 2020, the Government of Canada launched the Canada COVID-19 mobile platform. The platform provides users with;

- information and recommendations based on their personal risk
- the ability to track their symptoms
- links to reliable and up-to-date public health information sources
- educational information related to COVID-19 on subjects such as:
  - physical distancing
  - handwashing
  - food safety
  - pets

The App is accessible as a free mobile application for modern Apple iOS and Android smartphones and tablets. It is also available as a web application that can be accessed through any modern laptop or desktop computer.

We will continue to work with all of our partners to ensure that Canadians have access to up-to-date information, tools and resources on COVID-19.

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Q71. Why not just use the paper contact form instead of a mobile app?

This App allows for the seamless transition of contact information from the traveller to the border services officer upon entry to Canada.

The ArriveCAN App, launched during the week of April 29, will be an alternative to paper forms. It will enable faster processing at the border for travellers returning to Canada, and we encourage travellers to use it.

This electronic collection method also limits physical contact between travellers and Border Services Officers and Quarantine Officers. This protects both the travellers and the officers.

Q72. What is the difference between the App and the web version of the form?

The web version of the form can be accessed using the web browser on any laptop, tablet or smartphone and requires a constant connection to the internet. The web version requires a local token to be entered first. The token is provided only at the port of entry into Canada before allowing traveller(s) to enter and submit their information.

The ArriveCAN App is an application that a user can download directly to their mobile phone. The ArriveCAN App allows traveller(s) to enter their information without a token and before arrival at the port of entry into Canada. The ArriveCAN App requires only the token provided at the port of entry into Canada for the final submission step.

The ArriveCAN App enables all incoming travellers to submit information quickly, easily and securely.

Q73. Is this app going to track travellers?

The ArriveCAN App will not be used to automatically track people's location through their phone or via GPS, nor is it a surveillance tool. The protection of Canadians' information is a priority for the Government of Canada, and any tool used to collect personal information undergoes a rigorous privacy assessment.

Q74. We are aware that mobile applications for contact tracing are being considered/developed by provinces/territories. Is this App a contact tracing app?

The ArriveCAN mobile app is not a contact tracing app, and does not overlap with any existing mobile or digital solution. Pursuant to Emergency Orders under the *Quarantine Act*, every incoming traveller must provide information to the Government of Canada about their quarantine or isolation plans. The App is designed to collect mandatory information that will support compliance and enforcement of the mandatory 14-day quarantine or isolation requirements.

The ArriveCAN app is an opportunity to provide a digital solution that streamlines the collection of this mandatary information, while also making it easier on incoming travellers to submit their answers. It also supports physical distancing efforts as it limits contact with travellers and Border staff since information can be entered on to mobile devices easily and securely. The mobile app can be downloaded at any point in time, including prior to departure so that travelers can enter in their information and make their entry to Canada quicker and easier.

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Q75. What kind of information is the app collecting?

Information collected under ArriveCAN (as well as the paper and online form) is required under the *Quarantine Act* and includes:

- name, date of birth, flight number and destination details
- self-assessment on symptoms (yes or no question on whether traveller is showing signs of a cough, difficulty breathing, or fever)
- self-isolation plan (yes or no question on whether a plan is in place)

Q76. How is the ArriveCAN app different than the Canada COVID-19 app?

The Canada COVID-19 app provides general information and resources about COVID-19 to all Canadians. ArriveCAN is strictly for incoming travellers to submit their mandatory information in support of PHAC's compliance and enforcement mandates under the Emergency order of the *Quarantine Act*.

Q77. How will the information be protected?

Personal information under the control of a federal government institution is subject to the *Privacy Act*. Information is collected, used, disclosed, retained and disposed of in accordance with this law.

Q78. How is the information used?

The collected information will be used for three activities under subsection 15(1) of the *Quarantine Act*:

1. to monitor, verify or enforce compliance with the Mandatory Isolation Order;
2. to provide information to promote compliance with the Mandatory Isolation Order; and
3. for public health follow-up.

Compliance and enforcement officers may use the information provided to contact travellers during their mandatory isolation period to ensure they are respecting the requirement to stay in their place of isolation. It is not a surveillance or tracking tool.

Travellers are informed upon entry into Canada of the compliance monitoring and verification activities, the possible consequences of non-compliance, and the enforcement actions and penalties they could face.

The Public Health Agency of Canada is working with the Royal Canadian Mounted Police and provincial law enforcement agencies to verify the compliance of returning travellers with the mandatory isolation order using a risk-based approach, based on the information given by travellers at the border.

Q79. What gives the government the authority to require personal information?

This information is required pursuant to subsection 15 (1) of the Quarantine Act:

> ***15 (1)*** *Every traveller shall answer any relevant questions asked by a screening officer or* ***quarantine*** *officer and provide to the officer any information or record in their possession that the officer may reasonably require in the performance of a duty under this* ***Act****.*

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Q80. Why does ArriveCAN collect more information than the paper and online forms do? Why is there a discrepancy?

At present, the App includes all information to be collected to administer and enforce the *Minimizing the Risk of Exposure to COVID-19 in Canada Order (Mandatory Isolation) No. 2*. In comparison to the current paper and online forms, the App requires additional information, such as flight or border crossing information, and questions on whether travellers are exhibiting symptoms of COVID-19 and whether they have a self-isolation plan.

While some of this information is not captured in the paper or online form, that includes questions on self-assessment of symptoms and confirmation on whether a self-isolation plan has been considered by each incoming traveller, it is asked nevertheless by a border services officer and captured on their end.

The mobile app, paper and online options of the Coronavirus Form will eventually all align to collect the same information from all incoming travellers. PHAC is currently working with the operations team on this alignment.

Q81. What does the online form via ArriveCAN for Travellers entering Canada consist of?

Travellers entering Canada by air or by land must provide basic information using a traveller contact information form, available through the ArriveCAN mobile app, an accessible web-based form, or a paper form. The web-based form is restricted and can be accessed with a token that can be obtained at the airport. Please see the English traveller form and the equivalent French traveller form.

Travellers are informed upon entry of Canada's compliance monitoring and verification activities, the possible consequences of non-compliance, and the enforcement actions and penalties they could face. Individuals who contravene the mandatory isolation or the mandatory quarantine requirements may be subject to a range of enforcement measures under the Quarantine Act, which include verbal and written warnings, and arrest, or detention.

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

Q82. Why is the Government of Canada not conducting temperature testing at all ports of entry?

The Government of Canada continues to follow measures that have proven to be effective based on the latest science and situational assessments. Border Service Officers are not currently implementing temperature checking at ports of entry. The use of thermal scanning at ports of entry into Canada, historically, has not proven to be an effective measure to detect communicable disease in travellers. For example, during the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003, our intensive screening of 2.3 million travellers did not detect any cases of SARS using thermal scanning.

Each jurisdiction in Canada is looking at different situations and is developing risk-based approaches and assessments based on what is taking place within their jurisdiction.

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Q83. If the Government of Canada feels that temperature checking is not a reliable measure in reducing the spread of COVID-19 via people entering Canada, why is it allowing the Government of Alberta to implement this measure?

The Government of Canada works closely with its provincial and territorial counterparts in ensuring that federally sanctioned measures are supported. As the epidemiology of COVID-19 is different in each jurisdiction, provinces and territories will continue to develop their own risk-based approaches and assessments.

Q84. Why do the current Government of Canada border measures include the "do you feel as if you might have a fever" line of questioning if temperature screening is not being used?

Border Services Officers are required to screen individuals arriving at Canadian ports of entry in order to determine whether they are exhibiting symptoms associated with COVID-19. This question—whether an individual may have signs of a fever—is one of several that travellers must answer for officials to determine requirements for quarantine or self-isolation. The recent decision by the province of Alberta to conduct temperature checks at airports is a supplementary health screening measure based on assessment of what is taking place within its own jurisdiction.

Q85. Are screening efforts and the collection of information between the Federal and Provincial governments being duplicated?

Entry screening is an important part of the Government of Canada's multilayered response to the COVID-19 pandemic to gather information from, and share information with, travellers as they enter Canada. To avoid duplication and to ensure the alignment of public health measures, the Government of Canada collaborates with provincial and territorial governments at all ports of entry. Information on travellers entering Canada is being shared with all provinces and territories to support them in their public health efforts.

Provinces and Territories have their own individual Orders that have some degree of alignment with the federal government order, but may have additional considerations. PHAC continues to engage with the individual provinces and territories, as well as the Scientific Advisory Committee (SAC) comprised of Chief Medical Officers of Health to discuss border approaches.

Q86. What is the difference between Federal and Provincial roles and responsibilities for passenger screening at airports?

In terms of Federal roles and responsibilities, under the *Quarantine Act*, all arriving passengers are informed of their requirement to isolate or quarantine for a 14-day period that begins on the day on which they enter Canada. As part of the Public Health Agency of Canada's mandate under the *Quarantine Act*, travelers arriving in Canada are initially screened by a federal Canada Border Services Agency (CBSA) Officer who will query them on their health and symptoms, and if necessary their requirement to

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report to a federal screening officer or Quarantine Officer. Quarantine Officers are on site at airports and accessed remotely from land borders.

Through the ArriveCAN app, and through instructional hand-outs provided at airports and other ports of entry, travelers are informed of their responsibilities under the *Quarantine Act* as well as the need to consult their provincial or territorial public health authority for additional measures and/or restrictions regarding mandatory isolation and quarantine that may apply to their situation.

Provinces and territories have no direct regulatory or legislative oversight of travelers at the international border as it is under Federal jurisdiction. However, they may choose to add on additional screening measures for travelers that are aligned with their own requirements.

Q87. In terms of enhanced provincial screening measures, are these only carried out at airports? Are there different screening measures for other ports of entry?

The Government of Canada continues to collaborate with provinces and territories to prevent the spread of COVID-19 from our ports of entry.

As the COVID19 situation continues to evolve, supplementary health screening measures, such as those implemented by other jurisdictions, including Alberta's temperature checking at ports of entry, may also be subject to change. The government of Alberta has identified its two main airports (Calgary and Edmonton) as the priority locations for temperature checking of incoming travellers.

It remains important for travellers to consult their provincial or territorial public health authorities for the latest information on enhanced screening measures within their jurisdiction.

The Government of Canada has a list of resources to assist travellers departing from, and arriving into Canada:

- Canada.ca/coronavirus,
- Online awareness resources,
- The ArriveCAN app,
- Traveller handouts at all ports of entry and,
- The COVID-19 app

OIC 10 - Emergency Order – Mandatory Isolation

Q88. What is the new federal Emergency Order made pursuant to the *Quarantine Act* and why has the Government of Canada implemented it?

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Effective April 15, 2020, the Government of Canada has implemented a federal Emergency Order under the *Quarantine Act* requiring anyone entering Canada, whether by air, land or sea, to isolate for 14 days if they have symptoms of COVID-19 or, if not exempted, to quarantine themselves for 14 days if they do not have symptoms, in order to limit the introduction and spread of COVID-19.

This applies to all people entering Canada with few exceptions — and captures those who have symptoms of COVID-19 and those who do not have symptoms.

These measures will help protect the health of individuals in question, any individuals with whom they may live and Canadians in general, including people who are vulnerable, such as adults aged 65 years or over and people with pre-existing medical conditions who are at greatest risk of severe COVID-19 disease.

Q89. How is this new Order different from the first mandatory isolation Order?

Based on new scientific evidence showing that people without symptoms may transmit the disease, any traveller now arriving in Canada—whether they have symptoms (are symptomatic) or do not have symptoms (are asymptomatic)—is required to wear a non-medical mask or face covering while in transit to isolation (if symptomatic) or quarantine (if asymptomatic).

Previously, only symptomatic people were prohibited from isolating where a vulnerable persons would be exposed.

This Order extends that directive to asymptomatic individuals as well. As such asymptomatic individuals may not quarantine in a place where they would be in contact with vulnerable persons, such as adults aged 65 and over, and those of all ages with compromised immune systems or underlying medical conditions that makes them susceptible to complications relating to COVID-19.

If an asymptomatic person is unable to quarantine themselves in a suitable location, they will be transferred to a quarantine facility chosen by the Chief Public Health Officer of Canada.

In addition, the 14-day quarantine period is reset if the person develops any signs and symptoms of COVID-19, or if they are exposed to someone who is subject to the Order and exhibits signs and symptoms after entering Canada.

Q90. How will travellers be notified of the protocol for this type of situation upon re-entry?

Upon entering Canada, travellers will be asked questions about their health and symptoms, which they are required to report to a screening or Quarantine officer. They will also be asked to acknowledge that they are required, under the *Quarantine Act*, to isolate or quarantine for a 14-day period that begins on the day on which they enter Canada.

Travellers will be provided with a hand-out that informs them that they are subject to the Order, outlines the requirements of the Order, provides public health advice and provides a link to the Canada.ca/coronavirus website where they can obtain additional information.

Persons entering Canada should also consult their provincial or territorial public health authority for any additional measures and/or restrictions regarding mandatory isolation or quarantine.

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Q91. What does the Order made pursuant to the *Quarantine Act* require of persons entering Canada? What is the difference for travellers between what they can do at home if they have no symptoms versus if they have symptoms?

Every person entering Canada must answer relevant questions asked at the border and provide any information or record in their possession that is required. They must also wear a non-medical mask or face covering upon entry and while in transit to their place of isolation or quarantine.

The Order also requires that all persons entering Canada, who are not exempted, be placed into one of two categories: asymptomatic (without symptoms) and symptomatic (with symptoms).

Asymptomatic

Persons entering Canada who do not have signs and symptoms of COVID-19 are subject to the Order and must **quarantine** for 14 days, beginning on the day on which they enter Canada, because they are at risk of developing symptoms and/or infecting others.

Quarantine means the separation of persons entering Canada from others in such a manner as to prevent the possible spread of infection or contamination.

Asymptomatic persons entering Canada must:

- go directly to their place of quarantine, without delay, and stay there for 14 days
- not quarantine in a place where they will have contact with vulnerable persons such as adults aged 65 and over, and those of all ages with compromised immune systems or underlying medical conditions
- ensure they have a suitable place to quarantine where they will have access to the necessities of life
- monitor their health for signs and symptoms of COVID-19 until the expiry of the 14 day period
- not leave their place of quarantine unless it is to seek medical attention
- arrange for the delivery of essentials like groceries or medication
- not have visitors
- not use public transportation
- not go to school, work or any other public areas
- practise physical distancing at all times (i.e. keep a distance of at least 2 metres from others)

Asymptomatic persons are encouraged to take private transportation, such as a private vehicle to their place of quarantine. They can take public transportation to their place of quarantine, but must wear an appropriate non-medical mask or face covering while in transit. They must not make any stops on the way to their place of quarantine and practice physical distancing at all times.

Persons who do not have symptoms may be required to remain in a quarantine facility chosen by the Chief Public Health Officer of Canada if they plan to quarantine themselves for a period of 14 days in a place:

- where they would be in contact with vulnerable persons;
- where they do not have access to the necessities of life (e.g. food, heat, medication); or

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- that is not considered suitable (e.g. it is a shelter or other place where many people would be newly exposed by nature of staying there).

It is important to underscore that individuals entering Canada may be asymptomatic on entry but could subsequently become sick. There are unfortunate cases where an asymptomatic individual can develop symptoms and deteriorate quite quickly.

If a person develops symptoms within 14 days they must:

- isolate themselves from others
- immediately call a health care professional or public health authority and:
  - describe their symptoms and travel history
  - carefully follow the instructions provided

The 14-day quarantine period and associated requirements is reset (begins again) if the person develops any signs or symptoms of COVID-19 or if they are exposed to someone who is subject to the Order and exhibits signs and symptoms after entering Canada.

If anyone develop signs or symptoms of COVID-19 they must act in accordance with the instructions for symptomatic individuals.

Symptomatic

Persons entering Canada who have COVID-19 or signs and symptoms of COVID-19 or reasonable grounds to suspect they have signs symptoms of COVID-19 are subject to the Order and required to remain in **isolation** until the expiry of the 14-day period that begins on the day on which they enter Canada, because they are at risk of infecting others.

Isolation means the separation of persons who are infected with COVID-19 or who have signs and symptoms of COVID-19 from others in such a manner as to prevent the spread of infection or contamination.

Symptomatic persons entering Canada must:

- use private transportation (i.e. personal vehicle) to travel to their place of isolation
- wear a non-medical mask or face covering while in transit to isolation
- go directly to the place where they will isolate, without delay, and stay there for 14 days
- not isolate in a place where they will have contact with vulnerable persons such as adults aged 65 and over, and those of all ages with compromised immune systems or underlying medical conditions
- ensure they have a suitable place to isolate where they will have access to the necessities of life
- undergo any health assessments required
- monitor their signs and symptoms and report to the public health authority if they require additional medical care
- stay inside their place of isolation
- not leave their place of isolation unless it's to seek medical attention
- arrange for the delivery of essentials like groceries or medication
- not use public transportation
- not have visitors
- not go to school, work or any other public areas

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- practise physical distancing at all times (i.e. keep a distance of at least approximately 2 metres from others)

Symptomatic persons entering Canada may be required to remain in a quarantine facility chosen by the Chief Public Health Officer of Canada if they:

- have to use a public means of transportation to get to their place of isolation; or
- plan to isolate themselves for a period of 14 days in a place:
  - where they would be in contact with vulnerable persons;
  - where they do not have access to the necessities of life (e.g. food, heat, medication); or
  - that is not considered suitable (e.g. it is a shelter or other place where many people would be newly exposed by nature of staying there).

Q92. Who is considered a vulnerable person?

Persons aged 65 and over, and those of all ages with compromised immune systems or underlying medical conditions that makes them susceptible to complications relating to COVID-19. All of these groups are at an increased risk of more severe illness.

Q93. What is the difference between isolation and quarantine?

Isolation means the separation of persons who are infected with COVID-19 or who have signs and symptoms of COVID-19 from others in such a manner as to prevent the spread of infection or contamination.

Quarantine means the separation of persons entering Canada from others in such a manner as to prevent the possible spread of infection or contamination.

Q94. How is it determined if travellers meet the conditions to isolate or quarantine at home or in a place of their choice?

Upon entering Canada, travellers are asked questions about their health and to assess their ability to meet the conditions outlined in the Order to isolate or quarantine in an appropriate accommodation.

Considerations include whether the person is able to isolate or quarantine at a place that is suitable (e.g. it is not a shelter or other place where many people could be newly exposed by nature of the individual staying there), where they can get the necessities of life and are not in contact with vulnerable persons. If the traveller is unable to meet one or more of these conditions they will be required to complete their 14-day isolation in a quarantine facility chosen by the Chief Public Health Officer of Canada.

Persons entering Canada should also consult their provincial or territorial public health authority for any additional measures and/or restrictions regarding mandatory isolation or quarantine.

Q95. How do I monitor for signs and symptoms of COVID-19?

Symptoms of COVID-19 include cough, difficulty breathing, or fever equal to or greater than 38°C (signs of fever could include shivering, flushed skin, and excessive sweating). Information

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about COVID-19 is also available at www.canada.ca/coronavirus and by calling 1-833-784-4397.

Visit the provincial or territorial public health authority website where you are located for more information, including when to contact the public health authority.

Q96. When does the 14-day period start? Is it from the day of entry into Canada or the day the traveller arrives at the place where they will quarantine themselves or isolate?

The 14-day period begins on the day the person enters Canada.

Individuals should consult their provincial or territorial public health authority for any additional measures and/or restrictions, such as a provincial emergency order that requires individuals isolate themselves for 14 days upon entering their province from another part of Canada.

Q97. What is considered to be an appropriate non-medical mask or face covering?

Wearing an appropriate non-medical mask or face covering is an additional measure you can take to protect others around you, even if you have no symptoms. It can be useful for short periods of time to prevent respiratory droplets from contaminating others or landing on surfaces. Examples of appropriate non-medical masks and face coverings include a homemade cloth mask, a dust mask or a bandana.

An appropriate non-medical mask or face covering is made of protective layers of absorbent fabric (such as cotton) that fit snuggly over the nose and mouth and are secured to the face with ties or loops. Masks or coverings should allow for easy breathing, stay the same shape after machine washing and drying and be changed as soon as possible if damp or dirty.

Q98. Who determines if the traveller is wearing an appropriate non-medical mask or face covering upon entry into Canada?

Quarantine officers or screening officers will determine the appropriateness of non-medical masks or face coverings worn by travellers entering Canada.

If it is determined that the traveller is wearing an inappropriate non-medical mask or face covering they will be asked to remove it as per the guidelines provided by PHAC. The traveller will then be required to put on an appropriate non-medical mask or face covering.

Q99. Are co-travellers able to quarantine or isolate together if one of them is a vulnerable person?

Under the terms of the new Order individuals who travelled together are able to quarantine or isolate together if one of them is a vulnerable person as long as the person is a consenting adult or is the parent or minor in a parent-minor relationship.

Q100. Am I required to comply with the Order if my province or territory has their own legal requirements for quarantine or isolation?

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Yes, anyone entering Canada must comply with the Order with few exceptions.

Provinces and territories may implement their own legal requirements around quarantine and isolation. Persons entering Canada will be expected to comply with the federal government's Order and any measures and/or restrictions enforced by their province or territory as long as they do not contradict or replace those of the Order (i.e. they must be stricter than the requirements or the Order).

Individuals should consult their provincial or territorial public health authority for any additional measures and/or restrictions.

Q101. What type of masks or face coverings will be provided at border entries? If all travellers entering Canada will be required to wear masks, how will this impact the supplies available for healthcare workers?

Travellers require non-medical masks or face coverings upon arrival. Travellers can also wear homemade cloth face coverings. Masks or face coverings may be provided upon arrival as appropriate.

Medical masks, including surgical, medical procedure face masks and respirators (such as N95 masks), should be reserved for healthcare workers and those providing direct care to COVID-19 patients.

Even while wearing a non-medical mask or face covering, strict hygiene and public health measures, including frequent hand-washing and physical distancing, must be maintained to reduce your chance of passing on the virus to someone else. It is also important to be aware that wearing a non-medical mask or face covering in the community has not been proven to protect the person wearing it. Wearing a non-medical mask or face covering is an additional measure for people—including those who do not have symptoms—to take to protect others.

Q102. Will the new requirements (e.g. travellers having to confirm their planned place to isolate or quarantine; being given a non-medical masks or face covering) create back-ups at airports?

With the introduction of the updated Emergency Order, we are building on measures previously implemented on March 25th 2020, to reduce the introduction and further spread of COVID-19 in Canada. While it can be expected that processing travellers at the border may initially increase wait times, the additional measures being implemented will further contribute to the reduction and spread of COVID-19. Efforts will be made to expedite processing travellers at the borders, while respecting public health measures and guidance, such as physical distancing by maintaining a 2 metre distance between travellers. All travellers are expected to contribute to help keep Canadians safe.

Travellers With No Symptoms (Asymptomatic)

Q103. Why do travellers with no signs and symptoms of COVID-19 have to quarantine themselves? Is it mandatory?

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Yes, the Order to quarantine is mandatory for travellers without signs or symptoms. They must quarantine themselves without delay and monitor for signs and symptoms of COVID-19 until the expiry of the 14-day period that begins when they entered Canada.

Given the rapid spread of COVID-19 around the world, with widespread transmission in an increasing number of countries, people who travelled outside of Canada are considered to be at risk of exposure to COVID-19. Also, there are numerous examples of asymptomatic individuals arriving in Canada and falling ill and emerging public health science indicates that asymptomatic and pre-symptomatic individuals may potentially spread COVID-19. Therefore, it is extremely important for their own health and that of others, for persons entering Canada to quarantine and monitor for symptoms.

As such, additional stringent measures are required to reduce the possibility of spread by persons who do not have symptoms. The Government of Canada has implemented an Order requiring anyone who is asymptomatic upon entering Canada, whether by air, land or sea, (and is not exempt) to quarantine for 14 days in order to limit the introduction and spread of COVID-19.

Q104. Why can some people without symptoms quarantine at home or a place of their choice and others must go to a quarantine facility?

Asymptomatic travellers entering Canada will be instructed to go directly to their place of quarantine, without delay, and remain there for 14 days. If they are unable to quarantine themselves in accordance with the conditions of the Order they will be sent to a quarantine facility at the discretion of the Quarantine Officer.

Considerations include whether the person is able to quarantine at a place that is suitable (e.g. it is not a shelter or other place where many people could be newly exposed by nature of the individual staying there), where they can get the necessities of life and are not in contact with vulnerable persons. If the traveller is unable to meet one or more of these conditions they will be required to complete their 14-day isolation in a quarantine facility chosen by the Chief Public Health Officer of Canada.

Q105. If I don't have symptoms can I quarantine at home if there are vulnerable people living with me?

No. Asymptomatic travellers are unable to quarantine at home if they live with a one or more vulnerable persons who are at an increased risk of more severe illness as emerging science indicates that asymptomatic and pre-symptomatic individuals may potentially spread COVID-19.

Q106. Why does my quarantine period reset if I am exposed to COVID-19 from another person subject to the Order?

Under the new Order, the 14-day quarantine period is reset if the person develops any signs and symptoms of COVID-19, or if they are exposed to someone who is subject to the Order and exhibits signs and symptoms after entering Canada.

Persons who entered Canada may develop symptoms of COVID-19 while in quarantine and expose others who are in quarantine with them and also subject to the Order. As symptoms may take up to 14 days to appear after exposure more stringent measures are required to reduce the possibility of spread.

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Q107. Can travellers with no symptoms take public transportation (including taxi) or rent a vehicle (from the airport) to get home or the place where they will quarantine?

Yes. Persons not exhibiting symptoms may take public transportation and/or rent a vehicle to get to their place of quarantine. However, they must wear an appropriate non-medical mask or face covering while in transit and go directly to the place where they will quarantine themselves without delay.

While in transit, people must follow the instructions of the quarantine officers and screening officers to avoid spreading infection to others. For example, practise physical distancing — maintain a 2-metre distance — and practise good hand hygiene and cough etiquette.

Under the terms of the Order, public transportation includes an aircraft, bus, train, taxi, subway or ride-sharing service.

Persons returning to their home to mandatory quarantine should also consult their provincial or territorial public health authority for any additional measures and/or restrictions to travel within their jurisdiction.

Q108. Can travellers without symptoms who will transit home by private vehicle have someone pick them up and drive them or must they be the sole occupant of the vehicle? If someone drives them, does that person then need to quarantine for 14 days?

For asymptomatic travellers, it is recommended that you do not ask someone to pick you up.

However, if required to do so, you must wear an appropriate non-medical mask or face covering at all times, should not make any stops on the way home and must practise physical (social) distancing at all times. This is also the case if you need to take a taxi or public transit to your home to quarantine.

In either case, if getting gas, pay at the pump. Use a drive-thru to get a meal. If you need to stop to rest, use rest areas or other places where you can park and rest in your vehicle, avoiding contact with other people.

If private transportation is unavailable, the Public Health Agency of Canada may arrange medical transportation, depending on the distance of the traveller's home or place of quarantine.

Anyone who has been in direct contact with someone who has or is suspected to have COVID-19, must quarantine for 14 days.

Q109. Why do I have to wear a non-medical mask or face covering when taking public transportation to get to my place of quarantine if I do not have symptoms of COVID-19?

Emerging science indicates that asymptomatic and pre-symptomatic individuals may potentially spread COVID-19, which may account for the occurrence of a number of secondary cases. As

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such, more stringent measures are required to reduce the possibility of spread by persons who do not have symptoms.

Wearing a non-medical mask or face covering is an additional measure you can take to protect others around you, even if you have no symptoms. It covers your mouth and nose and can reduce the chance that others are coming into contact with your respiratory droplets. It can be useful for short periods of time, when physical distancing is not possible in public settings such as when using public transit.

Q110. Are travellers with no symptoms allowed to take connecting flights?

Yes. Persons not exhibiting symptoms may take connecting flights to their final destination to quarantine as long as they wear an appropriate non-medical mask or face covering while in transit.

Travellers will be instructed by quarantine officers or screening officers to follow additional precautions while travelling to their place of quarantine to avoid spreading infection to others. For example, practise physical distancing when possible — maintain a 2-metre distance — and practise good hand hygiene and cough etiquette.

Persons returning to their home to mandatory quarantine should also consult their provincial or territorial public health authority for any additional measures and/or restrictions to travel within their jurisdiction.

Q111. What happens if a Canadian traveller, not exhibiting symptoms, misses their connecting flight and has to stay overnight in a city, before getting on their connecting flight the next day? Can they stay at a hotel or with friends or family?

People entering Canada not exhibiting symptoms may be permitted by the instructions of a quarantine officer or screening officer to stay at a hotel for an overnight layover before making their connecting flight the next day. They must wear an appropriate non-medical mask or face covering while in public settings, and go directly to their hotel without any unnecessary stops along the way.

While staying at a hotel, travellers should stay in their room to avoid contact with others, practise physical distancing (maintain a 2-metre distance) and practise good hand hygiene and cough etiquette at all times. To get a meal, use room service as long as your meal is delivered and left outside the door of your hotel room.

It is not recommended to stay with friends or family where it could be harder to avoid contact with people compared to a hotel room.

Q112. If people arrive in Canada on a charter flight, not at one of the designated four International Airports, can they use a private vehicle to get to their final destination in another province to isolate there?

Yes. People who have access to private transportation may continue onward travel, including driving to another province to isolate.

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If you must stop, follow precautions to avoid spreading infection to others. You must wear an appropriate non-medical mask or face covering and avoid contact with others (maintain a 2-metre distance) and practise good hand hygiene and cough etiquette.

If getting gas, pay at the pump. Use a drive-thru to get a meal. If you need to stop to rest, use rest areas or other places where you can park and rest in your vehicle, avoiding contact with other people.

Once home, use food delivery services or online shopping to purchase essential items, and ask family, a neighbour or friend to help with essential errands.

Q113. What about people entering Canada by land – can they stay overnight in a hotel during their drive home?

Asymptomatic individuals may be permitted by the instructions of a quarantine or screening officer to stay in a hotel overnight if necessary, but should go directly to their hotel without any unnecessary stops along the way. An appropriate non-medical mask or face covering must be worn at all times when in public settings.

While staying at a hotel, travellers should stay in their room to avoid contact with others, practise physical distancing (maintain a 2-metre distance) and practise good hand hygiene and cough etiquette at all times. To get a meal, use room service as long as your meal is delivered outside the door of your hotel room.

It is important that travellers avoid any unnecessary stops on their way home and contact with others.

Q114. There are reports of RVs being spotted in store parking lots near the border. Are they allowed to stop there to shop on their return home?

Asymptomatic people travelling in an RV will generally receive instructions that it is permissible for them to stay in their RV overnight. Their RV is, essentially, their first place of quarantine.

If they must stop overnight they are to follow precautions to avoid spreading infection to others. They must stay in their RV and avoid contact with others (maintain a 2-metre distance) and practise good hand hygiene and cough etiquette. They must avoid going into stores to make purchases.

Q115. Can people stop to get gas, use a washroom or acquire essential items on their way home to isolate?

It is important for asymptomatic travellers entering Canada to avoid contact with others. As per the instructions provided upon entry into Canada, go directly to the place where you will isolate, without delay, and wear an appropriate non-medical mask or face covering while in transit.

If you must stop, follow precautions to avoid spreading infection to others. Avoid contact with others (maintain a 2-metre distance), and practice hand hygiene and cough etiquette at all times.

If getting gas, pay at the pump. Use a drive-thru to get a meal. If you need to stop to rest, use rest areas or other places where you can park and rest in your vehicle.

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Once home, use food delivery services or online shopping to purchase essential items, and ask family, a neighbor or friend to help with essential errands, if possible.

Q116. What happens if a traveller without symptoms is unable to get to a place to quarantine themselves for 14 days?

Quarantine facilities, for example, hotels designated by the Government of Canada, will be used to lodge asymptomatic persons unable to quarantine themselves in a place:

- that is considered suitable (e.g. it is a shelter or other place where many people would be newly exposed by nature of staying there);
- where they will not be in contact with vulnerable persons; or
- where they will have access to the necessities of life (e.g. food, heat, medication).

Transportation from the point of entry into Canada to the quarantine facility will be arranged by the Government of Canada.

Travellers With Symptoms

Q117. Why can some people with symptoms isolate at home and others must go to a quarantine facility or hospital?

People entering Canada who report having COVID-19 or signs and symptoms of COVID-19 or has reasonable grounds to suspect they have signs and symptoms of COVID-19 will be instructed to go directly to their place of isolation, without delay, and remain there for 14 days. If they are unable to fulfil the conditions of the Order and isolate themselves, they will be sent to a quarantine facility, or transported to a hospital, at the discretion of the quarantine officer.

Considerations include the severity of symptoms or illness and whether they have a suitable place to isolate where they will have access to the necessities of life and will not be in contact with vulnerable persons. In addition, symptomatic travellers must have private transportation to get to their home or place of isolation.

For example, if they have onward connections, or the distance to get home is too far for PHAC-arranged medical transportation, or if they live with one or more vulnerable persons, travellers will be required to complete their 14-day isolation in a quarantine facility chosen by the Chief Public Health Officer of Canada.

Q118. How is symptomatic being defined?

Anyone who has COVID-19, or has signs and symptoms of COVID19, or has reasonable grounds to believe they have signs and symptoms of COVID-19, are considered to be symptomatic. Signs and symptoms of COVID-19 include a fever and a cough or a fever and difficulty breathing.

Q119. Can symptomatic travellers who are going home to isolate by private transportation be picked up and driven by someone or must they be the sole occupant of the vehicle?

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Symptomatic individuals must have private transportation to get to their place of isolation. They cannot have someone pick them up.

If private transportation is unavailable, the Public Health Agency of Canada may arrange medical transportation, depending on the distance of the traveller's home or place of isolation.

If the distance to get home is too far for the PHAC-arranged medical transportation, travellers will be required to complete their 14-day isolation in a quarantine facility chosen by the Chief Public Health Officer of Canada.

Q120. If I am symptomatic, can I stop at a hotel while I'm driving home?

No. It is important that you avoid contact with others. Go to the place where you will complete you 14-day mandatory isolation without delay. This means you must:

- wear an appropriate non-medical mask or face covering while in transit to their place of isolation
- go directly to the place where you will isolate using private transportation (i.e. personal vehicle) and stay there for 14 days

If you must stop, follow precautions to avoid spreading infection to others. Wear an appropriate non-medical mask or face covering, avoid contact with others (maintain a 2-metre distance) and practise good hand hygiene and cough etiquette.

Q121. Can I stop at the store to acquire essential items on my way to isolate?

No. It is important that you follow the instructions of a quarantine officer or screening officer and avoid contact with others.

Once home use food delivery services or online shopping to purchase essential items, and ask family, a neighbour or friend to help with essential errands, if possible.

Q122. What happens if a traveller with symptoms is unable to get to a place to isolate?

If private transportation is unavailable, PHAC-arranged medical transportation, up to a distance of 12 hours, may be provided to get the traveller to their home or place of isolation. If the traveller has onward connections or the distance to get to their place of isolation is too far for the PHAC-arranged medical transportation travellers will be required to complete their 14-day isolation in a quarantine facility chosen by the Chief Public Health Officer of Canada.

Quarantine facilities, for example, hotels designated by the Government of Canada, will also be used to lodge symptomatic persons unable to isolate themselves in a place:

- that is considered suitable (e.g. it is a shelter or other place where many people would be newly exposed by nature of staying there);
- where they will not be in contact with vulnerable persons; or
- where they will have access to the necessities of life (e.g. food, heat, medication).

Transportation from the point of entry into Canada to the quarantine facility will be arranged by the Government of Canada.

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Compliance and Enforcement

Q123. Who will verify compliance with the Order (i.e., spot checks)?

When entering Canada, travellers are required to provide their contact information to the Government of Canada for compliance monitoring and verification purposes.

If there are concerns that a traveller is not complying with the requirements of the Emergency Order, the assistance of peace officers may be requested to establish contact with the traveller and confirm compliance. This could include a visit to the traveller's place of isolation. PHAC is working with the Royal Canadian Mounted Police (RCMP) and provincial law enforcement agencies to verify the compliance of returning travellers with the Emergency Order.

Q124. What happens if someone does not comply with the Order?

Failure to comply with this Order is an offence under the *Quarantine Act*. Individuals who contravene the mandatory isolation or the mandatory quarantine requirements may be subject to a range of enforcement measures under the *Quarantine Act*, which include verbal and written warnings, and arrest, detention or escort to a designated quarantine site.

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

Maximum penalties include a fine of up to $750,000 and/or imprisonment for six months. Peace officers will use their discretion in determining the most appropriate action in each circumstance. Further, a person who causes a risk of imminent death or serious bodily harm to another person while willfully or recklessly contravening this Act or the regulations could be liable for a fine of up to $1,000,000 or imprisonment of up to three years, or to both.

Amendments under the *Contraventions Act* now allow for increased flexibility in enforcement of offences under the *Quarantine Act*. Law enforcement agencies, including the Royal Canadian Mounted Police, local and provincial police forces, can issue tickets to individuals with fines ranging from $275 to $1000, based on the seriousness of the non-compliance to the Quarantine Act and the Order.

The Public Health Agency of Canada (PHAC) will work with federal and provincial partners to promote, monitor and verify compliance with the Order.

Q125. How is the Public Health Agency of Canada working with federal and provincial partners to verify compliance with the Order?

PHAC is working with the Royal Canadian Mounted Police and provincial law enforcement agencies to verify the compliance of returning travellers with the mandatory isolation order using a risk-based approach, based on the information given by travellers at the border.

The information required to follow up with travellers is collected at the border and shared with provincial law enforcement agencies.

As a result of regulatory amendments made under the Contraventions Act, enforcement authorities, including the Royal Canadian Mounted Police, as well as local or provincial police forces, can now issue tickets to individuals who do not comply with orders under the Quarantine Act, such as orders requiring individuals to isolate after international travel.

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Q126. How many Canadians have been punished under the *Quarantine Act* since the middle of March. Of this number, how many have received a fine? How many have been given a prison sentence?

PHAC recommends a risk-based gradual compliance approach, recognizing that authorities will exercise their discretion in response to violations. Amendments to the *Contraventionons Act* now allow for increased flexibility in enforcement of offences under the *Quarantine Act*. Law enforcement agencies, including the Royal Canadian Mounted Police, and local and provincial police forces can issue tickets to individuals with fines ranging from $275 to $1,000, based on the seriousness of the non-compliance to the *Quarantine Act* and the order.

Based on the information that we have received from the police to date:

- No punishments have been imposed under the *Quarantine Act* or under amendments to the *Contraventions Act* since the two mandatory isolation orders (issued on March 25 and April 24, 2020). Three Canadians have received verbal or written warnings from peace officers.
- A fine of $1,000 was issued under the amendments to the *Contraventions Act*;
- No summons or appearance notices, recommendations to prosecute or prison terms have been issued under the *Quarantine Act*.

Essential Service Workers

Q127. Are essential service workers exempt from the Order?

Certain persons who cross the border regularly to ensure the continued flow of goods and essential services, or individuals who receive or provide other essential services to Canadians, are exempt from the requirements to quarantine themselves, as long as they do not have symptoms of COVID-19 upon entry in Canada.

Officers with the Canada Border Service Agency will assess whether persons crossing the border are exempt from the Order.

Persons exempt from mandatory quarantine are still required to respect the intent of the Order to minimize the spread of COVID-19 in Canada including wearing an appropriate non-medical mask or face covering upon entry into Canada, and while in transit or public settings. They will receive a handout at the border advising them to monitor their health for symptoms of COVID-19, to be aware of and respect the public health guidance and instructions of the area where they are travelling or located and the link to the Canada.ca/coronavirus website where they can obtain further information.

Q128. Why are some essential service workers not allowed to work with persons 65 years of age or older until they complete their 14-day quarantine?

Adults 65 years of age and older are one of the populations at the greatest risk of severe COVID-19 disease. Recent circumstances have highlighted the fact that residents of long term care homes are vulnerable to infections due to their communal living spaces, shared healthcare providers, external visitors and transfers from other healthcare facilities.

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Persons entering Canada whose work requires them to provide direct care to persons 65 years or older must complete mandatory 14-day quarantine to reduce the possibility of spreading COVID-19.

Q129. How will employers of temporary foreign workers support compliance with the Order?

Employers have an important role to play in helping to prevent the introduction and spread of COVID-19. Importantly, employers must not prevent or inhibit workers from meeting their obligations under the *Quarantine Act* in any way. The employer is responsible for regularly monitoring the health of workers who are in quarantine, as well as any employee who becomes sick after the quarantine period. If a worker becomes symptomatic at any time, the employer must immediately arrange for the worker to be fully isolated from others, and contact local public health officials. It is also suggested that the employer contact the appropriate consulate.

The employer must house quarantined asymptomatic workers in accommodations that are separate from those not subject to quarantine. This may require finding alternate accommodations (e.g. hotel) if this requirement cannot be met. Appropriate quarantine accommodations must allow for an environment that ensures access to the essential necessities of life (e.g. food, water, heating, etc.) while at the same time preventing exposure to vulnerable populations.

Like all Canadians, the employer is asked to report a violation to the *Quarantine Act* on the part of a worker under quarantine or isolation to local law enforcement. This includes workers that do not respect the mandatory quarantine or isolation period.

Q130. I am a temporary foreign worker and do not have a place to quarantine myself for 14 days in Canada. What do I do?

Your employer must house quarantined asymptomatic workers in accommodations that are separate from those not subject to quarantine. This may require finding alternate accommodations (e.g. hotel) if this requirement cannot be met. Appropriate quarantine accommodations must allow for an environment that ensures access to the essential necessities of life (e.g. food, water, heating, etc.) while at the same time preventing exposure to vulnerable populations.

Quarantine facilities (for example, hotels designated by the Government of Canada), may be used to lodge symptomatic or asymptomatic persons unable to isolate or quarantine because they do not have appropriate accommodations.

Order In Council 11 – Minimizing The Risk Of Exposure To Covid-19 In Order (Prohibition Of Entry Into Canada From The United States)

Q131. Why is Canada accepting asylum seekers during a pandemic?

Canada is committed to protecting the health, safety and security of Canadians while continuing to uphold our domestic and international obligations with respect to asylum seekers. The Order in Council will continue to prohibit foreign nationals from entering Canada from the U.S.

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temporarily for the purposes of making a claim for refugee protection, subject to some exceptions For those that meet an exception however, we will assess their asylum claims.

Q132. The Government of Canada has implemented extraordinary restrictions at the border and within Canada on foreign nationals, permanent residents and Canadians to respond to the pandemic. What measures are in place to help mitigate any risks to public health that may be increased by re-opening the border to asylum claimants?

Foreign nationals who enter Canada at a place other than an official land port of entry will continue to be prohibited from entering Canada for the purposes of making a claim for refugee protection, unless they meet an exception or exemption to the prohibition.
Individuals ineligible to make a claim under the STCA would be removed to the U.S., a designated safe-third country, while those who are prohibited from entering Canada to make a claim for refugee protection will be directed back to the U.S. While the global flow of persons has slowed due to the pandemic, this policy change on asylum may result in increased numbers of people entering Canada. All foreign nationals who enter Canada including asylum seekers are still subject to the mandatory isolation period of 14 days upon entry into Canada.

Where they are not able to appropriately isolate or quarantine, the Federal Government will work with claimants to find suitable accommodations for the quarantine period upon entry into Canada. Discussions between PHAC, IRCC, and CBSA are underway to establish an efficient process at the border.

Q133. What are exceptions under STCA?

Exceptions to the Safe Third Country Agreement are based on principles that take into account the importance of family unity, the best interests of children and public interest.

There are four types of exceptions:

- Family member exceptions
- Unaccompanied minors exception
- Document holder exceptions
- Public interest exceptions

Despite qualifying for one of the exceptions outlined above, refugee claimants must still meet all other eligibility criteria of Canada's immigration legislation. For example, a person seeking refugee protection will not be eligible to make a refugee claim in Canada if he or she has been determined to be inadmissible to Canada on grounds of security, violating human or international rights, or criminality.

Q134. What are the exceptions to the prohibition of those coming between ports of entry by land or at airports?

Foreign nationals who enter other than at an official land port of entry (including those who enter at airports or in between official land ports of entry) to make an asylum claim entry will continue to be directed back to the U.S., a designated safe-third country, with exceptions for:.

- Unaccompanied minors
- U.S. citizens and stateless habitual residents of the U.S.

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NOTE: Parents and legal guardians of U.S. citizens under the age of 18 fell under the exceptions under OIC 9. However, this does not align with the STCA and is removed by OIC11.

Q135. Can refugee claims be made at airports?

Refugee claims will continue to be prohibited at airports and other non-land ports of entry, unless the claimant is an unaccompanied minor, US citizen or stateless habitual resident of the US.

Quarantine Facilities

Q136. How will the Public Health Agency of Canada house and feed people who enter Canada who are not allowed to return to their homes for 14 days?

The Government of Canada has established quarantine facilities, for example hotels, to prevent the potential spread of COVID-19. Quarantine facilities will be used to lodge persons entering Canada who are unable to isolate or quarantine because they are unable to meet the conditions of the Order (e.g. live with a vulnerable person, do not have private transportation if they are symptomatic). Transportation from the point of entry to the quarantine facility will be provided by the Government of Canada.

These measures will help protect older adults and medically vulnerable people, who are at the greatest risk of severe COVID-19 disease.

PHAC is working with partners to provide the necessary needs, including food and any medical needs, of travelers who will be in isolation at a designated quarantine facility.

Q137. If a traveller returning to Canada is required to stay in a quarantine facility, will they have to pay for the costs associated with their stay?

Costs associated with staying in a quarantine facility will not be billed back to travellers who are required by a Quarantine Officer to quarantine or isolate in a designated quarantine facility. Transportation to the facility will also be provided at no cost. When travellers are in a quarantine facility, they are provided with three meals daily and other essentials through our contract with the Canadian Red Cross. All of these items are delivered to their rooms. They also have access to a toll free phone number (Canadian Red Cross) where they can identify essential items that they require.

Q138. How will my medical needs be tended to if I am required to stay in a quarantine facility?

Persons requiring care for other medical conditions will have access to medical care and emergency medical services at the quarantine facility.

Q139. How many people are in quarantine in federal facilities?

Under the Quarantine Act, Canada's Chief Public Health Officer has designated 13 quarantine sites in 9 cities across the country. As of 12 May there are: 181 returning

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travellers as follows: Vancouver 42, Calgary 5, Toronto 83, Montreal 50, Halifax 0, Fredericton 1

MODELLING AND SURVEILLANCE

Q140. What is predictive modelling?

Predictive modelling uses mathematical equations to estimate how many cases of a disease may occur in the coming weeks or months. There are many variables included in the calculation that are based on what we know about the affected population, the disease, the virus and how it spreads.

We can then change the calculations in ways that reflect how pubic health measures would decrease transmission and assess how well these measures may control the epidemic.

Q141. What are the objectives of modelling?

The objectives are to:

- predict the possible number of cases of COVID-19 that may occur in the coming weeks or months; and
- assess the best methods to control the epidemic in Canada.

The various projections help us to decide what public health measures we need to use, and how to prepare the health care system for the anticipated number of patients affected by COVID-19.

Q142. What considerations or factors are the modelling data based on? What information are you using to make predictions?

There are two general types of model:

- Forecasting models use our knowledge of how the epidemic has evolved in Canada and in other parts of the world in recent days and weeks to forecast how many new cases we may expect to see in the coming week or so. These models assume that the number of cases will continue to grow as they have in previous days or weeks.
- Dynamical or mathematical models use our knowledge of the virus causing COVID-19 (the SARS-CoV-2 virus) and how it spreads based on studies from around the world. This knowledge is used to produce a mathematical representation (i.e., a model) of how COVID-19 may spread in the Canadian population under different public health measures to control the disease. We develop these models to help us with planning. The models are to be adjusted as we get better data on the actual epidemic situation, and the resulting predictions will change over time.

Q143. What are the different public health measures that are being used by communities and are modelled to anticipate their potential impacts on the epidemic?

The main public health measures are:

- Social or physical distancing—which includes measures such as closing schools, universities, meetings and meeting places, and teleworking, with the aim of reducing the possibility that an infected person will transmit the virus to another person.

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- Case detection and isolation—which is finding infected people through testing and public health surveillance and isolating them (at home or in hospital) so they cannot transmit the infection to someone else.
- Contact tracing and quarantine—which is finding people who have had contact with a COVID-19 case and making sure they remain in quarantine for 14 days (or longer if they themselves start to show symptoms) so they cannot transmit infection.

All of these public health measures aim to break chains of transmission in the community.

Q144. How reliable is the data?

Our knowledge of COVID-19 continues to evolve internationally. The epidemic in Canada also continues to evolve, and new data for cases become available every day. Model-based predictions will be updated and adjusted as the science evolves and as new data on the cases occurring in Canada become available. The models will also be updated to reflect any changes in the public health measures being used to control the epidemic.

This iterative approach to our modelling will help us to assess the possible impact of changes in public health measures over time. It will also help us prepare the health care system for the anticipated number of COVID-19 cases requiring hospital care.

The actions Canadians take every day will continue to influence the predictions and the actual numbers.

Q145. Why are you providing two different models? Isn't one enough? What's the difference in the two models and what are their limitations?

The **forecasts** are based on data from the epidemic as it is actually evolving in Canada and allow us to understand what is happening in the short term based on our experience so far in Canada and the experience of other affected countries.

The **dynamical models** provide a long-term view of possible ways the epidemic may evolve and help us evaluate which public health measures will minimize the impact on Canadians.

Q146. Do we have different projections from provinces and territories that have released modelling data? If so, why?

We are using similar methods for forecasting cases in the coming weeks, and modelling impacts of different public health measures. However, we are forecasting and modelling what is happening in Canada as a whole, while individual provinces have a local focus. The provincial models are based on data from their provincial cases, so their predictions will be different and specific to their evolving situation.

Q147. What external experts are advising on this work?

The Public Health Agency of Canada established an external advisory group to support our efforts to model and make predictions on the COVID-19 epidemic. This advisory group comprises 37 experts on infectious disease modelling and epidemiology from provincial and territorial public health organizations and from universities across Canada. The group meets twice a week.

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The Agency participates in the World Health Organization modelling group to learn from studies conducted around the world and to benchmark our studies against them.

Q148. When will modelling studies conducted outside PHAC be made available?

Modelling studies conducted outside the Agency have been published and are widely available. PHAC is committed to scientific excellence and will provide the detail of these results through reputable scientific publications. The process for these publications is already underway and PHAC will make these widely available as soon as possible after their release.

Additional Resources:

COVID-19 in Canada: Using data and modelling to inform public health action

Statement from the Chief Public Health Officer of Canada on the release of national modelling on the COVID-19 epidemic in Canada

Q149. Will these models show us whether we are achieving our objectives?

Models suggest what will happen with different types of public health measures. How effective these are will be reflected in surveillance data. We are continually evaluating the impact of our public health measures on the number of cases reported in surveillance, and we are adjusting them as needed in collaboration with our provincial and territorial partners. It is important to remember that it takes about two weeks before we can see the impact of public health measures in our surveillance data. This is because of the time lapse between when a case is infected and when they are reported to the Public Health Agency of Canada as a confirmed case.

Q150. Why is there a delay in measuring the mortality rate and are there plans to expedite the release of this data to reflect the current pandemic?

The Public Health Agency of Canada (PHAC) and Provincial and Territorial (PT) Public Health Authorities are working collaboratively to provide the best available and most accurate information to Canadians including number of COVID-19 cases and deaths. All efforts are made to have timely reporting, but as for any disease surveillance, and given the heavy burden that COVID-19 is currently causing on the PTs' staff, there are some delays in the reporting of data to PHAC, in particular for deaths. The Centre for Immunization and Respiratory Infectious Diseases (CIRID) program area is working on a data strategy including on a number of complementary indicators including more timely death data in order to supplement what can be found in the current case report forms for COVID-19 and beyond.

Q151. What is the median age of people who have died in Canada?

As of April 22, 2020 (noon EDT), the median age of COVID-19 related deaths is 84 years of age. This is based on analysis of 764 COVID-19 case report forms reporting an outcome of death and for which age information is complete.

Q152. In the daily epidemiological report, only about 1/3 of COVID-19 include hospitalization data. Why is this? Have certain provinces failed to provide hospitalization data? If yes, which provinces and for what reason?

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All efforts are being made to have timely information, but there are inherent delays in collating information in a surveillance system flowing from the local to the national level. PHAC and provincial and territorial public health authorities are working closely together to provide the most accurate information to Canadians. As noted, detailed data on cases have been received at the national level from the provinces and territories for approximately 65% of reported cases. Data on these cases are preliminary and may have missing values for characteristics of interest or they may be coded as "unknown." For the most part, when hospitalization information is not available to us on the case report form, it is because hospitalization status has been coded as "unknown."

Q153. Is Canada's total COVID-19 death toll greater than reported and that it will take modelling based on overall death statistics after the pandemic is over to understand the full extent of the death toll?

As of the morning of April 15, 2020, there were 27,063 cases and 903 deaths of COVID-19 reported in Canada, leading to a case fatality ratio (CFR) of 3.3%. The CFR is a commonly used method proposed by the World Health Organization and represents the number of deaths divided by the total number of cases.

As experienced in all countries, this measure varies over time during an epidemic. During the early phase of the epidemic, a lower estimate is usually obtained because people who die tend to do so late in the course of their illness. Other emerging factors, such as recent outbreaks in vulnerable populations at long-term care homes, as well as other factors affecting data reporting can influence this estimate at any given time. We are expecting the accuracy of the CFR to increase as we progress in the epidemic.

Our knowledge of COVID-19 continues to evolve every day. Model-based predictions will be updated and adjusted as the science evolves and as new data on the cases occurring in Canada become available.

April 28, 2020 Modelling Announcement

Q154. What are the modelling numbers now? How do they compare with those in the first release?

The current modelling estimates between 51,196 and 66,835 cumulative cases and between 3,277and 3,883 cumulative deaths across Canada by May 5.

The modelling presented on April 9 estimated between 22,580 and 31,850 cumulative cases by April 16. The actual number of cumulative cases reported by April 16 was 29,826.

The projection of deaths due to COVID-19 was between 500 and 700 by April 16. The actual number of cumulative deaths reported by April 16 was 1,048. The modelling has now been adjusted to address the underestimation of deaths in the last release.

Q155. With such a wide range between best and worst case scenarios, what's the value of this modelling exercise?

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The objectives of the modelling are to help predict the possible number of cases of COVID-19 that may occur in the coming weeks or months, and to assess the best methods to control the epidemic in Canada. As a result, modelling provides information on what could happen under various scenarios, to allow us to prepare for the worst case, and to guide public health action to enable the best possible outcome. These various projections help us to decide what public health measures we need to use, and how to prepare the health care system for the anticipated number of patients affected by COVID-19.

Q156. You were way off on the projected deaths two weeks ago. Why should we believe these numbers now?

The Public Health Agency of Canada (PHAC) forecasts the number of deaths by a statistical range based on a 2.2% case fatality rate, which is the ratio of the number of deaths to the number of cases. This ratio is also being used by the World Health Organization.

It is important to recognize that models have inherent limitations. The estimation of the case fatality rate is usually low during the early stages of an epidemic because the growth of confirmed cases in the denominator is much faster than the growth of the number of deaths in the numerator during this period.

Emerging factors, such as recent outbreaks in vulnerable populations at long-term care homes, were not included in our calculations. Modelling projections are also highly sensitive to changes in our actions (e.g., degree to which people follow physical distancing direction).

Q157. Have you fine-tuned your methodology so that the predictions are more accurate?

Models cannot predict what will happen. But they can help us understand what *might* happen. For the dynamic modelling approach, the models are constantly being updated as more information arises on the transmission of the virus causing COVID-19. For the weekly projections, the method will depend on what best aligns with the pattern of the epidemic—based on the number of reported cases and deaths in the preceding weeks.

The short-term projections for cumulative cases have been proven to perform well. The short-term projections for deaths are based on a different method. In the first release, the projections for deaths were based on a fixed value from the calculated case fatality ratio (CFR), which did not take into account the fluctuation of CFR over time. The CFR was especially affected by the significant number of deaths from long term care facilities. We believe that the new method will be more accurate.

Q158. What new data or variables, if any, have been added? What exactly are the variables you are using (age, gender, underlying health conditions)?

Predictive modelling uses mathematical equations to estimate how many cases of a disease may occur in the coming weeks or months. There are many variables included in the calculation that are based on what we know about the affected population, the disease, the virus and how it spreads.
We can then change the calculations in ways that reflect how public health measures would decrease transmission and assess how well these measures may control the epidemic.

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For these projections, the method uses the pattern of the epidemic—in terms of reported cases and deaths—in the preceding weeks. This dynamic modelling approach helps us try to predict possible total numbers of cases over the whole epidemic according to different scenarios for levels of control.

These total numbers are then used to assess how many Canadians may be mildly or severely affected, and how many may die, according to global estimates of differences in severity among different age groups, while accounting for the age profile of the Canadian population. Models are being developed by partners in universities to assess province-specific numbers of cases and health care needs that account for local data on underlying health conditions, age and gender.

Q159. What dates are the modelling projections based on?

The Public Health Agency of Canada (PHAC) is periodically updating its modelling work, which includes national projections of the total number of cases. The projection presented on April 9 was produced on April 6 or a 10-day window up to April 16. Similarly, the projection presented on April 28 was produced on April 24 for a 10-day window up to May 5.

Modelling projections based on data up to April 18 gave a 10-day projected range of 39,950 to 47,235 cumulative reported cases and 2,330 to 4,017 cumulative deaths for April 28.

Q160. Dr. Tam repeatedly says that this pandemic is not unfolding in the same way in every part of the country, or in every demographic. Are you developing any demographic-specific modelling or providing modelling that covers specific vulnerable populations, such as those who live in LTC homes or are homeless?

PHAC is using a range of modelling methods to assess and understand how COVID-19 may spread in Canada in the coming weeks and months. We know, that based on the data provinces and territories have provided about their cases, there are different patterns of spread and different populations affected in each jurisdiction.

We do not have modelling specific to transmission in long-term care homes. However, while we undertake model-based projections for the country as a whole, we are also developing models that consider the spectrum of differences amongst provinces and territories, municipalities, and vulnerable populations.

Such models, which can account for local variations in demography, reflect the complexity of epidemics within each province, are more useful for planning at provincial and local levels.

PHAC is committed to scientific excellence and will provide the details of its modelling results through reputable scientific publications. The process for these publications is already underway. PHAC will make these results widely available as soon as possible after their release.

Q161. Are you collecting data based on race and ethnicity, including Indigenous populations? Wouldn't that make your modelling more accurate?

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There is no indication that race/ethnicity is a risk factor for COVID-19. It is circumstances or settings that make it difficult to practice public health measures, such as physical distancing, that affect the risk of spread.

The national COVID-19 case report form collects data on Indigenous status (First Nations, Métis and Inuit). However, data on Indigenous status of COVID-19 cases reported by provinces and territories is not complete.

Q162. BC's and Ontario's modelling data show that they have already peaked in cases among community spread and numbers appear to be trending downwards. Is this the case for Canada as a whole? As provinces see a decline in cases and begin relaxing restrictions, how will it affect the modelling data?

Surveillance data suggest that, overall, the public health measures put in place across Canada are having a large impact and slowing the epidemic. The degree to which the epidemic is coming under control is highly variable among jurisdictions. We are watching this situation closely.

The epidemic in Canada continues to evolve, and model-based projections continue to be updated and adjusted as new data become available. The models are also updated to reflect any changes in the public health measures being used to control the epidemic.

Modelling allows us to assess the possible impact of public health measures over time, adapt calculations to reflect how public health measures decrease transmission and assess how well these measures may control the epidemic. The modelling data presented take into account changes to the public health measures (e.g., timing, type, location). Modelling data also help to inform when we can reopen schools, workplaces and other venues and when, if needed, restrictions need to be increased again.

It is important to remember that we must not let our guard down, and we must be realistic and recognize that this epidemic will continue for some time. If the public health measures are eased too quickly, it is likely that the epidemic would accelerate very quickly.

Q163. Have you factored in the reopening of certain provinces and territories, many of whom have begun announcing their plans? Could there be any spillover to and from other, more affected regions?

Surveillance data suggest that overall the public health measures put in place across Canada are having a large impact and slowing the epidemic. The degree to which the epidemic is coming under control is very variable among jurisdictions. We are watching this situation closely.

The epidemic in Canada continues to evolve, and model-based projections continue to be updated and adjusted as new data become available. The models are also updated to reflect any changes in the public health measures being used to control the epidemic. PHAC is working with partners in academia to explore the possible effects of removing public health measures.

Modelling allows us to assess the possible impact of public health measures over time, adapt calculations to reflect how public health measures decrease transmission and assess how well these measures may control the epidemic. The modelling data presented take into account

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changes to the public health measures (e.g., timing, type, location) and explore when we can reopen schools, workplaces and other venues and when, if needed, restrictions need to be increased again.

It is important to remember that we must not let our guard down and we must be realistic and recognize that we are still at the beginning of this epidemic. If the public health measures are eased too quickly, it is likely that the epidemic would return very quickly.

Q164. How can any government be talking about re-opening the economy when these figures show 3,277 to 3,883 deaths by May 5 if current measures don't continue?

While PHAC has undertaken model-based projections for the country as a whole, it is recognized that the nature of the epidemic is different in different parts of Canada. Each region will have a different schedule for relaxing current public health measures.

PHAC is collaborating with federal, provincial and territorial governments, and universities to explore the possible future spread of COVID-19 in Canada and to estimate the range of possible numbers of cases, hospitalizations and deaths that may occur in the coming weeks and months, given different scenarios for public health interventions.

We are continually monitoring the impact of our public health measures by reviewing and analyzing surveillance data on cases and outbreaks. In addition, we are adjusting our surveillance systems as needed in collaboration with our provincial and territorial partners.

Q165. The lack of quality and timely data has been touted as an issue with being able to develop this modelling. Did you experience any issues this past round? Any vulnerabilities in the info you are presenting us due to the lack of data?

All efforts are being made to have timely information however, there are inherent delays in collating information in a surveillance system flowing from the local to the national level. The epidemic in Canada also continues to evolve, and new data for cases become available every day. Model-based projections continue to be updated and adjusted as the science evolves and as new data on the cases occurring in Canada become available. PHAC and provincial and territorial public health authorities will continue to work closely together to provide the most accurate information to Canadians.

Q166. What improvements are being made to ensure you are getting quality and timely data for this modelling? Will there be better data for the next update, and when do you expect that will be?

For the dynamic modelling approach, the models are constantly being updated as more information arises on the transmission of the virus causing COVID-19. The projected number of cases and deaths are constantly being updated using forecasting methods, which includes analyses of the pattern of reported cases and deaths reported in the preceding weeks.

The short-term projections for cumulative cases have been proven to perform well. The short-term projections for deaths are based on a different method. In the first release, the projection of deaths was based on a fixed value from the calculated case fatality ratio (CFR), which did not take into account the fluctuation of CFR over time. The CFR was especially affected by the

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large number of deaths from long-term care facilities. We believe that the new method will be more accurate.

Q167. There have been reports of a significant decline in visits to ERs across the country for non COVID-19-related illnesses. Do you have numbers on how many Canadians may die because they're afraid to go to the hospital and catch the virus?

It is not currently possible to estimate or model the reasons behind changes in ER usage; therefore, this information is not part of our modelling data. The provinces and territories may have more detailed information about the situation within their individual jurisdictions.

We recognize that many Canadians may feel concerned about visiting a doctor's office or hospital given the current pandemic. However, we want to stress that it is very important that Canadians continue to seek care and talk to a health care professional if they feel unwell.

Q168. Are you presenting higher numbers than you believe, just to scare people into following the restrictions in their daily lives?

Models cannot predict what will happen. But they can help us understand what *might* happen. The purpose of releasing modelling is not to provide distorted or inaccurate pictures to scare Canadians into following public health measures. The objectives of modelling are to help us understand and see the possible number of cases of COVID-19 that may occur in the coming weeks or months, and to assess the effect that the public health measures have had on reducing the impact of the pandemic. The work the Agency has presented shows that public health measures are working and will continue to help slow the spread of COVID-19 if maintained.

PHAC is continually evaluating the impact of the public health measures, which aim to break the chains of transmission in the community. It is important to remember that we must not let our guard down and we must be realistic and recognize that we are still fighting this epidemic. If the public health measures are eased too quickly, it is likely that the epidemic would return very quickly.

Q169. Will the season (temperature) affect your prediction?

To date, the evidence does not suggest that the temperatures we expect to see in Canada during the summer will influence virus transmission. The short-term projections being released today do not take season (temperature) into account.

Q170. Is Health Canada advising provinces to Check past records for patients admitted for pneumonia before first case of COVID-19 was reported?

To our knowledge only one province has done this to date and no earlier cases have been detected in retrospect.

Understanding the virus that causes COVID-19, its origin, and subsequent evolution are important questions that are being studied. Retroactively testing samples from severe respiratory infections before the first cases were identified in Wuhan, China will provide valuable evidence as scientists learn more about the virus. However, public health

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measures right now are focused on testing active cases to stop transmission chains and inform important public health decisions to protect the health of Canadians.

Q171. What is PHAC's response to Dr. Amir Attaran criticisms of the Canadian COVID-19 modelling?

Models provide information on what could happen under various scenarios, to allow us to prepare for the worst case, and guide public health action to enable the best possible outcome. The possible outcomes presented in the Government of Canada's modelling are a synopsis of modelling studies including those conducted by the Public Health Agency of Canada (PHAC), and by other epidemiologists and modellers in Canada and elsewhere in the world. The three possible outcomes presented were: a "no controls" scenario in which an unconstrained outbreak occurs infecting a very high proportion of Canadians, a "weaker controls" scenario in which the epidemic is not brought under control by public health measures but is prolonged and the peak lowered by public health measures, and a "stronger epidemic control" scenario in which the epidemic is brought under control by a combination of public health measures. These scenarios are for planning purposes and not predictions of the future. Studies conducted outside PHAC have been published and are widely available, while those conducted within the Agency will be made available in the coming weeks.

We are collaborating with federal, provincial and territorial governments and universities to explore the possible future spread of COVID-19 in Canada and to estimate a range of possible numbers of cases, hospitalizations and deaths that may occur in the coming weeks and months given different scenarios for public health interventions. Predictive modelling for COVID-19 requires that we make assumptions based on incomplete data and evolving science. These assumptions change as we get new information about the virus and more data about the epidemic in Canada. We are continually improving the models to provide the best available information to Canadians about possible outcomes.

The work Dr. Attaran cites is consistent with our own studies and those of other groups. In the absence of public health measures, 70% or more Canadians may acquire infection. If public health measures are implemented and then all released suddenly or too soon, the epidemic will simply rebound. If public health measures are not sufficient to cause the epidemic to end, they may nevertheless somewhat reduce the percentage of Canadians that must acquire infection and become immune for "herd immunity" to cause the epidemic to die out.

Additional work by the Agency and other modellers, and consistent with observations in other countries, suggest that low percentages of infected Canadians (the 1-10% range) could be achieved with high levels of public health effort. This effort would include sustained public health measures to prevent reintroduction of transmission, to detect and isolate cases in Canada, and to trace and quarantine people who have come into contact with cases.

Q172. Prof Attaran also accused PHAC of censoring data provided to scientists. If true, why does PHAC censor data before disclosing it?

The Public Health Agency of Canada (PHAC) established an external advisory group to support our efforts to model and make predictions on the COVID-19 epidemic. This advisory group comprises over 40 experts on infectious disease modelling and epidemiology from provincial and territorial public health organizations and from universities across Canada. This collaborative group meets twice a week. PHAC is also committed to ensure that research and

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scientific information produced by the Agency is made available to the public in a timely manner and in keeping with the Government of Canada's Directive on Open Government, including a daily epidemiological report and preliminary data tables related to confirmed cases. In some cases, PHAC is not in a position to transfer some data if these are the property of a third party or if there are compelling reasons for limiting disclosure, such as for privacy reasons. Our knowledge of COVID-19 continues to evolve internationally. The epidemic in Canada also continues to evolve, and new data for cases become available every day. Model-based predictions will be updated and adjusted as the science evolves and as new data on the cases occurring in Canada become available.

Fluwatchers

Q173. Prior to COVID-19, what was the Fluwatchers program responsible for? Can you also share any numbers you may have e.g. how many Canadians have volunteered to participate in the Fluwatch in 2018 and 2019?

FluWatchers started in the Fall of 2015 and is part of FluWatch, Canada's National influenza surveillance program. It is a syndromic surveillance program used for the surveillance of influenza-like illnesses in Canada.

Traditional influenza surveillance programs, such as laboratory-based and hospital-based surveillance, only capture individuals who seek medical care or test positive for influenza and, as a result, miss a lot of potential influenza cases. For that reason, the Public Health Agency of Canada (PHAC) started FluWatchers with a goal of capturing cases of influenza-like illness in individuals who do not seek medical care or get tested for influenza. This program enables Canada to get a more robust picture of influenza cases in Canada during the typical influenza season. The FluWatchers program also provides additional valuable surveillance indicators such as how many symptomatic individuals seek medical attention, how many get tested and their results.

The weekly number of participants have been growing from 400 weekly participants in 2015, to 2,200 in 2018, to 3,200 in 2019.

Q174. When did the Fluwatchers program pivot towards tracking COVID-19, and why?

PHAC has been monitoring the FluWatchers data since the start of the pandemic in Canada for signals of unusual increases in Canadians experiencing cough and fever. Minimal changes were made to the questionnaire near the end of March 2020 to include COVID-19 specific questions. PHAC is using FluWatchers to track COVID-19 for the same reasons it is used to track influenza. The vast majority of individuals are likely not going to seek medical care or get testing; therefore, a large proportion of the population will not be captured in the traditional surveillance methods currently being used. The FluWatchers program will also provide an idea of how many symptomatic individuals seek medical attention and how many get tested and their results. This program will hopefully enable Canada to get a more robust picture of COVID-19 cases in the country, the same way it does for influenza.

Q175. How can you differentiate between the flu and COVID-19 in the responses you receive now?

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Syndromic surveillance programs such as FluWatchers are used for signal detection. If this program is signaling something, we usually use it as a trigger to look into our other surveillance data streams to validate the signal that we are seeing. We are able to validate the results we get from FluWatchers against data from our other influenza surveillance programs. For example, currently, based on our laboratory surveillance data stream, there is very little influenza or other seasonal respiratory viruses circulating in Canada. Our other influenza indicators such as hospitalizations and outbreaks surveillance are also reporting very low influenza activity. We can use this knowledge to differentiate the data being reported by FluWatchers. If influenza was in high circulation, we suspect that responses from FluWatchers would likely be influenza. Since there is currently very low circulation of influenza (and other respiratory viruses) and as we see the end of flu season, we can hypothesize that responses from FluWatchers could be attributed to COVID-19.

Q176. Can you share how many Canadians have participated in tracking COVID-19 via the Fluwatchers program? Have any trends emerged in your responses?

PHAC began increasing promotion of FluWatchers through social media since April 3, 2020, in an effort to recruit additional participants. Since then, our weekly participation rate has increased to from 3,200 to 8,700 weekly participants. The more participants reporting, the more accurate the data.

The percentage of participants reporting cough and fever has been low. For example, for the week of March 29, 2020, of the 6,200 participants, 0.5% (32 participants) reported having cough and fever. For the week of April 5, of the 8,700 participants, 0.3% (24 participants) reported having cough and fever. These low rates of cough and fever may be the results of physical distancing measures and we hope that these rates remain low in the coming weeks.

GPHIN's Role In Surveillance

Q177. During virus outbreaks, what data does GPHIN collect and use for alerts and in what languages is the data disseminated?

The Public Health Agency of Canada's Global Public Health Intelligence Network (GPHIN) is an early-warning and situational awareness system for potential chemical, biological, radiological and nuclear public health threats worldwide—including outbreaks of infectious disease.

GPHIN users include non-governmental agencies and organizations, as well as government authorities who conduct public health surveillance. GPHIN is a significant contributor to the World Health Organization's Epidemic Intelligence from Open Sources.

Every given day, about 7,000 articles are captured in the GPHIN system. The web-based application in the GPHIN system continuously scans and acquires news sources of information worldwide in nine languages (Arabic, Farsi, English, French, Portuguese, Russian, Spanish, and simplified and traditional Chinese).

GPHIN's main data provider is Factiva, a global news database and research platform that contains nearly 33,000 sources, including newswires, newspapers, and trade publications. GPHIN also mines specific RSS feeds from relevant publications and twitter accounts.

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In addition, GPHIN analysts have programmed specific Google Alerts and monitor other news aggregators applications, such as ProMED and HealthMap, to further increase the variety of what is included in GPHIN.

GPHIN analysts have extensive lists of websites and social media accounts from official governmental sources, medical expert forums and other relevant sources that they monitor on a daily basis. Once the data are in the GPHIN system, they are processed, validated, and assessed.

Q178. How are GPHIN threat assessments and analyses compiled?

GPHIN does not prepare threat assessments. Rather, it is an information management tool that uses machine learning and natural language processing to facilitate the work of a multidisciplinary team of analysts who review information in nine languages and conduct rapid risk assessments to detect public health threats.

Each day, over 7,000 articles are captured in the GPHIN system. Data in the GPHIN system is processed, validated, and assessed for inclusion in reports, including the Situational Awareness Daily Report published every morning.

Q179. When was data first collected on the coronavirus outbreak and from what source?

On December 31, 2019, at 05:16 AM EST, an article called "China probes mystery pneumonia outbreak amid SARS fears" was published by Agence France Presse and uploaded in the GPHIN system at 05:42 AM EST.

Q180. When did GPHIN first send out an alert about the coronavirus outbreak and to whom?

The GPHIN analysts conducting their daily review recognized the potential importance of this issue and highlighted it in the Daily GPHIN report, which was distributed at 07:50 EST that day to Canadian public health practitioners at the federal, provincial and territorial levels. The report included the following summary:

> **International Events of Interest**
> **China - China probes mystery pneumonia outbreak amid SARS fears (Media)**
> Authorities are investigating an outbreak of viral pneumonia in central China amid online speculation that it might be linked to SARS, the flu-like virus that killed hundreds of people a decade ago. There were 27 cases of "viral pneumonia of unknown origin" reported in Wuhan, in central Hubei province, the city's health commission said in a statement. Seven patients were in a critical condition.

Q181. Did Chinese officials ever brief Canadian officials on COVID-19? If so, when and what did they say?

Canada and China have exchanged information on a regular basis since the outbreak began at the outset of 2020. This has included discussions between the health officials of our two countries and numerous discussions between both health and foreign affairs officials, involving our respective embassies in Ottawa and Beijing. There have been interactions via multilateral processes such as the G20 as well.

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Minister Champagne discussed COVID-19 related matters with his Chinese counterpart, Foreign Minister and State Councillor Wang Yi, on three separate occasions: January 30, February 14, and April 2, 2020:

- January 30 - https://www.canada.ca/en/global-affairs/news/2020/01/readout-foreign-minister-holds-call-with-chinese-counterpart.html
- February 14 - https://www.canada.ca/en/global-affairs/news/2020/02/readout-minister-champagne-meets-with-chinas-foreign-minister.html
- April 2 - https://www.canada.ca/en/global-affairs/news/2020/04/readout-minister-of-foreign-affairs-speaks-with-chinese-counterpart.html

As part of his regular contacts with the Chinese Embassy, Paul Thoppil, Assistant Deputy Minister for Asia at Global Affairs Canada, also had a number of conversations with Chinese Ambassador Cong Peiwu on related matters early in the year to discuss the evolution of the outbreak. Other Global Affairs Canada officials in Ottawa and at the Canadian Embassy in Beijing, including Ambassador Dominic Barton, have also engaged in several COVID-19-related conversations with Chinese officials, starting in January. Early conversations focused on sharing information regarding the evolution of the outbreak and the evacuation of Canadian citizens from Wuhan, followed by discussions about Canada's offer to provide PPE material to assist China in fighting the outbreak.
Recent high-level discussions, both in Ottawa and Beijing, focused more specifically on procurement of medical supplies from China to Canada and global containment measures.

Q182. ***What was the Agency's first public notice/bulletin/news release that concerned COVID-19? Can you provide a link?***

The first Travel Health Notice was issued on **January 7, 2020.**

Q183. How have screening and testing guidelines changed as COVID-19 progressed? Please provide a timeline starting with what they were in early January, 2020.

Regarding screening measures at the border, enhanced measures were implemented on **January 22, 2020** to identify and screen travellers from Wuhan, China arriving at airports with direct flights from China (Vancouver, Toronto and Montreal). Information materials (e.g., handouts, on-screen messaging) were also made available on **January 22, 2020** at key airports to inform travellers entering Canada of their obligation to disclose to a Canada Border Services Agency (CBSA) Border Services Officer if they were experiencing symptoms such as fever, cough or difficulty breathing and advising them where they could find more information on the novel coronavirus from the Government of Canada. These materials were adjusted accordingly as the enhanced screening measures evolved. PHAC increased quarantine officer and public health officer presence at key airports to partner with CBSA Border Services Officers to screen ill passengers and to provide information to healthy travellers.

As the virus spread internationally, these measures were expanded to seven more airports, and on **March 6, 2020** to all land, rail and ferry points of entry. Screening measures were further expanded to identify symptomatic travellers from areas where there was an outbreak of COVID-19, including the Province of Hubei, China, as well as Iran and Italy.

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On **March 13, 2020** the Government of Canada issued an official global travel advisory to avoid non-essential travel outside Canada and all travellers entering Canada, regardless of their point of departure, were screened for symptoms of COVID-19 and asked to voluntarily self-isolate for 14 days upon entering Canada, whether or not they had symptoms.

The Government of Canada began limiting international flights to four international airports (Montreal, Toronto, Calgary and Vancouver) and, as of **March 18, 2020**, air operators were required under the *Aeronautics Act* to conduct basic health assessments of all air travellers boarding flights to Canada based on guidance provided by PHAC. In the event the traveller presents with COVID-19 symptoms, the air operator is required to refuse to board the passenger for a period of 14 days.

On **March 18, 2020** the Government of Canada implemented an Emergency Order that temporarily closed the country's international borders to prohibit foreign nationals from any country other than the U.S. from entering Canada. On **March 20, 2020**, a similar temporary Emergency Order was issued to prohibit entry into Canada from the U.S., which came into force on **March 21, 2020**.

On **March 25, 2020**, the Government of Canada implemented an Emergency Order for Mandatory Isolation requiring all travellers entering Canada to isolate (if they had symptoms of COVID-19) or quarantine (if they did not have symptoms).

On **March 26, 2020**, the Government of Canada replaced existing Emergency Orders to prohibit all foreign nationals from entering Canada, with certain exemptions including air crew, diplomats and those providing essential services.

Effective **April 15, 2020**, the Government of Canada issued a new Emergency Order for Mandatory Isolation requiring all travellers entering Canada to isolate (if they had symptoms of COVID-19) or quarantine (if they did not have symptoms) upon entry into Canada and to wear a non-medical mask or face covering while in transit to their place of quarantine or isolation. In addition, all travellers subject to the order could not quarantine or isolate in a place where they would be in contact with people who are vulnerable, such as adults aged 65 years or over and people with pre-existing medical conditions, or where they are unable to access necessities of life, such as food and medication.

New measures came into effect on **April 20, 2020** requiring all air passengers to wear a non-medical mask or face covering that covers their mouth and nose during travel.

On **April 22, 2020** the temporary Emergency Order prohibiting foreign nationals arriving from the United States to enter Canada was renewed for 30 days.

Q184. How do experts in Canada communicate? Does the Public Health Agency of Canada reach out to external experts or do Canada's health experts work within the organization? Does Canada rely on the WHO for expertise?

The Government of Canada has created the infrastructure to respond to the public health threats of the virus, and is well prepared to act—in collaboration with provincial and territorial governments and international partners—to minimize the health, economic, and social impacts of this rapidly evolving public health issue.

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PHAC officials are routinely in touch with key domestic and international partners. In the case of COVID-19, using existing mechanisms, such as federal, provincial and territorial public health tables, and in working with appropriate stakeholders, the Government of Canada has developed important guidance documents to help Canada implement public health measures across jurisdictions in efforts to flatten the curve.

Canada's response is based on plans and guidance related to pandemic preparedness, with the following guiding principles:

- **Collaboration** - all levels of government and stakeholders need to work in partnership to produce an effective and coordinated response.
- **Evidence-informed decision-making** - decisions should be based on the best available evidence.
- **Proportionality** - the response to a pandemic should be appropriate to the level of the threat.
- **Flexibility** - actions taken should be tailored to the situation and evolve as new information becomes available.
- **A precautionary approach** - timely and reasonable preventive action should be proportional to the threat and informed by evidence to the extent possible.
- **Use of established practices and systems** - well-practised strategies and processes can be rapidly ramped up to manage a pandemic.
- **Ethical decision-making** - ethical principles and societal values should be explicit and embedded in all decision-making.

These principles build on lessons learned from past events, particularly the Severe Acute Respiratory Syndrome outbreak in 2003, which led to dedicated legislation, plans, infrastructure, and resources to help ensure that the country would be well prepared to detect and respond to a pandemic outbreak.

Among our key international partners are the World Health Organization (WHO) and its regional office, the Pan American Health Organization. Canada continues to support the WHO in its efforts to help countries respond to the virus and has put in place public health measures in line with its guidance.

Canada has engaged with international country partners–some of whom are ahead of us in terms of the epidemiological curve–through various means since the novel coronavirus emerged. This international engagement has also enabled us to learn from others' experiences, expertise and best practices, and inform our domestic response. Existing engagement mechanisms, such as the Global Health Security Initiative, the Group of 7 and the Group of 20, have facilitated such information sharing. Canada also engages with other longstanding and ad hoc multilateral groups, such as the Asia-Pacific Economic Cooperation, the Organization of American States and others, both at the ministerial and officials level, as well as international NGOs, such as Médecins Sans Frontières.

Q185. What intelligence or modelling was PHAC and Dr. Tam operating with in early March when the messaging to Canadians was still that the risk is low. How did the risk assessment progress to high for all Canadians?

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In March 2020, the public health risk assessments evolved based on the risk of COVID-19 to Canadians in Canada at that time. The risk to the public within Canada evolved from being assessed as low (as there was no evidence that COVID-19 was circulating within the Canadian population), to low for the general population and moderate for the elderly and those with underlying medical conditions, followed by high for the full population because of the appearance of community spread of COVID-19 within the Canadian population.

Q186. What is the GPHIN Renewal Project? Why was the upgrade done in stages?

The objective of the Global Public Health Intelligence Network (GPHIN) Renewal Project was to create an enhanced web-based platform that was fully compliant with Government of Canada Information Technology policy requirements, and that allowed for greater automation in the collection, collation and analysis of open source information.

Work began in January 2016, and the initial upgraded capability was delivered in August 2016. The final version went live in September 2018 and the technical components of the project were completed in July 2019.

The project was designed as a collaboration between PHAC and the National Research Council.

The GPHIN Renewal Project met the following objectives:

- The platform is compliant with information technology policies, guidelines and standards, and the Government of Canada has the ability to further implement improvements and innovations to the system.
- GPHIN can leverage the variety, volume and velocity of data available—including from social media and from more websites—and provide visual representation of events in place and time with built-in analytics and assessment capacity as well as automated summaries of articles.
- The system's artificial intelligence can learn and improve its relevance scoring accuracy.

A phased approach enabled PHAC to develop, create, implement and test functionalities. A post-launch review of Release 1 identified quality and functionality issues that were addressed in Release 2, enabling further enhancements to be made to the system.

Q187. Were there complaints about the GPHIN search system following Release 1?

After the initial launch of the renewed system in August 2016, analysts noted that the speed of the search function was reduced. Over the summer of 2017, the NRC engaged an industry expert to analyze the issues and recommend changes. These changes were implemented by mid-2018, and evaluation measurements showed significant improvements.

Q188. Was GPHIN ordered to bring servers located outside of government on a private system to bring them within the GoC system by Shared Services Canada?

A Request for Information issued through Public Service and Procurement Canada seeking interest from private sector companies to upgrade the GPHIN platform did not receive any

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responses. In collaboration with the National Research Council (NRC), the GPHIN platform was upgraded within scope and under budget.

Q189. Were analysts ever told to stop reporting on COVID-19?

No. From the start of the COVID-19 outbreak, GPHIN was, and continues to be, an important source of public health intelligence for PHAC.

Q190. Is there a prohibition on sharing information with subscribers?

There is no prohibition on sharing information with subscribers. GPHIN continues to share information with its users on a routine basis. In addition, GPHIN has been providing special reports to users with respect to COVID-19 to address needs identified by organizations such as the World Health Organization.

Q191. Can you explain how the duties of analysts with GPHIN are allocated? How many are tasked to monitor domestic health surveillance (ie. vaping, lyme disease) and how many are tasked with monitoring the global picture (ie. COVID, avian-influenza)?

GPHIN analysts work collaboratively on global and domestic surveillance. While each analyst focuses on the regions and countries related to their language capabilities, they all share responsibilities for domestic surveillance. This has been the practice for many years.

Q192. What is the annual budget of GPHIN?

The annual budget for GPHIN is approximately $2.8 million including both human and operating resources.

Q193. How does GPHIN's selection of data, or analysis of data, differ from approaches taken by ProMED, HealthMap and commercial providers such as Blue Dot?

GPHIN consists of two critical components:

- A professional multidisciplinary team of life science analysts, reviewing information in nine languages and conducting rapid risk assessments to detect public health threats; and
- An Information Management Tool that uses machine learning and natural language processing to facilitate the work of the analysts.

GPHIN requires a free subscription from eligible users, which include non-governmental agencies and organizations, as well as government authorities who conduct public health surveillance.

ProMED uses information coming from volunteer "rapporteurs", as well as information from subscribers and from staff-conducted searches of the Internet, media, and various official and unofficial websites. Moderators assess these reports for plausibility, edit them as necessary, and often add comments or context before posting. ProMED is one of the many data sources of GPHIN.

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HealthMap's content is aggregated from freely available information (including ProMED) and automatically processed by machine learning algorithms. Unlike GPHIN, there is no human assessment of the information published, which could influence the system performance.

BlueDot is a private company for which you need to pay a subscription to access the data. It gathers information from official and mass media sources including the WHO and ProMED-mail.

Much of this work is complementary, and organizations rely on a broad range of inputs to help identify potential threats and provide early warning.

Q194. Is the Government of Canada using BlueDot's AI to trace COVID-19 contacts?

Both the Public Health Agency of Canada and Health Canada have contracts with BlueDot. Neither contract involves the use of AI to trace contacts.

Q195. I have confirmed with Public Health Ontario and the Institut national de santé publique du Québec that they are not collecting race/ethnicity data in relation to COVID-19. My understanding is that the Public Health Agency of Canada does not collect this type of data either. Could you confirm that?

It is true that the COVID-19 case report form does not include any questions on race or ethnicity, but it does include a section for identifying and classifying cases as Indigenous (First Nations, Metis, Inuit). This section is completed only when the affected person self-identifies as a member of one of the three Indigenous groups. Data in this section are often incomplete or missing.

Q196.* Are there any plans to add more social determinants of health (such as education or income) as risk factors to the case reporting form used for the collection of COVID-19 data*?

The case report form contains information on age and known risk factors, such as having a pre-existing medical condition or being a resident of a long-term care facility. These data are analyzed regularly and included in an epidemiological summary.

There are no plans at this time to add social determinants of health (education or income) as risk factors to the case report form used to collect data on COVID-19. If a revision of the form were to be considered, the Public Health Agency of Canada would call on a national advisory committee of provincial and territorial public health experts to discuss it, since responsibility for data collection rests with the provincial and territorial health authorities.

Q197. What is Health Canada's role in the Ontario's Health Data Platform? Will this become the norm across provinces? Does Health Canada endorse this plan, which is designed to slow the spread of COVID-19?

Understanding a patient's history is essential to safe and appropriate care. That is why sharing health information among health care providers, safeguarded by strong privacy and data security requirements, can lead to better outcomes through more informed, coordinated and integrated care. A system that is responsive to the needs of patients can also enable patients to have better access to their own health information. Health Canada is working with provincial and

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territorial partners, as well as key national data agencies, to support greater patient access to health data while ensuring the protection of personal health information.

Q198. Are there any Canadian studies on COVID-19 and sewage analysis?

At this time, the Public Health Agency of Canada is not aware of any Canadian studies collecting sewage samples for the detection and identification of COVID-19.

It is premature to consider this type of analysis because more research is required to understand the utility of this approach. The Public Health Agency of Canada is following the science in this area.

Under the recently funded Canadian Institutes of Health Research's Canadian 2019 Novel Coronavirus (COVID-19) Rapid Research Funding Opportunity, a project led by Dr. Jeffrey Joy, from the University of British Columbia, will collect environmental samples to better understand the epidemiology and evolution of COVID-19 (https://www.canada.ca/en/institutes-health-research/news/2020/03/government-of-canada-funds-49-additional-covid-19-research-projects-details-of-the-funded-projects.html). However, it is unknown at this time if sewage samples will form part of this work.

Q199. Why was the Event-Surveillance Platform for Emerging Infectious Diseases project initiated and what is its scope?

The Emerging Infections Surveillance Platform (ESP) was intended to improve internal processes to manage and assess data on emerging infectious diseases (EIDs). The pilot project, initiated in 2016, was limited to data related to zoonotic and vector-borne diseases. The pilot provided insights into how to improve processes, and informed new tools and mechanisms that have been put in place.

The Public Health Agency of Canada's (PHAC) readiness to manage EIDs is supported by:

- a Data Innovation Hub fully dedicated to meeting PHAC's data needs and applying digital tools to support timely access to data and rapid analysis;
- the Global Public Health Intelligence Network that constantly scans and analyses global information sources to detect early warnings of potential public health threats and triggers rapid risk assessments based on this intelligence;
- domestic disease surveillance programs, implemented with provinces and territories, that track infectious diseases and risk factors and alert us to trends that could signal increasing areas of risk;
- laboratory-based detection of signals that are beyond baseline expected rates of pathogen circulation and use of technologies, such as whole genome sequencing, to identify clusters of infections and support a rapid public health response; and
- international collaboration under the Global Health Security Initiative (GHSI) for real-time sharing of public health risk assessment, detection methods, and data collection approaches.

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The results of this pilot project were shared with GHSI as part of regular and ongoing information exchange.

NML'S RESPONSE TO OUTBREAK

Q200. Why did scientists from the NML make trips to the Wuhan Institute of Virology level-4 lab?

In response to a request from the Institute for viral samples of Ebola and Henipah viruses, the Public Health Agency of Canada sent samples for the purpose of scientific research in 2019. The National Microbiology Laboratory (NML) shares samples with other public health laboratories—as they do with the NML—to contribute to the advancement of science. Transfers are subject to strict protocols, including requirements under *the Human Pathogen and Toxins Act*, the *Transportation of Dangerous Goods Act*, the Canadian Biosafety Standard, and standard operating procedures of the NML.

The NML also provides training to international laboratory professionals and has previously trained scientists from many countries including China.

If Pressed

For privacy reasons, we will not comment on individual employees.

Any speculation about the role of the Public Health Agency of Canada (PHAC)'s scientists in the emergence of the novel coronavirus has no factual basis.

Q201. Is the government of Canada and PHAC supportive of examining the possibility that a lab accident or breach in Wuhan could have any connection to the pandemic outbreak? Will the Government of Canada provide updated information regarding the concerns that occurred in the Saskatchewan level-4 lab, and whether espionage or security breach connected to Chinese researchers is a concern?

Coronaviruses are naturally occurring and are known to transmit from animals to humans. There is no evidence to suggest any other source for the novel coronavirus that causes COVID-19.

Any speculation about the role of the Public Health Agency of Canada's scientists in the emergence of the novel coronavirus has no factual basis. We will continue to base our response to COVID-19 on scientific evidence.

TESTING AND CONFIRMING CASES

Q202. When did the NML develop its own test? Does the NML run the tests automated or manual?

The NML established an assay (test) based on peer-reviewed published targets endorsed by the World Health Organization (Corman et al., 2020). This assay was first tested at the NML on **January 26, 2020**. The assays that are now currently in routine use are based on the Corman et al. assays.

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In the early days, there were several other assays under consideration and use, either designed or modified by the NML. Some of these tests were used for initial detection of the virus in specimens, and some were used to confirm these initial results. These assays were modified from existing coronavirus tests we had at the NML, and all were designed against the genome sequence of the novel coronavirus released in January by China. This is described in a paper (see 'diagnostic testing'), which includes the dates for the first patient (thus the first use of the tests).

The reliance on this larger initial suite of tests was then refined towards those based on the Corman et al. assay, to both streamline the testing process but also to support expansion of testing to additional sites. A validated, streamlined testing approach allows individual labs to issue confirmed results without needing additional testing at a reference lab like NML.

The NML employs manual and automated testing protocols depending on the volume of incoming samples.

Q203. Can you confirm if the National Microbial Laboratory "validates" class 1 medical devices and what it means for a product to be "validated"?

The Public Health Agency of Canada's National Microbiology Laboratory (NML) does not validate Class 1 medical devices.

The NML's role is to undertake scientific studies of diagnostic tests and supplies to support provincial laboratories in their decisions on adopting these tests for use in clinical settings. These studies are done in collaboration with provincial laboratories and clinical researchers to determine how well a test performs under real-world conditions. Results on the performance of diagnostic tests are shared with manufacturing companies, all provincial laboratories and Health Canada to add to the evidence on the accuracy of diagnostic tests.

Q204. How is Canada currently testing patients for COVID-19?

Canadians can be confident in the methods and laboratory capabilities of Canada's NML.

The NML is internationally recognized for its scientific excellence.

Provincial public health laboratories can test for COVID-19 with a very high degree of accuracy.

The NML is providing all provinces and territories with laboratory reference services. These testing services provide a variety of support to provincial and territorial laboratories across Canada including confirmatory testing, quality assurance, and in-depth analysis of difficult to diagnose specimens.

Q205. What is the Public Health Agency of Canada's testing capacity?

We continue to test at a very high rate in Canada—one of the highest in the world. We know that testing is key to finding new cases and to identifying and stopping new lines of transmission. We are now testing over 20,000 people daily—almost double the volume of testing from April, and this number continues to grow.

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There is no definite number for how many tests need to be done each day to relax physical distancing measures in Canada, and this will vary across jurisdictions. The target of 60,000 tests per day is based on what we can achieve by maximizing current public health laboratory capacity and is useful for planning purposes. Provinces continue to add more testing capacity to meet their needs. On some days, in some provinces, the capacity exceeds the number of individuals seeking to get a test.

Canada has been maintaining around a 6% to 7% positivity rate, which is within a good range to accurately detect where the disease is circulating. We want to have the most accurate picture possible of what is happening in our communities. This shows that we have a relatively sensitive testing system. We are continuing to increase our laboratory capacity to make sure that this continues to be the case.

The primary focus is testing people who present with symptoms to identify cases and rapidly conduct contact tracing. Another key focus is to ramp up testing in high-risk situations, including long-term care facilities, health care settings and correctional facilities, with a goal to support outbreak control in any setting.

Our priorities continue to be accessing testing reagents, evaluating rapid point-of-care tests, and accessing authorized test kits to help ensure that provinces and territories are equipped to ramp up testing, according to their requirements.

Q206. Does PHAC recommend doing temperature checks at public places before entry? If not, why? Is this something that will be implemented when things start to gradually reopen?

The Public Health Agency of Canada's (PHAC's) Infection Prevention and Control for COVID-19: Interim Guidance for Long Term Care Homes recommends staff screening measures be put in place, including a temperature check twice daily. However, fever is not usually the first symptom of COVID-19 and in some cases a fever never develops, so implementing measures based solely on fever detection is not recommended.

During the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003, more than 6.5 million screening transactions occurred at Canadian airports, including inbound and outbound travellers. Of these, 2.3 million travellers were screened using thermal scanners. Despite this intensive screening effort, no cases of SARS were detected using this method. For this reason, temperature checks at borders before entry to Canada is not recommended.

The Special Advisory Committee, comprising Canada's Chief Medical Officers of Health, continues to work closely together to develop a coordinated approach in response to the outbreak that is based on the best available science and evidence.

Q207. What specific tests are currently allowed in Canada for COVID-19 testing?

With the implementation of new diagnostic tests for the novel SARS-CoV-2 virus, Canadian public health laboratories have used the collective strengths of their network to evaluate these new tests to ensure that they are accurate, while also promoting the ability to rapidly distribute testing capacity across Canada.

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After the release of the genetic sequence of the virus in January, it was possible to immediately develop multiple molecular tests (polymerase chain reaction) that detect specific genetic traits of the virus. The network of Canadian laboratories recommended that molecular tests targeting two different traits of the virus would be used to diagnose infections, and that for select cases (such as travel from countries that had not yet reported COVID-19 infections), further testing would include genetic sequencing to provide definitive evidence for the presence of SARS-CoV-2. With the use of multiple testing approaches, and by conducting tests at multiple sites, such as when tests were presumptively positive in provinces and then confirmed by the National Microbiology Laboratory, Canada was able to ensure that each confirmed case was a true case.

With a level of confidence in the tests, but needing to streamline the testing approach so that it could be conducted in additional laboratories across Canada, the case definition has been successively adjusted to allow for cases to be confirmed as positive using a single molecular test. The selection of this test has been based upon the knowledge of how different tests have been performing across the different Canadian laboratories, with the most sensitive targets now being used routinely.

In regards to false negative results, more understanding of COVID-19 infections and the course that that the virus takes during infections is needed at this time. It is conceivable that very early or very late in infections, the amount of detectable virus is low and the current molecular tests do not detect these cases. However, as shown throughout this outbreak response, the laboratories will seek to continually improve their testing approach as supported by evidence.

Further, the current molecular tests that are being used throughout the country, and which where born by the collective sharing of information and tools by laboratorians, will soon become the gold standard to compare to and implement the next phase of testing, where rapid point of care tests will be implemented in order to allow testing to occur within health care settings, rather than requiring shipment of specimens to a laboratory for testing.

Q208. What are the requirements from Health Canada in terms of testing machines that have not received approval from Health Canada? Does Health Canada discourage the use of machines for COVID-19 testing that have not been approved? Do swab results from unauthorized testing kits need to be confirmed in another laboratory (using authorized Health Canada testing kits)?

Only diagnostic tests authorized by Health Canada can be imported into or sold in Canada. Unauthorized tests have not been reviewed by Health Canada and their accuracy has not been validated. Health Canada has confirmed that authorized COVID-19 tests are well supported by evidence indicating that they will provide accurate and reliable results. A list of authorized diagnostic devices for use against COVID-19 is available here.

The Xpert Xpress SARS-CoV-2 was authorized under the Interim Order (IO) on March 24, 2020.

The BD SARS-COV-2 REAGENTS FOR BD MAXTM SYSTEM was authorized under the IO on April 19, 2020. It will appear on the list of authorized devices in the next two days.

Health Canada does not have any pending submissions for a COVID-19 device manufactured by Altona. The Department contacted the Prince Edward Island provincial laboratory to confirm that Altona's PCR kit was marketed and sold to them for research purposes and internal use

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only. Based on the information obtained to date, no non-compliance with the Medical Device Regulations was found.

The Department encourages anyone who has information regarding the potential non-compliant sale or advertising of any health product claiming to treat, diagnose, prevent or cure COVID-19 to report it using the online complaint form.

Q209. Will testing be available to whoever wants to be tested?

Accurate and timely testing is an essential part of the public health response to this pandemic. Such testing enables early detection of cases so that further spread can be controlled. The Government of Canada is taking action to ramp up testing capacity as quickly as possible so that Canadian public health and diagnostic laboratories have the resources to test for COVID-19. There are several Health Canada-approved commercial reagents that can be used for testing for COVID-19 infection. There is a global shortage of many of these reagents, and this affects laboratory capacity. We need made-in-Canada solutions to tackle this problem. This shortage is affecting Canada's testing capacity. The Public Health Agency's National Microbiology Laboratory (NML) has developed a reagent to help address this shortage. This reagent is being mass produced by LuminUltra Technologies Ltd., a New Brunswick-based company. Even with increased capacity, testing will still need to be prioritized to meet appropriate public health objectives.

Q210. Is a lack of certain testing components preventing more tests from being completed?

The Government of Canada has ordered more than 11 million swabs from various domestic and global suppliers to be delivered in batches on an ongoing weekly basis. The Government is procuring and producing other necessary laboratory test components to support provinces and territories in their overall laboratory testing efforts. Further, we are looking at options to ensure an ongoing secure supply of sterile swabs, including options to produce swabs in Canada.

Q211. What is the biggest challenge in scaling up testing to capture a larger portion of the population?

The Government of Canada is investing $150 million to support federal public health measures such as enhanced surveillance, increased testing at the 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 diagnostic tests and methods, and coordination of the supply and distribution of reagents and lab supplies with provincial and territorial authorities to increase testing capacity across the country.

Q212. Which universities and manufacturers are now involved in either creating testing components or aiding in testing in some way?

To date, Innovation, Science and Economic Development Canada has received almost 6000 responses to the call to action from companies across the country. Once these responses are received, we engage with respondents to assess how they can support the urgent needs of Canadians and front-line health workers. Canadian industry is playing an important role in building domestic testing capacity. Of particular note, LuminUltra (New Brunswick) is providing extraction reagent to federal and provincial labs across the country and enabling a growing level

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of diagnostic testing. Similarly, Spartan Bioscience is delivering a Health Canada-approved point-of-care diagnostic test that will support testing in rural and remote locations.

Q213. How does Health Canada's list of COVID-19 symptoms compare to the one from the CDC? Does the list get updated and how important is it for Canadians as they watch for signs of the disease at home?

Public health is a shared responsibility in Canada. The Canadian public health directives pertaining to COVID-19 change as the body of evidence grows and the new virus is better understood. We are continually reviewing the latest scientific data and are working with our provincial and territorial partners and with other public health partners across the country and around the world in order to learn more. The Public Health Agency of Canada is reviewing its online tool, and it may modify or revise it as it receives new information.

Regarding the differences between the federal government's self-assessment tool and Ontario's tool, the federal government provides general advice; whereas the provinces and territories, which manage and deliver the health care services, can give more detailed advice based on their epidemiological data, their assessment of the risks, and the availability of health care services. As for the differences between the symptoms list established by the Government of Canada and the one by the Centers for Disease Control in the United States, each country develops its own directives based on various factors, including its epidemiological data and its risk assessments.

Q214. How are labs sharing information about positive test results with public health authorities?

The means by which provincial public health officials collect and disseminate information regarding positive COVID-19 test results varies from province to province. Provinces are best placed to provide further information on the methods used in their jurisdictions.
However, provinces and territories are submitting their lab results to the Public Health Agency of Canada (PHAC) for national tracking.

Canada's public health laboratories work together through a network called the Canadian Public Health Laboratory Network (CPHLN). CPHLN is a network of federal/provincial/territorial public health laboratory professionals who work together to strengthen Canada's public health system through coordinated laboratory services and leadership. Through CPHLN, the provinces and territories are submitting their COVID-19 laboratory results on a daily basis using a variety of tools.

One of these tools is an online platform—System for Analyzing Laboratory Test counts (SALT)—which is a component of the Canadian Network for Public Health Intelligence (CNPHI). CNPHI is a scientific public health informatics and bio-surveillance platform developed and managed by scientists at PHAC's National Microbiology Laboratory. SALT provides a centralized and secure web-based environment for sharing test results for COVID-19 amongst public health officials, including real-time visual analytics.

Q215. Has the authorization for Real-time Fluorescent RT-PCR Kit for detecting SARS 2019-NCOV limited to research or other use? How does it works?

This test was authorized for sale and import under the Interim order respecting the importation and sale of medical devices for use in relation to COVID-19. The use of this device is not

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limited to research use. The Real-time Fluorescent RT-PCR Kit for Detecting SARS 2019-NCOV is a nucleic acid based COVID-19 diagnostic test.

The Real-Time Fluorescent RT-PCR Kit for detecting 2019-nCoV(SARS-CoV-2 is a nucleic acid test used to detect SARS-CoV-2 from individuals who are suspected to have COVID-19. It is intended for use by trained clinical laboratory personnel. The test is a type of polymerase chain reaction test, known as PCR, which is the most common and most accurate type of test to determine whether someone is currently infected with the coronavirus.

The test uses a throat swab or sputum sample from a patient which is placed in a machine called a thermocycler. The thermocycler uses temperature cycling to amplify any SARS-CoV-2 nucleic acid that is present in the sample. If a patient's specimen contains SARS-CoV-2, the virus's genetic material will be amplified, and the machine will return a positive result. If the specimen has no SARS-CoV-2, the machine will return a negative result.

The authorization for this device included three conditions. The company has already revised materials to address the first two conditions relating to 1) the length of time the product is claimed to be stable and 2) the need for extra information in the previous instructions. Health Canada is assessing whether the information provided by the company is sufficient to remove those conditions. The third condition is that the company provide data on cross-reactivity to bacteria. The company has committed to providing these data.

Remdesivir for the treatment of COVID-19

Q216. Can remdesivir be used for any patient who is infected with COVID-19? Will it be effective for everyone?

At this time, it is too early to say whether remdesivir could be used for all patients infected with the coronavirus SARS-CoV-2. There is some evidence to suggest that remdesivir may have the potential to shorten the symptoms of disease in some hospitalized patients with advanced COVID-19. Patients given remdesivir had a 31% faster time to recovery than those who received placebo. Specifically, the median time to recovery was 11 days for patients treated with remdesivir compared with 15 days for those who received placebo. It is only available as an intravenous form.

Q217. Are there clinical trials underway to determine whether remdesivir is effective?

Remdesivir is still considered an experimental treatment for COVID-19. The most appropriate way to access experimental therapies that have potential to be helpful in treating COVID-19 is through a clinical trial. Clinical trials provide Canadians with access to new therapies aimed at treating COVID-19, as well as an opportunity for the healthcare community to systematically collect information on the effectiveness of the treatments and their associated risks. To date, Health Canada has approved two clinical trials for remdesivir in the context of COVID-19 in Canada: the CATCO trial with remdesivir, part of the World Health Organization's SOLIDARITY study, and Gilead's open label trial on remdesivir. Access through clinical trials is available at multiple sites across the country. More information about the trials is available on our website.

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Health Canada is also aware of several international clinical studies with remdesivir in the treatment of COVID-19. Some of these studies have been completed or are nearing completion. Health Canada is closely monitoring clinical trial developments and emerging results for remdesivir.

Q218. What is the Emergency Use Authorization granted in the U.S.? Does it mean that the drug has been approved there for treatment of COVID-19?

On May 1, 2020, the U.S. Food and Drug Administration (FDA) announced that it has granted emergency use authorization (EUA) for the investigational antiviral remdesivir to treat COVID-19. According to the information released by the U.S. FDA, "the authorization is temporary and does not take the place of the formal new drug application submission, review and approval process. The EUA allows for the distribution and emergency use of remdesivir only for the treatment of COVID-19; remdesivir remains an investigational drug and has not been approved by FDA." Additional information of the U.S. FDA EUA for remdesivir can be found on the FDA website.

Q219. What is a rolling review? If faster, why not apply this process all the time?

A rolling review is one of the regulatory tools available to Health Canada to speed up the assessment of a drug submission in urgent public health situations.

Under normal circumstances, all data supporting a marketing authorisation application must be submitted at the start of the evaluation procedure. In the case of a rolling review, the Department reviews data as it become available. Several rolling review cycles can be carried out during the evaluation of one product as data continue to emerge. Any new data that becomes available for evaluation during this rolling review will need to be considered in the context of all other existing data and identify a drug's benefits and risks as soon as possible.

While the specific timeline for a rolling review cannot be predicted, this approach will allow earlier filing of submissions and enable Health Canada to start a review earlier without compromising its high standards of safety, efficacy, and quality.

Rolling reviews can allow Health Canada to review to begin the review of drug submissions easier than a standard drug review, and are also more labour-intensive on the review side because of the multiple rounds of review. For this reason, it is a rarely-used regulatory flexibility, reserved for urgent public health situations.

Q220. Are you satisfied with Canada's current level of access to remdesivir, through clinical trials and SAP?

Health Canada has been closely monitoring developments for potential treatments for COVID-19, including remdesivir. Remdesivir is an experimental drug that is being administered by intravenous infusion to some hospitalized patients suffering from COVID-19. In Canada, remdesivir can be accessed through approved clinical trials which are the most appropriate way to access experimental therapies. Clinical trials provide Canadians access to new therapies aimed at treating COVID-19, as well as an opportunity for the healthcare community to systematically collect information on the effectiveness of the treatments and their associated risks.

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To date, two clinical trials have been approved for remdesivir in the context of COVID-19 in Canada and they are located at multiple sites across the country. More information about the approved trials is available on Health Canada's website. Information from these clinical trials may help support a submission to Health Canada.

Health Canada has authorized 12 requests for remdesivir through its Special Access Program (SAP); and currently is providing it through the program for pregnant women and children with confirmed COVID-19 and severe illness.

Q221. Are you concerned that Canada's access of remdesivir may be limited in future?

Health Canada been in regular communication with Gilead Sciences Canada, Inc. regarding access to remdesivir in Canada and their plans for filing a submission for review. Once Gilead Sciences Canada, Inc. files a submission for remdesivir with Health Canada, the Department will exercise the regulatory flexibility to expedite the submission review for access to Canadians while ensuring the safety, efficacy and quality for this drug. Health Canada has also been working with international regulators, including the U.S. Food and Drug Administration, to share scientific information on drugs and vaccines for COVID-19 including remdesivir, and aligning requirements for safety and efficacy where possible to expedite the review and approval processes.

COVID-19 home test kits

Q222. What kind of tests have been promoted for use at home?

To date, Health Canada has not authorized the importation or sale of any diagnostic tests or sample collection kits intended for use by the general public to detect or self-diagnose COVID-19.

Lateral-flow antibody tests, commonly referred to as "rapid tests" have been illegally promoted for home use. This type of test does not require laboratory equipment, and the result is displayed as a coloured band on a small stick-style device. However, Health Canada has not authorized any tests of this type for sale or importation and this type of home testing is not recommended because the patient would not have the support of a medical professional to interpret the results.

Patients who test positive for COVID-19 also need to be advised by a medical professional on how to care for themselves and how to help reduce the spread of COVID-19 by self-isolating. In addition, public health authorities need access to the results of all testing to make decisions relating to the spread of COVID-19 in Canada.

Based on the current available information, the World Health Organization recommends the use of rapid tests only in research settings.

Q223. What is Health Canada doing to stop the sale of unauthorized COVID-19 test kits?

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Health Canada continues to monitor the use of unlicensed medical test kits, including for COVID-19, and takes appropriate action to stop their sale as required. When Health Canada identifies or is notified of non-compliance with the *Food and Drugs Act* or its Regulations, it takes action and informs Canadians as necessary.

For example, on April 21, 2020, Health Canada worked with the RCMP to seize over 1500 unauthorized test kits in B.C.

On May 7, 2020, Health Canada issued an advisory notifying Canadians not to use or rely on unauthorized COVID-19 test kits presented for individual sale or personal use.

Q224. Are COVID-19 home test kits available in other jurisdictions?

Other international regulators, including the U.S. Food and Drug (FDA) Administration, have not approved home test kits for COVID-19.

There was recent media coverage claiming that the U.S. FDA had approved its first home test kit; however, this is not accurate. The U.S. FDA has approved the COVID-19 RT-PCR Test for which only the collection of a fluid sample is done at home. The swab then needs to be sent to a laboratory for testing. These are subject to strict transportation requirements.

Q225. What type of COVID-19 tests have been authorized by Health Canada or are under consideration?

Health Canada has authorized the sale and importation of COVID-19 diagnostic tests intended for use only by health care professionals or trained operators.

Amendments to the Authorization of the Spartan Test Kit

Q226. What is the Spartan device and how does it work?

Spartan's test kit consists of a portable analyzer called the Spartan Cube. The Cube performs the test with Spartan's COVID-19 test cartridges and proprietary swabs. The test kit can diagnose COVID-19 in less than an hour without having to send a sample to a lab.

Q227. Could there be similar issues with other medical devices approved under the Interim Order?

Each product is reviewed on a case-by-case basis based on the technology, and may require different standards of evidence. While no similar issues are anticipated at this time, Health Canada will not hesitate to take action should any issues be identified.

Q228. When Health Canada says it is approving devices "that may not fully meet regulatory requirements", what requirements specifically is it willing to set aside or have lowered?

Regulatory framework for medical devices in Canada: In Canada, medical devices are regulated under the *Medical Devices Regulations* and are categorized into four classes based on the risk associated with their use. Class I devices present the lowest potential risk (e.g., a

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tongue depressor, masks, gowns) and Class IV devices present the greatest potential risk (e.g., a pacemaker).

Health Canada issues two types of licenses for medical devices:

- Medical Device Licences (MDLs):
  - Issued for specific products, authorizing manufacturers to sell a class II, III, or IV medical device in Canada.
- Medical Device Establishment Licences (MDELs):
  - Issued to class I medical device manufacturers, as well as importers or distributors of all 4 medical device classes, to permit them to import or sell medical devices in Canada.

Additional information on how medical devices are approved and authorized in Canada under the *Medical Devices Regulations* is available here.

In the COVID Context: Health Canada's top priority is the health and safety of Canadians and the Department is facilitating access to products—including medical devices—needed to combat COVID-19. In order to expedite the availability of medical devices in support of COVID-19 response efforts, three different measures have been implemented:

1. The Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19, signed by the Minister of Health on March 18, 2020, provides an expedited Health Canada authorization pathway to promptly review and authorize medical devices for use in Canada. This pathway, applicable to manufacturers of Class I to IV medical devices, requires a scientific assessment to ensure the safety and effectiveness of the medical device. Information on how to submit an application for medical devices under this Interim Order is available in our Guidance document. Requirements for serological antibody tests submitted under the Interim Order is also available online.

2. The Interim Order respecting drugs, medical devices and foods for a special dietary purpose in relation to COVID-19, signed by the Minister of Health on March 30, 2020, builds on existing practice to facilitate access to alternate supplies of health products and improves transparency in Health Canada's work with multiple stakeholders to prevent and alleviate shortages resulting directly or indirectly from COVID-19. Products included on the List of Medical Devices for Exceptional Importation and Sale include those that do not fully meet the usual regulatory requirements under the *Medical Devices Regulations*, such as those related to labelling. Health Canada will add products to the list only if there is no impact on the health and safety of Canadians. Currently, most of the products on the list are Class I personal protective equipment products, such as masks and gowns. An MDEL is still mandatory to import and sell these products and regulatory requirements remain in place, including those related to record keeping, complaint handling, mandatory problem reporting, distribution records and recalls as per Sections 44 to 65.1 of the *Medical Devices Regulations*. In addition, importers must notify Health Canada at least five days before importing, providing details of the device; and make those details available to consumers as appropriate.

3. Health Canada is also expediting the review and issuance of MDEL applications for companies applying to manufacture Class I medical devices, or import or distribute Class I-IV medical devices in support of COVID-19 response efforts. Manufacturers, importers and distributors of medical devices continue to be subject to all of the applicable requirements set out in the *Medical Devices Regulations* and are responsible for ensuring the medical devices (of

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all classes) they sell are compliant with safety and effectiveness requirements outlined in the Regulations.

As with all health products—including medical devices—Health Canada will assess and continue to monitor the safety and effectiveness of these products once they are on the market. Health Canada will take appropriate compliance and enforcement action, as required, to protect the health and safety of Canadians.

Q229. Were any test kits used to diagnose patients?

Spartan Bioscience informed the department that none of the tests were used for diagnosis purposes. As part of the voluntary recall requested by Health Canada, the company will be asked to re-confirm whether any of the test kits were used for the purpose of diagnosis.

Q230. Why is the Spartan test no longer approved for use beyond research purposes? How and when did the problem emerge?

On March 26, 2020, Health Canada issued a conditional authorization to Spartan Bioscience Inc. for its Spartan Cube for research use only. This authorization was made under the Interim Order for medical devices in the context of COVID-19, which enables Health Canada to authorize devices under an expedited scientific review process, on the basis of minimum requirements.

On April 11, 2020, Health Canada completed its scientific review to ensure that the device was supported by evidence that it meets requirements for safety and effectiveness. Health Canada's scientific review relied on analytical data from laboratory studies provided by the company, and took into consideration that further clinical validation would be carried out by public health laboratories in order to determine performance in clinical settings. Health Canada amended the conditions on the authorization, enabling the sale of the Spartan Cube, but requiring the provision of data from additional technical studies as well as sales information.

On May 1, 2020, the National Microbial Laboratory (NML) of the Public Health Agency of Canada provided Health Canada with a final report of clinical testing performed in three provinces (Alberta, Ontario and Manitoba), using Spartan swabs to collect specimens from patients under clinical conditions. These clinical trials are key in identifying any performance issues that could not have been identified in a laboratory setting. The report identified that while the Spartan Cube performed in a laboratory setting, as per manufacturer specifications, there were performance issues identified in the clinical trial. These issues appear to be related to the proprietary swab, which may not sufficiently collect mucosal material necessary for testing.

In light of the clinical results, Health Canada has placed conditions on the company's authorization to restrict the use of the product to research use only until adequate evidence of clinical performance can be provided. The Spartan product can continue to be used for research purposes only. It's important to note that the company informed the Department that none of the tests were used for diagnosis purposes.

Health Canada will continue to work with Spartan as they address the regulatory requirements to enable utilization of the point of care test kit.

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Q231. Why didn't Health Canada wait for the results of the clinical studies before authorizing the Spartan device for sale?

The scientific review of the Spartan diagnostic test device was completed under expedited timelines as part of the Interim Order announced on March 18, 2020.
Health Canada's regulatory decision was based on in-laboratory testing of the device and not on clinical trial data of its effectiveness. The review took into consideration that further validation would be carried out by public health laboratories in order to determine performance in clinical settings. This is consistent with the approach taken by other trusted regulators.

As planned, Health Canada continued to monitor and assess the safety and effectiveness of these rapid test kits in the field to help ensure that they perform appropriately and deliver accurate results. In light of the clinical results, Health Canada has amended the terms and conditions on the company's authorization to restrict the sale of the product for research use only, until adequate evidence of clinical performance can be provided.
For information about the performance of the Spartan test, please contact the manufacturer directly.

Q232. Did the NML test all or some of the Spartan samples? When was this done and involving how many samples and where?

The Public Health Agency of Canada's National Microbiology Laboratory (NML) collaborated with provincial partners—Alberta, Ontario and Manitoba—to test the Spartan Cube using Spartan swabs to collect specimens directly from patients under clinical conditions. These tests were done in April, and the NML delivered the final report to Health Canada on May 1.

Specimens were collected from patients already known to be positive for COVID-19 (i.e., confirmed through existing, validated tests) and these specimens were then tested in parallel on the Spartan Cube and on other diagnostic platforms currently under review. It's important to note that the samples run on the Spartan Cubes were part of a clinical and scientific review to test the efficacy of the Spartan Cube and results were not relied upon for diagnostic decisions of positive or negative results.

Q233. Are there other jurisdictions that received the Spartan Cube? Has Health Canada told them to stop using the device?

Spartan Bioscience confirmed that it had distributed 5,500 test kits for research purposes only in a clinical setting to four public health organizations, including the Public Health Agency of Canada.

These organizations are aware of Health Canada's new conditions on Spartan's authorization. Health Canada asked the company to voluntarily recall the products to prevent their use in diagnostic settings at this time. The company has indicated agreement to do so. The Department sent a regulatory letter to the company on May 2, 2020, to indicate the new conditions in accordance with Section 7 of the Interim Order. This letter also described the steps that the company needed to follow for the voluntary recall. Health Canada has restricted the sale of the test kits to research use until adequate evidence of clinical performance can be provided and assessed.

Q234. Is there a minimum level of specificity and sensitivity a test must have to gain Health Canada approval?

Health Canada considers the U.S. Food and Drug Administration Emergency Use Authorization guidance for molecular-based test kits to be appropriate for the identification of tests that are

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both sufficiently sensitive and specific. However, this guidance is a starting point, and Health Canada's scientific review also considers other factors (e.g., the number of samples tested, the recommended type of sample (e.g. nasopharyngeal, vs. nasal, vs. sputum), whether the samples were clinical or lab developed (spiked with known amounts of virus), etc.). In addition, Health Canada's review considers the urgent public health need for access to testing devices in the context of the COVID-19 pandemic. This is a new virus and new disease. As research evolves, we are learning key information that will help us determine the optimal specificity and sensitivity in consideration of all these factors. Health Canada considers each application on a case-by-case basis, and performs the scientific review based on the information provided by the manufacturer. The Department monitors performance once a test is authorized and will take action if a test is found not to perform as intended.

Serology

Q235. What is serological testing used for?

Serology-based tests are essential to understanding the immune response to virus infection. They will play a key role in determining the extent of exposure to the virus though sero-surveillance studies.

Serological testing is not authorized to diagnose COVID-19 infections because it detects antibodies produced by the patient's immune response. Those antibodies are not likely to develop until later in the infection, thereby giving false negative results in many cases.
For diagnostic testing, it is preferred to test directly for traits of the actual virus while infections are occurring, using molecular tests from swabbed specimens.

Q236. How will the results of serological testing be used?

Using validated and effective serological tests for COVID-19 will be an important step in Canada's public health response.

On April 23, the Government of Canada launched the COVID-19 Immunity Task Force to lead a Canada-wide unified effort to test blood samples for signs of COVID-19.
Rapid and representative national surveys will provide a snapshot of where we stand now, and what to expect in a possible second wave of infection. They can also shed light on the potential immunity status of vulnerable populations such as Indigenous communities, and residents of nursing homes and long-term care facilities.

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

Q237. Is the government considering the possibility of serological or immunity passports or certificates to allow people with immunity to move freely again?

There is an active international effort to assess whether those who have recovered from illness are safe to resume daily activities.
More research is needed before making decisions in Canada.

Other respiratory viruses generally do not provide an individual with 100% immunity after recovery.

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

Q238. How is Canada currently testing patients who are suspected to have COVID-19?

Provinces and territories conduct diagnostic testing for the virus that causes COVID-19. Canada's National Microbiology Laboratory works in collaboration with provincial public health laboratories to ensure high quality diagnostic testing according to laboratory standards.

Q239. How will Health Canada ensure that test kits are safe and effective?

The Interim Order creates a tailored approval pathway for the importation and sale of medical devices that support Canada's response to COVID-19. This Interim Order, and the tailored approval pathway it creates, provides the Minister with flexibility to consider the urgent circumstances relating to the need for the medical device, authorizations granted by foreign regulatory authorities, or possible new uses for medical devices that are already approved in Canada.

As with all drugs and medical devices, Health Canada assesses and monitors the safety and effectiveness of all products authorized under this Interim Order, and will take immediate action if required to protect the health and safety of Canadians.

Manufacturers are still required to follow strict post-market safety requirements such as mandatory problem reporting, recall procedures and complaint handling.

Q240. Why did it take so long for Health Canada to authorize a serological test?

Providing the Canadian population and individuals with accurate information about appropriate public health measures and infection status is a pillar of the country's response to the pandemic. Canada has maintained a science-informed approach to managing the pandemic including maintaining requirements for pre-market authorization of COVID-19-specific tests.
Health Canada authorized the test after completing a scientific review that was supported by evidence to ensure that the test will provide accurate and reliable results. More than a dozen COVID-19 testing devices are now accessible in Canada. The list of authorized testing devices is posted on Health Canada's website.

If pressed:

- Each public health laboratory across Canada will decide whether it wants to use the DiaSorin LIAISON® serological test, based on its own needs and scientific review and requirements.

Q241. What's the difference between swab tests and serological tests? How are they used differently?

Serology tests are used to indicate if an individual has been infected by the virus that causes COVID-19. As an infection progresses, the patient's immune response will produce antibodies against the virus, and it is the presence of these antibodies in blood samples that are the basis of serological testing. Alternatively, traits of the actual virus, rather than the human immune

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response, are the basis for the molecular tests that are now in place to diagnose COVID-19 from swabbed specimens.

The results from serological testing are valuable for determining within certain settings or communities the rates of infection and the prevalence of those who have protective antibodies. This would include in health care workers. These results are also important to better understand the overall immune response to the virus, including to inform the development of COVID-19 vaccines.

Serological testing is not recommended to diagnose COVID-19 infections because antibodies are not likely to develop until later in the infection, thereby giving false negative results in many cases. For diagnostic testing, it is preferred to test directly for the virus while infections are occurring.

Q242. I think I had COVID but was never tested. How can I get a serology test to find out if I have immunity or not?

Canadian laboratories may use serological tests to detect antibodies specific to COVID-19. It will be up to provincial or territorial public health authorities to determine which serology-based tests they plan to implement. At this time, serological testing will not be used to diagnose cases in individual patients, but it can provide helpful evidence if someone has had a recent or past infection. Molecular tests are now used to detect active COVID-19 infections.

If you suspect you might have COVID-19, please contact your health professional or your local public health authority (PHA). They will provide advice on what you should do.
You can also use this self-assessment tool to help you determine if you need further assessment or testing: http://ow.ly/e4XQ50yRYE4

Contact tracing

Q243. Can you tell me more about the federal government program to recruit people to perform contact tracing?

As part of the comprehensive federal, provincial and territorial response to COVID-19, the Government of Canada is supporting provinces and territories by facilitating a virtual inventory for recruitment and mobilization of skilled Canadians to provide surge capacity in key areas.

To assist provinces and territories, the Government of Canada is working with them to identify their needs. They have identified contact tracing and case recording as areas where they require assistance. Therefore, the skills required include case management, data collection and management, public outreach and telephone interview skills. Other call-outs may be issued as jurisdictions identify new areas requiring assistance. As needs evolve, support in other areas requiring assistance will be provided.

The Government of Canada is reaching out in stages. The first and second stages are already underway. The first stage was to enlist qualified federal public servants, who are currently not in roles essential to ongoing federal work, to work in those jurisdictions feeling the most pressure. The second stage includes leveraging the inventory established as part of a COVID-19

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Volunteer Recruitment campaign, and reaching out to faculties of health, public health, and science across the country to disseminate a call for interested individuals to register in the inventory. A third stage will reach out to all health professional and health science associations for retirees or individuals currently not engaged in the COVID-19 response.

Q244. How many volunteers will be accepted for the National COVID-19 Volunteer Recruitment Program and what will the total number of volunteer contact tracers be? When will they be deployed in the field?

At the closing of the poster on April 24, there were over 53,769 volunteers registered in the inventory. The lists of volunteers have been shared with a number of jurisdictions, mostly to support long-term care. Each jurisdiction will be determining when and how they will be deploying volunteers. Please follow up with provincial and territorial governments regarding their specific plans.

Q245. Is the ministry studying the possible use of digital data technology such as cell phone Apps to improve contact tracing? What type of digital data model is the ministry examining?

Mobile apps can help to encourage physical distancing by empowering Canadians to modify their activities and reduce risky behaviours. These could complement public health measures aimed at flattening the curve, such as:

- avoiding crowded places and non-essential gatherings;
- washing your hands often with soap and water for at least 20 seconds; and
- avoiding touching your eyes, nose, or mouth with unwashed hands.

However, any support from the federal government would be highly contingent on measures taken by developers to protect the privacy and security of users.

Q246. A partly Canadian-based company has developed a smart-phone app that helps with contact tracing, similar to one in place in Singapore. Would the government adopt this kind of technology to aid contact tracing?

Contact tracing is an important public health action that aims to identify persons with potential COVID-19 exposure and to ensure those persons take precautions (such as self-isolation and monitoring for symptoms) to prevent further exposure to others. Contact tracing is a provincial and territorial responsibility and has been ongoing since the beginning of the COVID-19 outbreak. While an essential public health tool, contact tracing is resource-intensive. Phone apps using location or proximity data to help alert those who have come into contact with COVID-19 patients may be a useful tool in combatting the epidemic. Please direct questions on specific provincial or territorial policies or regulations with regards to contact tracing to the relevant provincial or territorial public health authorities.

DRUG, HEALTH PRODUCTS AND MEDICAL SUPPLIES

Medical supply availability

Q247. Does Canada have an adequate supply of diagnostic tests?

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We anticipate that there will be adequate supply of diagnostic tests.

Health Canada has been working with manufacturers to enable market access for commercial diagnostic devices in order to increase Canada's COVID-19 diagnostic capacity.

The Minister of Health has signed an Interim Order, as an emergency public health measure, to allow expedited access to COVID-19-related medical devices.

With the Interim Order, two new diagnostic tests are made readily accessible in Canada:

- the Roche Molecular Systems Inc. cobas SARS-CoV-2 diagnostic device; and
- the ThermoFisher Scientific TaqPath™ COVID-19 Combo Kit.

This will help improve access to medical devices that could permit faster and more convenient testing of patients in Canada.

Point-of-care diagnostic tests are in development and may become available through this Interim Order, which would also permit quicker and more convenient testing of patients.

Q248. Is Health Canada looking to the cannabis sector for additional COVID-19 testing?

A number of options are being assessed to increase testing capacity to support provincial and territorial public health authorities. As part of this, Health Canada is working to identify lab capacity that might be available across the country in various sectors, including at licensed cannabis production sites, to assist with supporting COVID-19 testing. On March 26, Health Canada sent an email to all licence holders, asking those with lab capacity that are interested in assisting to notify the Department by email. Several labs have responded indicating their willingness to assist. The department is currently confirming next steps, including confirming whether they have the appropriate equipment, certifications and protocols to assist.

Q249. Is the government thinking about increasing supply of the flu shot for the next flu season in light of the demand the COVID-19 pandemic?

The Public Health Agency of Canada (PHAC) is planning ahead for the potential for simultaneous outbreaks of the flu and COVID-19 infections in Canada this fall. To help minimize challenges this may cause to the healthcare system, the 2020 flu campaign will put a special emphasis on at-risk populations such as seniors and people with compromised immune systems or with underlying medical conditions.

PHAC assists in coordinating and overseeing the distribution of influenza vaccines for public programs, in collaboration with Public Services and Procurement Canada, Health Canada, vaccine manufacturers, and federal, provincial and territorial partners. PHAC does not decide how much vaccine provincial and territorial governments purchase for their populations; this decision is made by each provincial and territorial government based on past experience, the influenza season forecast, and the requirements of its immunization program.

In light of the COVID-19 pandemic, provincial and territorial governments are reviewing their vaccine supply orders for next year's influenza season to determine whether they are sufficient or should be increased. There is still an opportunity to increase orders before final commitments need to be made.

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Q250. Is Health Canada aware of any medical device shortages due to COVID-19, and what is being done to monitor supply?

At this time, Health Canada has not received any medical device shortage notifications from manufacturers of medical devices as a result of COVID-19.

The Department has engaged medical device industry stakeholders to seek any early signals of potential supply issues and none have been identified to date. Health Canada continues to monitor the situation and will take appropriate action, as required, to mitigate any impact on Canadians.

Q251. Will 3D printed medical devices be allowed to be used to alleviate supply shortages in Canada during this pandemic?

Health Canada is aware that groups here in Canada and in other countries (e.g. the UK, the U.S., Italy, China) may be using various manufacturing techniques to address some supply issues.

Health Canada, together with other federal organizations and private sector, is facilitating the assessment of existing 3D printing capacity in Canada and will help determine possible next steps to augment capacity where needed.

It is important to note that Health Canada remains the regulatory authority for all medical devices that are intended to be sold or imported and has dedicated processes to quickly assess safety, efficacy, and quality for medical devices manufactured for the COVID-19 response, including those manufactured by 3D printing.

Health Canada has reached out to its trusted 3D printing network in the medical device industry, hospitals, universities, colleges and industrial manufacturing facilities. As of March 20, we have received responses from 34 organizations with 3D printing experience who are willing to help.

Q252. Is there an estimate in terms of how many ICU beds Canada will require as the epidemic reaches its peak? And how many ICU beds are available now?

According to the Canadian Institute for Health Information (CIHI), there were 3,902 ICU beds in Canada (excluding Quebec, Nunavut and Yukon), in 2017-18, which is the most recent and most complete data available. Further details can be downloaded from CIHI's web site.
Health care system officials in the provinces and territories are closely monitoring their jurisdiction's health system capacity, including the demand and supply for key assets such as ICU beds and ventilators as the number of COVID-19 cases rise. The situation continues to evolve as many jurisdictions are taking various actions, including cancelling elective surgeries and moving alternative level care (ALC) patients to other sites to improve their acute care capacity in hospitals.

Health Canada is currently discussing with provincial and territorial officials the availability of ICU and ventilator capacities.

Q253. How many ventilators does Canada have now, and how many would be needed when the epidemic reaches its peak?

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The collaborative federal, provincial and territorial procurement order also includes ventilators. The federal government has contracted for more than 1,500 ventilators and is working to support the acquisition of additional ventilators in support of provinces and territories.

The global demand for these items is high, and PHAC will continue to assess needs with the provinces and territories as this event evolves.

Q254. What is the federal government doing in terms of increasing the supply of ventilators and masks?

The Government of Canada is investing $2 billion to purchase PPE, including for bulk purchases with provinces and territories. This includes masks and face shields, gowns, ventilators, test kits and swabs, and hand sanitizer.

Discussions are continuing within the Government of Canada (Innovation, Science and Economic Development Canada, Public Services and Procurement Canada, Health Canada and the Public Health Agency of Canada) to explore alternative PPE supply routes and to scale up domestic production with Canadian companies such as Thornhill Medical and Medicom. To ensure that these production lines meet the technical specifications appropriate for use in frontline response, Health Canada and the Public Health Agency of Canada are conducting technical evaluations. This includes the Minister of Health's most recent signing of an Interim Order to allow expedited access to COVID-19-related medical devices. The list of authorized COVID-19 devices (with authorization dates) is available here and all licensed medical devices are listed in the Medical Device Active Licence Listing.

Q255. Is Health Canada reaching out to the three RCMP forensic labs to provide personal protective equipment to health care workers?

The Government of Canada has not asked the Royal Canadian Mounted Police to provide personal protective equipment to health care workers. We are working directly with the provinces and territories to identify needs and buy in bulk to leverage our collective buying power. We are also accepting donations, enhancing domestic industrial capacity, and expediting the regulatory process to ensure we are able to get critically needed products to Canadian markets.

Q256. Will the federal government consider to have a plan in place to increase the speed of donated medical supplies to fulfil the medical equipment shortage?

PHAC and Health Canada have been working closely with the Canadian Border Services Agency to expedite medical supply donations.

In response to the COVID-19 pandemic, Health Canada has implemented interim measures to expedite the importation of medical equipment including hand sanitizers, disinfectants, and personal protective equipment (such as masks and gowns)—as well as swabs. Details on Health Canada's interim measures can be found here.

Q257. Does Canada have a stockpile of syringes/needles or other vaccination-related equipment for a pandemic immunization campaign?

The National Emergency Strategic Stockpile (NESS) currently stockpiles assets that address a variety of threats and risks that could be used for a pandemic immunization campaign, such as

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needles, syringes and sterile gauze pads, along with personal protective equipment (PPE). These supplies could supplement assets held by the provinces and territories. It is not the practice of the NESS to divulge specific quantities of stock in its holdings. The Public Health Agency of Canada (PHAC) works with the provinces and territories on an ongoing basis to assess all pandemic requirements and to ensure that every effort is made to maintain adequate supply in Canada.

Q258. Will Health Canada ensure there is an adequate supply of immunization supplies for when a COVID-19 vaccine is eventually available?

PHAC and Health Canada are currently working with key partners and stakeholders to identify anticipated supply chain risks or capacity gaps that may affect mass vaccination campaigns across Canada for the COVID-19 vaccine.

PHAC will continue to work with provincial and territorial partners to identify potential gaps in the supply chain and will be prepared to support the timely procurement of additional assets, such as needles, syringes as well as PPE and possibly medication that will be required for the mass vaccination campaigns for the COVID-19 vaccine in Canada.

Q259. What is the current wait time for Canadian PPE manufacturers (not importers) to receive approval to sell and distribute their products to healthcare facilities? How many firms are currently waiting for these certificates?

Canada's Medical Devices Regulations (the Regulations) set out a system for classifying medical devices into one of four classes — Class I representing the lowest risk and Class IV representing the highest risk.
Health Canada issues two types of licences for medical devices:

- Medical Device Licence (MDL) - a licence issued to manufacturers authorizing them to import or sell their Class II, III or IV medical devices in Canada.
- Medical Device Establishment Licence (MDEL) - a licence issued to Class I manufacturers, as well as importers or distributors, of all four device classes to permit importation or distribution (sale) of a medical device in Canada.

The regulatory review process for authorization of medical devices has been modified in the context of the COVID 19 pandemic. On March 18, 2020, the Minister of Health approved an Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19. The interim order enabled an expedited review of medical devices indicated to diagnose, treat, mitigate or prevent COVID-19, at no cost for reviewing submissions.

Health Canada has received a significant number of Interim Order applications for PPE as well as applications for Medical Devices Establishment Licences.

Applications received under Interim Order *Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*

There are currently 359 PPE Interim Order applications in process. Most of these applications are on hold while Health Canada awaits additional evidence to demonstrate the devices meet necessary requirements. The timeframe under which a COVID-19 application is authorized is highly dependent on the quality of the application and supporting information provided to Health Canada. It is currently taking an average of approximately 9 days to process an application that does not have any deficiencies. A list of COVID-19 Diagnostic Device Applications Authorized

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by Health Canada can be accessed at the following Health Canada's web page: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

Medical Devices Establishment Licences applications

Most PPE devices (e.g. masks, face shields, gowns) are Class I medical devices, and thus deemed low risk compared to other classes. Companies wishing to manufacture, import or distribute PPEs require a Medical Device Establishment Licence (MDEL) if they do not have an Interim Order authorization number. Health Canada's regular service standard for issuing a MDEL is 120 days, however, our goal is to process MDEL applications related to COVID-19 as quickly as possible to facilitate access to necessary medical devices.

In light of the current demand for medical devices to help combat COVID-19 and the high number of companies making efforts to supply these products in Canada, Health Canada has encountered an unprecedented increase in applications for Medical Devices Establishment Licences.

As of April 27, 2020, Health Canada has expedited the issuance of over 750 MDELs related to products such as masks, gowns and respirators, with approximately 450 applications remaining in queue.

In order to facilitate rapid access to needed supplies to help combat COVID-19, Health Canada has implemented a temporary discretionary measure by assigning MDEL applicants an interim submission number while MDEL applications continue to be processed as soon as possible. The submission number allows an applicant to conduct licensable activities while they await the issuance of their MDEL. As of April 27, over 380 submission numbers have been issued to applicants while their MDEL applications continue to be processed. This temporary submission number is assigned to applicants that have submitted **a complete application.** Applicants in receipt of a submission number or MDEL must conduct activities in accordance with all of the requirements set out under the Medical Devices Regulations (MDR) and are responsible for ensuring the medical devices (Class I to IV) they sell are compliant with safety and effectiveness requirements outlined in sections 10 to 20 of the MDR. Health Canada takes a risk-based approach to compliance and enforcement (C&E) with primary objective of mitigating the risk associated with the non-compliance. The Department employs a range of C&E tools to verify compliance and takes immediate action to stop the importation and sale of any non-compliant products. Examples of C&E tools include: written notices (regulatory letters or warning letters), inspections, public advisory, seizures/seizures of imports at the border and recalls, as detailed in Health Canada's Guidance on Medical Device Compliance and Enforcement (GUI-0073).

All authorized Medical Device Establishment Licences (MDEL) are posted at Medical Devices Establishment Licence listing.

Additional information regarding the measures the Department has taken to increase supplies of PPE can be accessed at the following Health Canada's web pages: COVID-19 personal protective equipment (PPE).

Q260. What has the response been to the call by the federal government for medical devices that we are low on (http://www.ic.gc.ca/eic/site/080.nsf/eng/00048.html)?

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As an emergency public health measure, the Minister of Health signed on March 18, the Interim order respecting the importation and sale of medical devices for use in relation to COVID-19 to allow expedited access to COVID-19-related medical devices. The Interim Order will help ensure that COVID-19-related medical devices are available to treat, mitigate, or prevent COVID-19, as necessary.

As part of the Government of Canada's response to the COVID-19 pandemic, the *COVID-19 Emergency Response Act* was passed on March 25. The amendments to the *Food and Drugs Act* enable Health Canada to put in place more robust tools to support efforts to alleviate shortages and, when possible, prevent shortages. On March 30, the Minister of Health signed the Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19, an Interim Order permitting the exceptional importation and sale of drugs, medical devices, and foods for a special dietary purpose needed to prevent or alleviate the effects of shortages directly or indirectly related to COVID-19.

The Interim Order permits the exceptional importation of specified drugs that may not fully meet Canadian regulatory requirements, such as bilingual labelling, but are manufactured according to comparable standards, to safeguard the Canadian drug supply and protect the health of Canadians during this time.

We are aware of the shortage of personal protective equipment (PPE) and medical supplies across Canada and are committed to doing what is necessary to protect the health of Canadians, especially frontline healthcare workers, from COVID-19. The Government of Canada continues to coordinate with provincial and territorial governments to quickly assess needs for PPE items, such as N95 respirators, surgical masks, face shields, nitrile gloves, gowns and other protective clothing, as well as medical supplies such as sanitizer, ventilators, swabs and testing kits. To meet these needs, we are purchasing large quantities of equipment and supplies, working with Canadian companies to increase their manufacturing capacity to produce additional supplies, and investing in COVID-19 testing. We have also received donations from international and domestic organizations. Heath Canada also considered conservation strategies, including the decontamination of respirators and the use of expired masks, as a strategy to ensure the continued availability of these devices.

The Public Health Agency of Canada, Health Canada and the National Research Council of Canada are conducting technical reviews to verify that the products meet the Government of Canada technical specifications for COVID-19, as indicated on the Public Services and Procurement Canada's buy and sell website.

Q261. How has Canada resolved the mask shortage when the U.S has yet to do so?

The Government of Canada is coordinating with provincial and territorial governments to continually assess needs for personal protective equipment (PPE) items, such as masks.

To address these needs, the Public Health Agency of Canada (PHAC) has been working with Public Services and Procurement Canada to advance bulk procurement orders and has been allocating PPE and medical supplies to the provinces and territories as per an approach agreed upon by federal-provincial-territorial Ministers of Health. PHAC is also deploying PPE and ventilators from its National Emergency

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Strategic Stockpile (NESS) to provinces and territories that have submitted requests for assistance. The purpose of the NESS is to help supplement provincial and territorial resources through the provision of surge support.

Shortages of PPE is an ongoing concern as the global demand remains high, which is why, in addition to procuring PPE and increasing domestic manufacturing capacity, the Government of Canada promotes a variety of measures to flatten the epidemiological curve such as frequent hand washing and physical distancing.

Q262. What are PHAC's forecasts for how much PPE will be needed across industries for when the economy fully reopens? Is there a breakdown by sector and by region?

The Government has a multi-pronged approach to securing access to medical supplies and Personal
Protective Equipment (PPE) through:

- Sourcing and procuring PPE internationally and domestically
- Building domestic manufacturing capacity
- Expediting regulatory approvals
- Issuing guidance on appropriate use of PPE
- Verifying quality

Health Canada and the Public Health Agency of Canada (PHAC) are working closely with the provinces and territories to understand their PPE needs for the health care sector and allocate PPE appropriately.

Federal departments are also engaging regularly with business stakeholders and industry associations in all sectors of the economy to better understand their PPE needs and strategies. Federal departments are also working with experts to better understand and assess the PPE needs of Canada's society and economy, based on the most up-to-date public health advice.

A COVID-19 Ministerial Working Group on Personal Protective Equipment, chaired by the Minister of Public Services and Procurement, has been established to review needs and consider support for PPE for essential services, beyond those involving health care workers and front line federal workers. Additionally, the Working Group has been tasked with identifying emerging areas of potential concern for further action.

For more information on the government's efforts to secure the necessary equipment and supplies to fight COVID-19, including new and existing sources of supply, both here at home and internationally, please visit:
https://www.tpsgc-pwgsc.gc.ca/comm/mc-cd/provisions-supplies-eng.html

Distribution and quality control

Q263. When did Canada start to procure personal protective equipment and supplies to prepare for COVID-19?

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In January 2020, the Public Health Agency of Canada (PHAC) began monitoring the coronavirus outbreak in China and started assessing its inventories in the National Emergency Strategic Stockpile (NESS). That same month, PHAC initiated work with Public Services and Procurement Canada to procure supplies needed to respond to a possible outbreak in Canada with bulk orders for medical supplies in addition to orders placed for the NESS.

Q264. How much PPE was exported to China from mid-January through March 31, through all known channels (institutional, retail, community)?

As announced on February 9, 2020, the Government of Canada donated approximately 16 tonnes of personal protective equipment to China, in collaboration with the Canadian Red Cross

Q265. Where will medical supplies be stored before they are distributed by Canada Post or Purolator to hospitals?

Amazon will work directly with Canada Post to provide warehousing, and leverage its current third-party delivery channels, through Canada Post and Purolator, to deliver the products to provincial and territorial health authorities, across the country, for the frontline healthcare response.

Q266. How many shipments have been sent using Amazon Canada to send PPE to the provinces as of May 1st?

To date, each province and territory has received five shipments of PPE via Amazon.

Q267. Do you ever have concerns about the quality/standard of medical equipment donated to Canada?

The Government of Canada is receiving donations of medical supplies from companies both internationally and domestically, and is working to make them available for use by frontline healthcare workers.

Currently, donations are being managed through the Public Health Agency of Canada (PHAC), and additional partners will assist to ensure that the volume is handled as efficiently as possible and that the distribution reach is maximized.

When the federal government receives a donation, it must assess its quality. The objective is to conduct this process as rapidly as possible so that products that meet specifications can be distributed to the provinces and territories without delay.

In addition to working off a pre-existing list of product specifications, PHAC and Health Canada have formed a technical review team to assist in this regard.

An interdepartmental, multidisciplinary technical assessment committee has been established to assess donated medical supplies to verify that they meet the Government of Canada technical specifications for COVID-19 as available on the Public Services and Procurement Canada's buy and sell website. The process for assessment varies depending on the medical device.

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The interdepartmental, multidisciplinary technical assessment committee comprises representatives from the Public Health Agency of Canada (including the National Microbiology Laboratory), Health Canada and the National Research Council of Canada.

Q268. Has the Public Health Agency of Canada rejected any donated supplies that it has quality controlled? Has any equipment failed quality control tests in the last two months?

Personal protective equipment (PPE) and medical supplies received by the Government of Canada, whether donated or procured by Public Services and Procurement Canada (PSPC) are verified by the Public Health Agency of Canada (PHAC) to ensure they meet the Government of Canada's technical specifications for COVID-19. If PHAC cannot account for the quality, they will not be allocated to the provinces and territories for frontline healthcare response.

To date, PHAC has received some supplies that do not meet the Government of Canada's specifications for healthcare settings. Although such products are non-compliant with the specifications for the frontline healthcare response, they are subsequently assessed to determine potential use in non-healthcare settings.

For example, items can sometimes be damaged in transit, and PHAC works to ensure that those items are not distributed to provinces and territories. In the context of COVID-19 response, PHAC has had a small quantity of PPE that was not released as it was damaged in transit, and PHAC continues to verify PPE as it is received. The same is true of donations received by PHAC.

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Due to intense global competition for PPE and medical supplies, countries are engaging with a diverse number of new suppliers and manufacturers to meet the demands of the COVID-19 response effort. As a result, PHAC is conducting its due diligence on products procured by PSPC, verifying the quality of procured and donated supplies upon receipt. To date, PHAC has identified approximately 1 million KN95 masks as non-compliant with specifications for healthcare settings. These items were not distributed to provinces and territories for frontline healthcare response, and are being subsequently assessed for use in non-healthcare settings.

Q269. What happens to those items that fail inspection? Are they destroyed? Shipped back to donor country?

PPE requirements for healthcare workers are more stringent than what is appropriate for outside the healthcare setting. Equipment that does not meet specifications for healthcare settings will be further assessed for potential use in the community.

Q270. How many shipments of N95 masks have been inspected and a) accepted and b) rejected?

The number of N95 respirators and equivalents (e.g., KN95 respirators) received changes on a daily basis, as does the number of respirators in testing. N95 respirators that do not meet their technical specifications for healthcare settings for the COVID-19 response are not distributed to provinces and territories and are subsequently assessed for use in non-medical settings.

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If pressed:

To date (May 8), of the approximately 11.5 million N95 respirators received so far, approximately 1.5 million met the technical specifications for healthcare settings for COVID-19 response; approximately 8.5 million did not; and 1.5 million are currently undergoing testing.

Q271. Does the government have any requirements on the standards of medical supplies used by local health agencies? If so, what are they?

PHAC is directing suppliers online to provide information on the items we are seeking, as well as the expedited process for suppliers to follow, including information on product specifications.

Q272. How many swabs did Canada receive to date and how many have been distributed?

The Government of Canada has ordered more than 11 million swabs from various domestic and global suppliers, to be delivered in batches on an ongoing weekly basis. Further, we are looking at options to ensure an ongoing secure supply of sterile swabs, including ways to produce swabs in Canada. The Government is procuring and producing other necessary laboratory test components to support provinces and territories in their overall laboratory testing efforts.

The Public Health Agency of Canada (PHAC) has shipped more than 700,000 testing swabs for distribution in Canada. PHAC is anticipating weekly deliveries of approximately 500,000 swabs from orders placed with a variety of companies. PHAC is working to rapidly allocate these swabs to provinces and territories, on a per capita basis.

Q273. Recent media coverage has highlighted that during the week of April 6, Canada received 320,000 swabs from China that were contaminated with mould. What measures are being taken to ensure that this does not happen again? Is there other medical equipment coming from China that could not be used because it does not meet Health Canada's criteria?

When provinces and territories identified issues with the shipment of swabs in question, the company recalled the product and made a commitment to take corrective action and issue product replacement.

The Government of Canada is looking at options to ensure a secure supply of sterile swabs to support laboratory testing, including options to produce swabs in Canada. The Government of Canada has ordered more than over 11 million swabs, and is supporting provinces and territories in lab testing efforts, including ensuring that the demand for swabs is met.

Personal protective equipment and other medical supplies received by the Government of Canada, whether donated or procured, are verified by PHAC to meet the Government of Canada technical specifications for COVID-19 before they are allocated to provinces and territories. If PHAC cannot account for the quality of equipment or supplies, it will not deploy them for frontline healthcare response. The verification process varies depending on the medical device. For example, KN95 respirators, which are an accepted alternative to N95

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respirators, are visually inspected to check for defects in design and construction, and tested to confirm they meet specifications for filtering face pieces. Gowns and surgical masks are visually inspected and tested for fluid penetration.

IF PRESSED:

PHAC has received some supplies that do not meet Government of Canada specifications. Although such products are non-compliant for frontline healthcare response, they are subsequently assessed to determine potential use in non-healthcare settings.

Q274. Has an investigation been opened for determining why contaminated scientific equipment from ESBE Scientific was sent to Canada?

ESBE Scientific shipped 380,000 EZ PRO swabs between March 28 and April 3, 2020, which were sent to various locations in Canada. On April 11, 2020, the company issued an urgent recall notice due to a problem with swab contamination. The company recalled the product and committed to taking corrective action and replacing the product. The provincial and territorial public health laboratories were immediately informed of the recall. Health Canada worked with the company to ensure that it ran smoothly. The Department posts all health product recalls in its Recalls and Safety Alerts database. Information about the recall of EZ PRO swabs appears here.

ESBE Scientific holds a valid medical device establishment licence (company number 103659). Health Canada will continue to work with the manufacturer to ensure that it takes the required corrective action and follows the appropriate protocols.

It was determined that an ethylene oxide treatment made it possible to sterilize the swabs. All provincial public health laboratories were informed about that on April 13, 2020. The Public Health Agency of Canada (PHAC) immediately made arrangements with a company for sterilizing the swabs. Health Canada authorized that sterilization process under the interim order signed on March 18, 2020. The provinces and territories can choose between throwing out the swabs or re-sterilizing them.

The Government of Canada ordered over 11 million swabs from a variety of suppliers and is providing or producing other items required for laboratory tests in order to support the provinces and territories. It is currently looking into ways of ensuring a steady, safe supply of sterile swabs, including options for producing and sterilizing swabs in Canada. A contract has been signed with PAMA Manufacturing and Sterilization (Mirabel, Quebec) for swab sterilization.

The PHAC is continuing to work directly with the provinces and territories to determine their medical supply needs in order to place bulk orders. Public Services and Procurement Canada is continuing to identify all suppliers capable of meeting Canada's needs.

Q275. If products don't meet all of Health Canada's regulatory requirements, should Canadians be concerned about their safety?

No. While these products are typically subject to certain regulatory requirements, such as licensing and bilingual labelling, Health Canada is allowing these low-risk products to be distributed in Canada to address their current unprecedented demand to help slow the spread of COVID-19.

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The expedited process requires companies to complete and submit a notification form that allows Health Canada to maintain a record of all hand sanitizers, hard surface disinfectants and personal protective equipment being sold in Canada under this interim approach. As with all health products, Health Canada will continue to monitor the safety of these products once they are on the market and will take action to protect the health and safety of Canadians, if necessary.

Health Canada will continue to use all tools at its disposal to expedite the supply of safe and effective health products related to COVID-19. However, the department is not providing blanket approval of unauthorized drugs or devices.

We will update Canadians with any new information as it arises.

Consumers and patients are encouraged to report any health product adverse events to Health Canada.

Q276. Has Health Canada/PHAC had any complaints about a batch of masks supplied to Alberta health care institutions?

The Public Health Agency of Canada (PHAC) is not aware of the circumstances of the purchase so can't comment. We have reached out to see if we can provide assistance to Alberta.

Q277. Are there any concerns about 3D printers being produced without the usual quality checks or certification processes?

Medical devices sold, imported or distributed in Canada must meet the safety, effectiveness, and quality regulatory requirements of the *Medical Devices Regulations* or the Interim Order in cases of devices involving COVID-19. These regulated devices include medical devices manufactured via 3D printing. Health Canada is the regulatory authority for all medical devices and has dedicated processes to quickly assess safety, efficacy and quality for medical devices manufactured for the COVID-19 response.

There are risks if devices such as personal protective equipment are not of high enough quality to properly protect patients and healthcare workers. We are working with conventional medical device manufacturers and certified 3D printing organizations regarding required device specifications and quality so Canadians can have timely access to medical devices that are safe, efficacious and of high quality.

Q278. What steps are being taken to get the necessary equipment/products to the food producing and processing businesses?

The Government of Canada is coordinating with provincial and territorial governments to quickly assess needs for personal protective equipment (PPE) for health professionals (e.g., N95 respirators, surgical masks, face shields, nitrile gloves, gowns and other protective clothing) as well as medical supplies (e.g., sanitizers, ventilators, swabs and testing kits). To meet these needs, we are purchasing large quantities of equipment and supplies, and working with Canadian companies to increase their manufacturing capacity to produce additional supplies.

The priority of the Public Health Agency of Canada (PHAC) and Health Canada is to support provinces and territories with PPE for the frontline healthcare response. PHAC has developed guidance to support employers and employees in preventing transmission of COVID-19 in the

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workplace. The most important measures are physical distancing, rigorous hand hygiene, respiratory etiquette, cleaning and disinfection of surfaces and objects, use of physical barriers, and redesign of the workspace to maintain physical distance.

The Government of Canada is working to assess the needs across essential service sectors and to increase the domestic capacity to manufacture PPE.

Invitation to Submit an Expression of Interest for Logistics Services

Q279. What will the logistics provider be required to do?

The logistics provider will be expected to handle customs documentation, secure warehousing, inventory management, reporting and transportation of the personal protective equipment to various locations in each of the provinces and territories.

The logistics provider will be expected to handle shipments by all modes of transportation, including receiving and moving products from sea ports, airports, railheads and commercial transition points.

Q280. How long is the contract for?

The logistics services will be required for a period of one year with a possibility of extension. Questions about the contract and tender process should be addressed to PSPC.

Q281. How is the Government of Canada handling the importation and distribution of PPE in Canada right now?

The Government of Canada uses existing National Emergency Strategic Stockpile (NESS) locations and resources. In addition, on April 1, 2020, a contract was awarded to Amazon to help facilitate the distribution of large quantities of PPE and medical supplies to support the COVID-19 response.

Q282. Weeks ago the Government of Canada announced an agreement with Amazon and Canada Post to receive and distribute PPE in Canada. What is the status of that agreement and why is another one needed through this new expression of interest?

On April 1, 2020, the Government of Canada awarded a contract to Amazon to help distribute PPE and medical supplies to support the COVID-19 response. Amazon is working directly with the Government of Canada and Canada Post to manage warehousing, and Purolator to deliver the products to provincial and territorial health authorities across the country, for the frontline healthcare providers.
This new expression of interest relates to an end-to-end logistics solution that is different than what the Amazon agreement provides for. However, the intent is that the new solution will complement Amazon's services, and the service provider will be capable of working with the Amazon technology.

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Q283. What role does the NESS play in storing and distributing PPE to provinces and territories?

Canada's National Emergency Strategic Stockpile (NESS contains supplies that provinces and territories can request in emergencies when their own resources are insufficient, such as during infectious disease outbreaks, natural disasters and other public health events. The purpose of the NESS is to provide surge support to provinces and territories; it is not intended to replace supplies that provinces and territories hold or procure. Provinces and territories are responsible for preparing and maintaining their own supply capacities.

Drug Shortages

Q284. What is driving the potential for drug shortages?

There are a multiple factors that may impact the availability of a drug and increase the potential for a shortage. These include manufacturing disruptions, availability of ingredients, supply chain disruptions, and increase in demand. Health Canada works with companies and partners to identify the root cause of shortages and mitigate any impact on patients as quickly as possible. Health Canada recently advised Canadians not to purchase more medication than they need, and health professionals to avoid prescribing or dispensing larger supplies of medication than necessary, to help prevent shortages caused by increased demand.

Q285. What is the difference between a 'drug shortage' and an 'anticipated drug shortage'?

A shortage refers to a situation in which a market authorization holder (MAH) for a drug is unable to meet demand for the drug. An anticipated shortage is a situation in which a MAH can meet demand in the short term but does anticipate disruptions at a future date.

Q286. What is the extent of COVID-19 related drug shortages and what is being done to address them?

Health Canada has been actively monitoring the impact of the COVID-19 pandemic on the supply of drugs in Canada and is aware that an increased demand has resulted in supply constraints and reported shortages. The Department has been proactively looking at the Canadian supply chain to identify areas where supply may be vulnerable and addressing those vulnerabilities before shortages develop. These increased surveillance efforts include regularly engaging provinces and territories, industry, health care and patient groups—in some cases on a daily basis. Health Canada is also working with international regulatory partners, including the European Medicines Agency, the United States Food and Drug Administration, the Australian Therapeutic Goods Administration, and the World Health Organization to share information on any signs of global supply disruptions. This engagement has enabled us to better identify early shortage signals, potential mitigation strategies and to coordinate responses.

As part of the whole-of-government response to the COVID-19 pandemic, the *COVID-19 Emergency Response Act* was passed on March 25. The amendments to the *Food and Drugs Act* enable Health Canada to put in place more robust tools to support efforts to alleviate shortages that occur and prevent shortages from happening when possible. For example, on

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March 30, the Minister of Health signed an Interim Order to help prevent or alleviate shortages related to COVID-19. This Order permits the exceptional importation and sale of drugs, medical devices, and foods for a special dietary purpose that may not fully meet Canadian requirements related to licensing and labelling, but are manufactured according to comparable standards. Information for companies on how to request that a drug be added to the *List of Drugs for Exceptional Importation and Sale* is available on Health Canada's website.

Drug shortages that have been designated as Tier 3 shortages qualify to be added to the *List of Drugs for Exceptional Importation and Sale*. Tier 3 shortages are those that have the greatest potential impact on Canada's drug supply and health care system and are being actively managed by Health Canada, in collaboration with the provinces and territories, industry and health care professionals, to identify measures to mitigate the impact on patients. The Tier 3 list currently includes drugs that are being used to support COVID-19 patients, such as muscle relaxants, inhalers, sedatives, blood pressure stabilizers, antibiotics and pain medications, and will be updated as needed. Tier 3 assignments are determined based on a recommendation from a Tier Assignment Committee, which includes federal and provincial/territorial governments, healthcare professionals and industry stakeholders.

Working with companies to address existing shortages and mitigate the impacts on patients is the top priority for Health Canada. The Department is also looking at options for long-term stability. As part of these efforts, the Government of Canada issued four Requests for Information (RFI) on April 19, 2020 and three on April 21, 2020 that ask companies to indicate if they have access to additional supplies of these critical drugs.

The RFIs will be used to identify additional supply that has not already been earmarked to meet Canada's current needs. The Government of Canada is not looking for information on products already identified to mitigate a current supply constraint or shortage, but additional products to bolster the overall supply. RFIs have been posted for Salbutamol, Cisatracurium, Fentanyl for injection, Propofol, Norepinephrine, Epinephrine and Azithromycin. The RFIs indicate that the government is interested in procuring up to a twelve-month supply, which could be acquired incrementally, at elevated demand levels. The government will consider additional RFIs for other critical drugs in shortage and drugs that are showing promise in clinical trials as potential COVID-19 treatments.

Health Canada will continue to work with other federal departments, provincial and territorial governments, international partners, and industry to mitigate the impact on Canadians of any shortages related to COVID-19. These efforts will help ensure that Canadians have access to the drugs they need during the COVID-19 pandemic now and as the situation continues to evolve.

Q287. When you say you're working with drug suppliers, what actions does that involve?

Health Canada is working with industry, provinces and territories, and other healthcare partners to mitigate the impact on Canadians of any shortages related to COVID-19. When an anticipated or actual shortage is reported to Health Canada, the Department works with companies from across the supply chain to better understand root causes, plans to resolve the shortage and measures that can be taken to mitigate the impacts on Canadians. In the event of a critical national shortage, Health Canada engages with the company reporting the shortage, as well as other companies that supply the Canadian market, in order to explore all options for

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meeting Canadian demand. This includes options to facilitate access to alternative supply as needed and working with companies that are able to ramp up supply for Canadians.
Health Canada is working with other federal departments, provincial and territorial governments, international partners, and industry so that Canadians have access to the drugs and medical devices they need during the COVID-19 pandemic.

Q288. What role do provinces and territories play in being alert to potential shortages in their jurisdictions?

Addressing the complex issue of drug shortages is a multi-stakeholder responsibility requiring collaborative action from provinces and territories, manufacturers, distributors, health care professionals, and the federal government. Health Canada works closely with the provinces and territories, who notify the Department of shortages of concern.

When a critical national shortage occurs, Health Canada works with stakeholders across the drug supply chain to coordinate information sharing and identify mitigation strategies. Factors such as whether the shortage is national in scope, whether alternative supplies are available, and whether the product is considered medically necessary are considered in determining the potential impact and any necessary actions by Health Canada. More information on the roles and responsibilities in addressing drug shortages can be found on our website.

Q289. Can you confirm whether or not Health Canada is looking for alternative sources for Salbutamol or Ventolin?

Health Canada is aware that an increase in demand has led to shortages being reported for a number of salbutamol inhalers, including Ventolin. Information regarding these shortages is available at www.drugshortagescanada.ca.

Health Canada is working closely with companies, other federal departments, provinces and territories, and other stakeholders such as the Canadian Thoracic Society to identify and implement mitigation options. This includes working with companies that can ramp up supply for the Canadian market and exploring international supply, to help ensure continued supply in Canada.

The Department recently advised Canadians not to purchase more medication than they need, and asked health professionals to avoid prescribing or dispensing larger supplies of medication than necessary, to help ensure that all Canadians continue to have access to the medications they need and prevent shortages caused by increased demand.

Q290. What is the current supply of the following drugs: Chloroquine and hydroxychloroquine; Ritonavir/lopinavir; and Ritonavir/lopinavir and interferon-beta?

Health Canada is closely monitoring the supply of any potential treatments for COVID-19 and working with companies to help ensure continued supply in Canada, including working with companies that can ramp up supply for the Canadian market.

Hydroxychloroquine is marketed in Canada by four companies: Apotex Inc., JAMP Pharma Corporation, Mint Pharmaceuticals Inc., and Sanofi-Aventis Canada Inc and is currently not reported to be in shortage.

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Chloroquine is marketed in Canada by Teva and is reported to be in shortage with an anticipated end date of December 31, 2022 due to a shortage of an active ingredient.

Ritonavir/lopinavir is marketed in Canada by AbbVie and is currently not reported to be in shortage.

Interferon-beta is marketed by EMD Serono Canada and Biogen Canada Inc in Canada and neither are reporting a shortage.

Health Canada will continue to closely monitor supplies of these drugs in Canada and will take any necessary actions in collaboration with the companies, provinces and territories, and other stakeholders to help ensure continued supply in Canada. Companies are the best source for information regarding the supply of a particular drug and should be contacted for any questions about market status and the availability of a particular drug. Canadians may also wish to visit www.drugshortagescanada.ca for the latest information on any reported drug shortages in Canada.

Q291. What is Canada doing to ensure there is an adequate supply of Remdesivir available in Canada? Do you have some now, or do you plan to obtain it? Would you consider compulsory licensing if there is a shortage here?

Remdesivir is an experimental drug that is being administered by intravenous infusion to some hospitalized patients suffering from COVID-19. Health Canada has been closely monitoring developments for potential treatments for COVID-19, including remdesivir. The most appropriate way to access experimental therapies that have potential for treating COVID-19 is through a clinical trial. Clinical trials provide Canadians access to new therapies aimed at treating COVID-19, as well as an opportunity for the healthcare community to systematically collect information on the effectiveness of the treatments and their associated risks.

In Canada, remdesivir can be accessed through two mechanisms: approved clinical trials and the Special Access Program.

To date, two clinical trials have been approved for remdesivir in the context of COVID-19 in Canada, involving multiple sites across the country. More information about the approved trials is available on our website. Information from these clinical trials may help support a submission to Health Canada. The Department has been in regular communication with Gilead Sciences regarding access to remdesivir and their future plans for filing a submission for review. Once Gilead Sciences Canada, Inc. files a submission for remdesivir with Health Canada, the department will exercise the regulatory flexibility to expedite the submission review for earlier access to Canadians while ensuring the safety, efficacy and quality for this drug. Health Canada has also been working with international regulators, including the U.S. Food and Drug Administration, to share scientific information on drugs and vaccines for COVID-19 including remdesivir, and aligning requirements for safety and efficacy where possible to expedite the review and approval processes.

Prior to authorization of the clinical trials, and for certain groups who may not be eligible for access under the trials, remdesivir has been accessed on a case-by-case basis through Health Canada's Special Access Program (SAP). The SAP for drugs is another mechanism for Canadians to access health products on a case-by-case basis. The SAP may provide emergency access to non-authorized, non-marketed drugs to individual practitioners treating a patient with a serious or life-threatening condition where conventional therapies have failed, are

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unsuitable, or unavailable. In some circumstances, non-marketed drugs—such as remdesivir—may be requested via the SAP. Each SAP request is reviewed individually. To date, Health Canada has authorized 12 SAP requests for remdesivir.

Q292. Why has the federal government issued requests for information to ask drug companies for data on the supply and demand of fentanyl, salbutamol, propofol, and methotrimeprazine?

Health Canada has been actively monitoring the impact of the COVID-19 pandemic on the supply of drugs in Canada and is aware that an increased demand has resulted in supply constraints and reported shortages.

The Department has been proactively looking at the Canadian supply chain to identify areas where supply may be vulnerable and addressing those vulnerabilities before shortages develop. These increased surveillance efforts include regularly engaging provinces and territories, industry, and health care and patient groups—in some cases on a daily basis. Health Canada is also working with international regulatory partners, including the European Medicines Agency, the United States Food and Drug Administration, and the Australian Therapeutic Goods Administration, as well as the World Health Organization to share information on any signs of global supply disruptions. This engagement has enabled us to better identify early shortage signals, to develop potential mitigation strategies and to coordinate responses.

A number of drugs, including fentanyl for injection, salbutamol, propofol and methotrimeprazine, have been designated as Tier 3 shortages. Tier 3 shortages are those that are currently in shortage or in high demand and have the greatest potential impact on Canada's drug supply and health care system. Tier 3 shortages are being actively managed by Health Canada, in collaboration with the provinces and territories, industry and health care professionals, to identify measures to mitigate the impact on patients. The Tier 3 list currently includes drugs that are being used to support COVID-19 patients, such as muscle relaxants, inhalers, sedatives, blood pressure stabilizers, antibiotics and pain medications. It is updated as needed. Tier 3 assignments are determined based on a recommendation from a Tier Assignment Committee, which includes federal and provincial/territorial governments, healthcare professionals and industry stakeholders.

The Government of Canada is currently reviewing the information submitted by companies in response to the Requests for Information. Health Canada will continue to work with other federal departments, provincial and territorial governments, international partners, and industry to mitigate the impact on Canadians of any shortages related to COVID-19. These efforts will help ensure that Canadians have access to the drugs they need during the COVID-19 pandemic now and as the situation continues to evolve.

Q293. Is there a shortage of fentanyl? Can you please share who is affected by the shortage and why more is required?

Health Canada has been actively monitoring the impact of the COVID-19 pandemic on the supply of drugs in Canada and is aware that an increased demand has resulted in supply constraints and reported shortages.

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The Department has been proactively looking at the Canadian supply chain to identify areas where supply may be vulnerable and addressing those vulnerabilities before shortages develop. These increased surveillance efforts include regularly engaging provinces and territories, industry, health care and patient groups—in some cases on a daily basis. Health Canada is also working with international regulatory partners, including the European Medicines Agency, the United States Food and Drug Administration, the Australian Therapeutic Goods Administration, and the World Health Organization to share information on any signs of global supply disruptions. This engagement has enabled us to better identify early shortage signals, potential mitigation strategies and to coordinate responses.

Fentanyl for injection has been designated as a Tier 3 shortage. Tier 3 shortages are those that are currently in shortage or in high demand that have the greatest potential impact on Canada's drug supply and health care system and are being actively managed by Health Canada, in collaboration with the provinces and territories, industry and health care professionals, to identify measures to mitigate the impact on patients. The Tier 3 list currently includes drugs that are being used to support COVID-19 patients, such as muscle relaxants, inhalers, sedatives, blood pressure stabilizers, antibiotics and pain medications (including Fentanyl for injection), and is updated as needed. Tier 3 assignments are determined based on a recommendation from a Tier Assignment Committee, which includes federal and provincial/territorial governments, healthcare professionals and industry stakeholders.

Health Canada will continue to work with other federal departments, provincial and territorial governments, international partners, and industry to mitigate the impact on Canadians of any shortages related to COVID-19. These efforts will help ensure that Canadians have access to the drugs they need during the COVID-19 pandemic now and as the situation continues to evolve.

Misinformation

Q294. What has Health Canada done regarding the advertising or sale of misleading or false COVID-19 products?

As of April 15, Health Canada has followed up on nearly 200 cases of health products making false or misleading claims related to COVID-19 identified through proactive monitoring or complaints received.

Health Canada has contacted all parties involved in non-compliant advertising and directed them to immediately stop making illegal, false or misleading claims and to remove the advertisement. If the party refused to comply, Health Canada would take stronger subsequent action, which could include stopping the sale of the product making the claims, conducting site visits, issuing public communications, recalling or seizing products and advertising materials. Health Canada has not approved any product to treat or cure COVID-19. Selling or advertising health products making false or misleading claims is illegal in Canada under the *Food and Drugs Act*.

On March 27, Health Canada issued a public advisory to warn Canadians about the risks associated with products making false and misleading claims related to COVID-19. Canadians are encouraged to report any information on potential false and misleading advertising or the sale of products that have not been approved by Health Canada to the Department using the online complaint form. To keep Canadians informed, Health Canada will continue to update its

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online table of products and corresponding companies or advertising media found to engage in non-compliant marketing.

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its associated regulations, it takes steps to confirm whether non-compliance has occurred and takes action based on the risk to the health of Canadians. The Department will continue to monitor and take action as needed to ensure that health products making false and misleading claims to diagnose, prevent, treat, or cure COVID-19 are removed from the market.

Q295. Is there a list of non-compliant parties that is available to the public?

In the context of its transparency commitment, Health Canada publishes a weekly updated list of products and parties found to engage in non-compliant advertising that have been addressed or are in the process of being addressed by the Department. Health Canada considers a number of factors in determining the appropriate action to address non-compliance, including the compliance history of a company. The Department will continue to use the most appropriate intervention to address non-compliance and potential risks to Canadians.

Q296. Has Health Canada been made aware of any misinformation or false claims about alcohol-based hand sanitizers?

In Canada, alcohol-based hand sanitizers are considered natural health products. Alcohol-based hand sanitizers that have been authorized for sale by Health Canada will have an eight-digit Natural Product Number (NPN) on the product label.

Health Canada has received complaints about health products that make false or misleading claims related to COVID-19. The Department is currently addressing these cases and has directed companies to remove these claims from their websites and advertising materials. Health Canada continues to monitor websites for these claims and is working with online retailers to ensure that products making these claims are removed. Selling or advertising health products making false or misleading claims is illegal. The Department takes this issue seriously and will not hesitate to use all mechanisms and tools at its disposal to stop these activities.

On March 18, 2020, in light of the unprecedented demand and urgent need for products that can help limit the spread of COVID-19, Health Canada issued an advisory announcing that the Department is facilitating access to products that may not fully meet current regulatory requirements, as an interim measure. This includes hand sanitizers, disinfectants and personal protective equipment (e.g., masks and gowns), as well as swabs. While these products are typically subject to regulatory requirements, such as licensing and bilingual labelling, the Department is allowing certain products to be sold in Canada that may not fully meet all requirements under this interim measure. Health Canada is maintaining an updated list of products sold in Canada through this measure on its website for consumers to consult.

In addition, Health Canada is expediting approvals of products, as well as establishment and site licences related to these types of products. A list of more than 550 authorized hand sanitizer products has been published on Health Canada's website. The list is updated daily and includes information on alcohol-based and non-alcohol based hand sanitizers approved by Health Canada. If consumers see a disinfectant or hand sanitizer for sale that is making false or misleading claims, they are encouraged to report it to Health Canada using its online complaint form.

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More information to help inform Canadians on buying and using drug and health products safely is available here.

Q297. Has Health Canada sent masks for testing to ensure that they are safe and not fraudulent products?

Due to the intense global competition for personal protective equipment (PPE) and other medical supplies, countries have needed to engage a diverse number of new suppliers and manufacturers. The Government of Canada is coordinating with provincial and territorial governments to quickly assess needs for PPE items such as N95 respirators, surgical masks, face shields, nitrile gloves, gowns and other protective clothing, as well as medical supplies such as sanitizer, ventilators, swabs and testing kits. The Public Health Agency of Canada (PHAC) has been conducting its due diligence and verifying the quality of procured supplies upon receipt. To date, PHAC has not identified any fraudulent products. However, it has assessed some items that do not meet the technical specifications for use in healthcare settings for COVID-19 response. These items are not distributed to provinces and territories for frontline healthcare response, and are subsequently assessed for use in non-healthcare settings.

The Canada Border Services Agency (CBSA) can refer shipments of health products to Health Canada, at its discretion. When a referral is received, Health Canada evaluates the product to determine whether it is in compliance with Canadian regulations. Shipments of health products that are deemed non-compliant are refused entry into Canada, or may be seized by Health Canada.

When Health Canada identifies potential fraudulent health products, it takes appropriate action—including working with the Competition Bureau, PHAC, and the CBSA to address the issue of false and misleading claims related to COVID-19. Health Canada remains committed to managing risks posed to the public and has processes in place to prevent these imported products from entering the Canadian marketplace.

On April 14, Health Canada issued a warning after receiving reports that fraudulent and uncertified N95 respirators, falsely claiming to protect consumers against COVID-19, were being illegally sold to consumers online and in some stores. Health Canada encourages Canadians to report health products with the potential non-compliant importation or false and misleading claims related to COVID-19. The Department takes this issue seriously and will not hesitate to use all tools at its disposal to stop these activities.

Q298. Is Immune-Tami going to be licensed for sale in Canada?

Health Canada has not authorised any product with the brand name 'Immune-Tami' or received any product licence application from Meon Supplements.

Health Canada opened a case after receiving a complaint regarding this product and will take action to address any confirmed non-compliance with the *Food and Drugs Act* and/or its Regulations.

Q299. Is the company Mona Lisa Healing licensed/authorized to produce CBD infused products in Canada?

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Mona Lisa Healing is not licensed to conduct activities with cannabis in Canada. The list of federal cannabis licensed holders can be found here.

On March 24, 2020, Health Canada issued a warning letter to Mona Lisa Healing to raise concerns about what appeared to be activities with cannabis without a valid licence and non-compliant promotion of cannabis.

In its response to Health Canada, Mona Lisa Healing confirmed that it has completely suspended all licensable activities with hemp CBD, including prohibited promotion, that it will not conduct any licensable activities with hemp CBD without a valid licence, and that it will not engage in any prohibited promotion to Canadians.

Health Canada can confirm that changes have been made to Mona Lisa Healing's online presence, including the addition of a pop-up window informing browsers that "MonaLisa Healing CBD is not a cure or preventative for COVID-19, Coronavirus."

Should any additional non-compliance with the *Cannabis Act* be identified, the Department will take action, if warranted.

Q300. Has Health Canada seen other examples of claims being made about CBD in relation to COVID-19?

Health Canada continuously monitors the promotion of cannabis. No additional COVID-19-related promotion of cannabis products has been noted at this time.

Every week, Health Canada publishes an updated list of health products and companies/e-commerce platforms found in non-compliance with the *Food and Drugs Act* (FDA). If Health Canada becomes aware of false or misleading advertising for products subject to the FDA, the Department will take all required compliance and enforcement actions to achieve compliance, which may include seizing the product being advertised.

Cannabis products and their promotion are subject to the provisions of the *Cannabis Act* and its regulations. Compliance and enforcement actions, including the issuance of warning letters under the *Cannabis Act*, are reported in Health Canada's quarterly reporting on inspection data. Health Canada is updating this information and expects to complete the update in the coming weeks.

Health Canada is committed to protecting the health and safety of Canadians, and encourages Canadians to report any information or evidence of actions contrary to the *Cannabis Act* by using these contact details.

Reagents

Q301. What is the scope of Canada's need for reagent chemicals used for testing COVID-19?

Canada's COVID-19 response depends on laboratory testing to detect infection early and take effective public health measures to reduce spread. Canada's public health laboratories work together through a network called the Canadian Public Health Laboratories Network to support COVID-19 diagnosis according to validated testing protocols. The global shortage of testing reagents is affecting laboratory capacity. The Public Health Agency of Canada's National

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Microbiology Laboratory is supporting provincial requirements for testing reagents by developing in-house reagents as an interim solution and by working with the industry sector to procure supplies in bulk as they become available. Our priorities are accessing testing reagents, evaluating rapid point-of-care tests and accessing authorized test kits so that provinces and territories are equipped to ramp up testing according to their requirements.

Q302. Is the bioMérieux reagent product the only one you have been manufacturing? Are you, or will you, replicate others?

Since the beginning of the COVID-19 outbreak, Health Canada has been working with the Public Health Agency of Canada, other federal departments and provinces and territories, to ensure a coordinated response to anticipate and meet Canadians' health product needs. This includes working diligently with manufacturers in Canada to bring products to market and increase domestic production of therapies and diagnostic devices.

The Public Health Agency of Canada (PHAC) continues to explore all options to help provinces meet the demands for testing. This includes reagents for which recipes have been published that may work on current testing devices, laboratory plastics or new designs for nasopharyngeal (i.e., nasal) swabs.

Q303. Did Biomerieux share its proprietary formula with the Public Health Agency of Canada?

In an innovative public-private partnership, bioMérieux Canada has provided the Government of Canada the right to manufacture their products used for COVID-19 testing in Canada.

The agreement with bioMérieux Canada provides a temporary licence. Further, the facilities that the Government of Canada will use to meet an expected temporary surge in demand were never intended for use in long-term manufacturing. In the long run, they will revert to their normal purposes.

Q304. Is Canada paying for the temporary license from Biomerieux?

The Public Health Agency of Canada has signed a temporary licence agreement with bioMérieux Canada at no cost, to receive the rights and formulation for their reagents that are used in COVID-19 diagnostics. The production systems for the products used to produce these reagents are in various stages of development and testing, with the goal of alleviating some of the shortages of reagents in the near future. If successful, this will improve access to COVID-19 testing kits.

Masks

Q305. Has Health Canada approved KN95 masks for use in Canada. If not why not?

Yes, we have approved KN95 full face respirators in the context of the pandemic on the basis of equivalent standards to N95 respirators.

Q306. Is the KN95 respirator NIOSH certified? Does it meet an equivalent alternate standard?

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No, KN95 respirators are not NIOSH certified. They meet GB2626-2006, which is an equivalent standard to NIOSH-42CFR84. Equivalencies for masks and other equipment can be found at https://buyandsell.gc.ca/specifications-for-COVID-19-products#100

Q307. Can anyone sell a mask that is advertised for non-medical use? Does it matter if there is no English on the mask?

If not used in a clinical setting, and if it is explicitly clear in the product labelling that they serve a non-medical purpose (e.g., "not for medical use", "industrial use only"), masks and respirators are not considered to be and are therefore not regulated by Health Canada.

Q308. What is the status of Health Canada's review of the "WOODBRIDGE INOAC MASK" and whether it can be used at hospitals?

Health Canada has authorized the "WOODBRIDGE INOAC MASK" on April 4. 2020. The device is intended to mitigate the wearer's exposure to hazardous particles. This device is not an N95 respirator; it is a surgical mask Level 3 which can be used in hospitals settings in accordance with the manufacturer's labelling.

N95 Masks – Decontaminating and Reuse

Q309. What are the potential decontamination methods under evaluation?

Several proposed systems of decontamination are being assessed in Canada and around the world. The decontamination systems already authorized (e.g., Stryker Sterizone VP4 Sterilizer, Sterrad sterilization systems, Steris sterilization systems, Clean Works Clean Flow Healthcare Mini, and Bioquell Hydrogen Peroxide Vapour Generator) use various methods including, vaporized hydrogen peroxide, ozone or ultraviolet light. There is ongoing evaluation of new decontamination methods as applications are submitted under the Interim Order for medical devices.

Health Canada assesses proposed methods to ensure they meet the standards required for safety, quality and effectiveness and that the requirements for the key performance and safety endpoints to ensure the integrity of N95 are maintained following reprocessing to the validated limit of reprocessing cycles.

Q310. Is there good evidence to support these methods?

Although the virus that causes COVID-19 is a novel virus, evidence from previous studies using similar viruses supports the safety and effectiveness of some reprocessing methods.

Manufacturers will be required to provide evidence to demonstrate the safety and effectiveness of their selected method of decontamination.

At a minimum this includes:

- disinfection of all harmful organisms (e.g., bacteria and viruses) likely to be present in the standard medical setting;
- demonstration that respirator filter and fit performance are maintained;

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- evidence that there are no residual chemical hazards related to reprocessing; and
- ensuring adequate labelling that describes validated methods and reprocessing conditions applied to the respirator.

Q311. What are the drawbacks to reprocessing versus new masks?

Health Canada recognizes that reprocessing single-use masks is one potential solution to provide continued access to masks for healthcare workers who rely on them for protection.

Instructions from each manufacturer of an authorized decontamination device should be followed.

Fit is an extremely important aspect of N95 use. The drawback for reprocessed N95 mask versus new mask is that the nosepiece has been bent and may not allow a good fit. This is why PHAC recommends that respirator be returned to the original wearer, to increase the likelihood of fit. Should the reprocessed mask be put back into general circulation, it becomes very important to undertake the standard user seal check and to only use those masks that fit the user's face.

Q312. Has vaporized hydrogen peroxide ever been used to sterilize N95 masks in Canadian hospitals? If so, when did that start? If not, when will that be possible?

Hospitals have been permitted to use a vaporized hydrogen peroxide system to decontaminate N95 respirators since April 5, 2020.

Q313. How can a health care worker be sure that an N95 mask that has been sterilized four times is as safe as a new mask? Is it 100% guaranteed?

Decontamination with vaporized hydrogen peroxide is one method of removing pathogens from an N95 respirator if it has to be reused to limit equipment usage. Decontamination is an acceptable way of making masks safe for reuse. The number of times an N95 respirator can be decontaminated, which depends on the labelling and the manufacturer's decontamination process, ranges from one to twenty.

Q314. Have other regulators approved decontamination methods? Are we also considering these?

Health Canada is aware that a number of devices have received Emergency Use Authorization (EUAs) from the US Food and Drug Administration to reprocess N95 masks (link). Health Canada continues to evaluate guidance from other agencies such as the US Centers for Disease Control and Prevention (CDC) for optimizing the re-use of respirators.

Chloroquine/Hydroxychloroquine

Q315. What is this drug usually used for? What are the approved indications?

Hydroxychloroquine is an antiparasitic drug that is indicated for the treatment of malaria, as well as autoimmune diseases such as rheumatoid arthritis and lupus.

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Q316. Are there clinical trials underway to determine whether this drug is effective in children?

Yes, Health Canada has authorized one clinical trial on the use of hydroxychloroquine to treat COVID-19 in Canada in children, and is aware of other ongoing clinical trials across the world. Health Canada is closely monitoring their developments.

Any company or healthcare practitioner treating patients with COVID-19 who wishes to conduct a clinical trial to evaluate the effectiveness of these or other drugs is encouraged to contact Health Canada.

A list of clinical trials approved for the prevention or treatment of COVID-19 or its complications can be found at: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-clinical-trials/list-authorized-trials.html

Q317. Can hydroxychloroquine be used to treat any patient who is infected with COVID-19? Will it be effective for everyone?

There is some evidence to suggest that hydroxychloroquine may be effective for some patients; however, these are preliminary findings from a few, very small studies. There is also very limited information about the safety and effectiveness of hydroxychloroquine in children.

Q318. Hasn't hydroxychloroquine been shown to not work against COVID-19?

Preliminary results of clinical trials involving hydroxychloroquine have been mixed. Each trial is designed to study the medication in specifically identified groups of patients and for a specific purpose. The effect of hydroxychloroquine may differ depending on the intended usage (prevention or treatment of mild disease, or treatment of serious disease in hospitalised subjects). There is little information on how effective hydroxychloroquine may be for children who are quite ill with COVID-19. The CATCO-Kids trial proposes to treat children hospitalized with COVID-19 using hydroxychloroquine. Information from clinical trials remain the best approach to determine whether hydroxychloroquine may have a benefit in preventing and/or treating COVID-19, and whether this benefit is greater than the risks associated with its use.

Q319. Has Health Canada been made aware of the influx of Chloroquine which has been coming through our borders? How equipped are we to police this, considering the danger it poses to the health of Canadians?

Health Canada works closely with the Canada Border Services Agency (CBSA) to verify that imported health products meet the regulatory requirements of the *Food and Drugs Act* and associated Regulations.

The CBSA can refer shipments of health products to Health Canada, at its discretion. When a referral is received, Health Canada evaluates the product to determine whether it is in compliance with Canadian regulations. Shipments of health products that are deemed non-compliant are refused entry into Canada, or may be seized by Health Canada.

Chloroquine is a prescription drug in Canada for the treatment of malaria and extraintestinal amebiasis. Under the *Food and Drug Regulations*, prescription drugs can be imported only by a

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practitioner, a drug manufacturer, a wholesale druggist, a pharmacist, or a resident of a foreign country while visiting Canada. In specific circumstances, so as not to interrupt a course of treatment, Canadians returning from abroad may be permitted to bring with them on their person, a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a prescription drug. Any other importation of prescription drugs is illegal in Canada. Over the past few weeks, there has been an increase in the number of referrals of commercial shipments of chloroquine from the CBSA to Health Canada. Shipments that were determined to be compliant with legislative or regulatory requirements were released. Those that were assessed to be non-compliant with the legislative or regulatory requirements were refused entry into Canada.

When Health Canada identifies non-compliant products, it always takes appropriate action—including working with the CBSA—to prevent importation of these products. During these unprecedented times, Health Canada remains committed to managing risks posed to the public and has processes in place to ensure continuous delivery of critical services to Canadians. Health Canada encourages anyone who has information regarding the potential non-compliant importation, sale or advertising of any health product to report it using the online complaint form.

Q320. Has Health Canada investigated or charged any individuals selling chloroquine or hydroxychloroquine as a treatment for COVID-19? Has Health Canada seized any unauthorized hydroxychloroquine or chloroquine?

Health Canada has not approved any product to treat or cure COVID-19. Selling or advertising unauthorized health products or health products making false or misleading claims is illegal in Canada under the *Food and Drugs Act* (FDA). It is also illegal to directly or indirectly advertise experimental therapies or the off-label use of authorized drugs.

Health Canada has been undertaking proactive monitoring of online sites to detect health products making false or misleading claims related to COVID-19. A list of products and companies/media found in non-compliance is being updated on a regular basis. To date, the Department is not aware of any cases of illegal, false, or misleading advertising of chloroquine or hydroxychloroquine through its proactive monitoring of online sites.

Health Canada works closely with the Canada Border Services Agency (CBSA) to verify that imported health products meet the regulatory requirements of the FDA and associated regulations. The CBSA can refer shipments of health products to Health Canada, at its discretion. When a referral is received, Health Canada evaluates the product to determine whether it is in compliance with Canadian regulations. Shipments of health products that are deemed non-compliant are refused entry into Canada, or may be seized by Health Canada.

On referral from the CBSA, Health Canada has seized a shipment of chloroquine that was not compliant with the applicable laws.

Canadians should not take any prescription drug that has not been prescribed to them by a healthcare professional, who can assess and advise the patient about potential side effects—including serious side effects—and drug interactions. Health Canada recently warned Canadians of the serious side effects associated with chloroquine and hydroxychloroquine, including heart rhythm problems, liver or kidney problems, low blood sugar (hypoglycemia) and nervous system problems.

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Health Canada also reminds Canadians that buying health products online may be putting their health at serious risk and about the risks of purchasing health products that make unauthorized claims to prevent, treat or cure COVID-19.

The Department takes this issue seriously and will not hesitate to use all tools at its disposal to stop these activities. When Health Canada identifies or is notified of potential non-compliance with the FDA or its associated regulations, it takes steps to confirm whether non-compliance has occurred and takes action based on the risk to the health of Canadians. A number of compliance and enforcement options are available to manage the risk posed to public health and safety by false or misleading claims related to COVID-19 including on site inspections, regulatory letters, recalls, public communications or product seizures. In certain circumstances, when the regulatory enforcement responses are not appropriate to achieve compliance Health Canada may also refer its findings to the Public Prosecution Service of Canada for potential prosecution.

The Department will continue to monitor and take action as needed to ensure that health products making false and misleading claims to diagnose, prevent, treat, or cure COVID-19 are removed from the market. Any information regarding potential non-compliant sale or advertising of chloroquine or hydroxychloroquine or any health product as a treatment for COVID-19, should be reported to Health Canada using the online complaint form.

Q321. Considering the known health effects of chloroquine, if taken improperly or mixed with another drug it's not supposed to be taken with, what's Health Canada's advice to Canadians who are getting it shipped here with the intent of taking it as a precautionary, easier way to prevent COVID-19?

It is illegal to directly or indirectly advertise experimental therapies or the off-label use of authorized drugs. If Health Canada becomes aware of a situation in which there is illegal advertising of an experimental therapy, the Department will contact the party involved to seek immediate cessation of the advertising and take all required compliance and enforcement actions to achieve compliance, which may include seizing the product being advertised.

Canadians should not take any prescription drug that has not been prescribed to them by a healthcare professional, who can assess and advise the patient about potential side effects—including serious side effects—and drug interactions. There are several serious side effects associated with chloroquine, including heart rhythm problems, severely low blood pressure and muscle and nerve damage.
Health Canada also reminds Canadian that buying health products on line may be putting their health at serious risk and about the risks of purchasing health products that make unauthorized claims to prevent, treat or cure COVID-19.

Q322. How many cases have there been of Canadians becoming ill because they took chloroquine?

Health Canada received 1,305 adverse reaction reports concerning hydroxychloroquine as the suspected active ingredient between January 1, 2020, and April 24, 2020. Of the 1,305 reports received, only one had the active ingredient—hydroxychloroquine—indicated for COVID-19.
The number of adverse reaction reports received can be attributed to:

- Reports by manufacturers that have patient support programs (PSP)

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- PSPs deal directly with patients, caregivers and health care professionals in order to support patient care with a specific health product. Hydroxychloroquine is one of a number of suspected products in these adverse reaction reports.

- The large number of duplicate reports submitted to Health Canada in January and February 2020

  - This situation can occur when someone submits an adverse reaction report to a certain number of manufacturers when several products are suspected of being responsible for an adverse effect or when a manufacturer learns about a report for its product as a suspected product, among others, through another manufacturer or the Canada Vigilance Online Adverse Reaction Database.

Warnings

- It is often impossible to determine whether an adverse effect reported to Health Canada resulted from the use of a specific health product. A person's health problems or problems caused by other health products being used at the same time are other factors that could have contributed to the reaction in question.

- Adverse reaction reports are presumed associations reflecting the reporter's opinion or observation. The information does not reflect any evaluation by Health Canada of the link between the health product and the reactions.

- Please consult the following link for further warnings concerning the Interpretation of Suspected Adverse Reaction Data gathered by the Canada Vigilance Program

Interim Order Respecting Drugs, Medical Devices And Foods For A Special Dietary Purpose In Relation To COVID-19

Q323. How will Health Canada assess these health products for safety and effectiveness?

The Interim Order allows for the importation and sale of drugs, medical devices, and special foods that support Canada's response to COVID-19.

As with all drugs and medical devices, Health Canada will assess and monitor the safety, quality, and efficacy of all products allowed for import and sale under this Interim Order.

Drug and medical device manufacturers will be required to follow strict post-market safety requirements.

Q324. Is Canada guaranteed to receive adequate supply of these items?

Supply issues related to drugs, medical devices, or foods for special dietary purposes could occur at any time. That's why Health Canada is monitoring supplies of prescription drugs, medical devices, and health products such as hand sanitizers, and enabling the continued supply of these products to Canadians.

Q325. How does this Interim Order compare to the interim measure the Department announced last week to allow for the importation of hand

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sanitizers, disinfectants, personal protective equipment and swabs that do not fully meet Health Canada requirements?

This Interim Order applies to a greater variety of products, including prescription drugs and certain special foods, and creates shortage reporting requirements for medical devices.

Q326. And how does it compare to the shortage provisions in the Legislative Amendments?

Both the Interim Order and the amendments have provisions to allow products that are not approved for sale to be sold in Canada with certain restrictions.

The legislative amendments provide more flexibility on what may be imported, and provide additional powers such as allowing another company to make, use or sell a drug or medical device that is protected by patent in order to meet demand, when needed supplies cannot be obtained from the patent holder, subject to certain conditions as described in the interim order.

Q327. What are the new requirements for medical device shortage reporting?

Manufacturers and importers will be required to notify the Minister of shortages of devices considered critical during the COVID-19 pandemic. Manufacturers and importers will have to notify Health Canada within five days of becoming aware of a real or anticipated shortage. This is similar to what is already required of drug companies.

A manufacturer may allow an importer to report information on its behalf, to avoid duplication.

Having an accurate understanding of real and anticipated medical device and drug shortages will help the Minister decide which products to consider allowing for import and sale.

Q328. How does this affect personal importation?

This Interim Order will not alter Health Canada's existing position, policies, and laws with respect to personal importation.

Q329. What qualifies as a "food for a special dietary purpose" under the Interim Order, other than infant formula?

Foods for a special dietary purpose could include foods that are specially formulated to meet the needs of consumers with health conditions, such as low-protein foods for those suffering with kidney disease. These could also be foods that are the primary or sole source of nutrition for a person, such as infant formulas and specially formulated liquid diets for those unable to get proper nutrition through solid food.

Q330. How will access to disinfectants and hand sanitizers be expedited?

The Interim Order changes an application requirement for biocide drugs (hard surface disinfectants and certain hand sanitizers) to allow for their expedited review and authorization. In addition, the Interim Order exempts certain hand sanitizers, regulated under the *Food and Drug Regulations* (FDR), from establishment licensing.

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Q331. What is the Government currently doing to address any drug and medical device shortages related to COVID-19?

Health Canada is actively monitoring the potential impact of the COVID-19 pandemic on the supply of drugs and medical devices in Canada.

Health Canada continues to actively engage the pharmaceutical drug and medical device industry and provinces and territories to monitor for any signals of supply disruptions in Canada. Health Canada is also working in collaboration with international regulatory partners, including the European Medicines Agency, the United States Food and Drug Administration, the Australian Therapeutic Goods Administration, and the World Health Organization (WHO) to share information on any global supply disruptions.

Drug companies are required by regulation in Canada to publicly report actual and anticipated drug shortages and discontinuations within a specified timeframe on drugshortagescanada.ca. Drug and medical device shortage signals may also be reported to Health Canada by the provinces and territories, health care professionals or the public.

Health Canada has contacted all Drug Establishment Licence holders in Canada to remind them of the requirement to report anticipated and actual drug shortages, and to notify the Department of any event that may affect the quality, safety or efficacy of a drug. Medical Device Establishment Licence holders have also been requested to report any shortages to Health Canada.

Health Canada is also closely monitoring the supply of any potential treatments for COVID-19 and working with companies to help ensure continued supply in Canada, including working with companies that can ramp up supply for the Canadian market.

The Department will continue to closely monitor this situation and take any necessary action in collaboration with companies, provinces and territories and other stakeholders to help ensure continued supply of medications in Canada.

Q332. How will these amendments enhance the Government's ability to manage drug shortages?

These amendments will allow the Government of Canada to put in place more robust tools to support efforts to help prevent and alleviate shortages. For example, it enhances the Government's ability to put in place, through the Interim Order, a regulatory framework that allows for the importation of drugs and medical devices necessary to prevent or alleviate a shortage related to COVID-19.

Q333. Will Health Canada use these amendments to the *Patent Act* to bypass patent protection (sometimes called compulsory licensing) and allow other companies to produce patented drugs?

The Government of Canada respects patent rights and their importance to business, and knows that industry will do everything it can to meet the needs of Canadians.

To address a pandemic such as COVID-19, the Commissioner of Patents can authorize the Minister of Health to allow another company to make, use or sell a drug or medical device that is

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protected by patent in order to meet demand, when needed supplies cannot be obtained from the patent holder.

The amendments to the *Patent Act* that were introduced the week of March 22, 2020, would only be used in exceptional circumstances, and include several safeguards to protect the interests of patent holders, including ensuring that a patent holder receives adequate remuneration for the use of the patent and placing limitations on the duration of the authorization.

The Minister of Health's power to seek authorization for third-party manufacturers to supply needed patented inventions is in place until September 30, 2020.

To date, the Minister of Health has not had to exercise the powers under Bill C-13 related to the *Patent Act* amendments.

Expediting Access To Hand Sanitizers, Hard Surface Disinfectants, Personal Protective Equipment And Swabs

Q334. Were these changes made through new regulations?

These are interim measures implemented given the unprecedented demand and the urgent need for products that can help limit the spread of COVID-19, including hand sanitizers, disinfectants and personal protective equipment (e.g., masks and gowns). This is not a new regulation.

Q335. What does this new rule mean?

It is an interim measure and expedited approach. It is meant to facilitate access to imported hand sanitizers and disinfectants that do not fully meet the regulatory requirements under the Food and Drugs Act. Health Canada will allow certain products to be sold in Canada under this interim measure, including:

- products that are already authorized for sale in Canada but are not fully compliant with Health Canada requirements (e.g., labelling in one official language, different packaging from what was authorized); and
- products that are not authorized for sale in Canada, but are authorized or registered in other jurisdictions with similar regulatory frameworks and quality assurances.

Health Canada will allow these low-risk products to be distributed in Canada to address the current shortage in supplies. The expedited process requires an attestation form that helps Health Canada maintain a record of all hand sanitizers and disinfectants on the Canadian market. As with all health products, Health Canada will continue to monitor the safety of these products once they are on the market and will take action to protect the health and safety of Canadians, if necessary.

Q336. Is Health Canada actively reaching out to manufacturers to get more products imported?

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Information about this expedited process was shared with all drugs, natural health products and medical device establishment licence holders and product licence holders in Canada and with relevant industry associations.

Products permitted to be sold under this interim measure are being added to the list posted on Health Canada's website. At the time the advisory was posted on March 18, only hand sanitizers and disinfectants had met the criteria for sale under this interim approach. Since then, medical devices have been identified and will be added to the list in the coming days.

Q337. How are medical devices regulated in Canada? What are Class I devices?

Canada takes a risk-based approach to the regulation of medical devices, where the level of review before approval depends on the potential risk that the use of the device presents. This approach balances the need to provide the healthcare system with timely access to new and innovative technology, with the appropriate level of oversight and time required to assess safety and effectiveness.

In Canada, medical devices are categorized into four classes based on the risk associated with their use, with Class I devices presenting the lowest potential risk (e.g., a mask or gown) and Class IV devices presenting the greatest potential risk (e.g., a pacemaker). Class II, III and IV medical devices must have a Medical Device Licence to be sold in Canada. Companies selling Class I medical devices in Canada are required to have a Medical Device Establishment Licence. However, during this pandemic situation, Class I to IV devices can instead receive authorization under the Interim order respecting the importation and sale of medical devices for use in relation to COVID-19.

Health Canada is currently expediting its review of licensing applications related to any medical device related to COVID-19. In addition, as with hand sanitizers and disinfectants, Class I medical devices that may not fully meet all regulatory requirements and are notified to Health Canada under this interim measure are being allowed on the market.

Q338. How can consumers distinguish between a fraudulent product and a product imported through this interim measure?

Health Canada will maintain an updated list of products sold in Canada through this measure on its website for consumers to consult.

Hand sanitizers and hard surface disinfectants authorized for sale by Health Canada have an eight-digit Drug Identification Number (DIN) or Natural Product Number (NPN) on the product label. These products are listed on Health Canada's Drug Product Database or Licensed Natural Health Products Database.

Class I medical devices are not licensed by Health Canada, but companies importing or manufacturing them do require a Medical Device Establishment Licence from Health Canada. These are listed on Health Canada's website.

If consumers see a hand sanitizer or disinfectant for sale that does not have a DIN or NPN on the product label and is not on the list identified in the advisory, or if they become aware of a company importing or manufacturing a class I device without the required licence, they are encouraged to report it to Health Canada.

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COVID-19-specific medical devices authorized for sale by Health Canada are listed on Health Canada's website.

Q339. What else is Health Canada doing to improve the supply of health products during the COVID-19 pandemic?

The Minister of Health signed an Interim Order on March 18, 2020, to speed up access to medical devices for COVID-19. The list of COVID-19 medical devices authorized under the Interim Order is available on Health Canada's website.

Q340. Can people obtain access to medical devices and drugs that have not been authorized in Canada, but are available in other countries?

Healthcare professionals can request access to COVID-19-related medical devices not yet licensed in Canada and drugs related to the management of patients with COVID-19 through Health Canada's Special Access Program (SAP). Applications are considered on a case-by-case basis.

For questions related to the SAP for medical devices, please contact the program via email.

Interim Order Respecting COVID-19-Related Medical Devices

Q341. When will Health Canada be able to approve the first test kits for COVID-19 as medical devices?

Health Canada has been actively working with manufacturers to enable market access for commercial diagnostic devices in order to increase Canada's COVID-19 diagnostic capacity.

On March 13, 2020, Health Canada received two applications for a diagnostic device: one from Roche Diagnostics and one from ThermoFisher Scientific. These applications have received expedited review and are now approved for access by healthcare professionals through our Special Access Program (SAP).

Health Canada will immediately communicate the availability of these diagnostic devices to the concerned laboratories, the Public Health Agency of Canada and the provincial and territorial ministries of health.

Health Canada is also working with a number of other companies that are in the process of preparing and submitting information for review and will expedite those applications as well.

Q342. How quickly are reviews of submissions sent to Health Canada regarding COVID-19 tests being done?

Health Canada is working to increase the access to diagnostic tests in Canada through an expedited review pathway. The list of authorized COVID-19 devices (with authorization dates) is available here and all licensed medical devices are listed in the Medical Device Active Licence Listing.

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On March 18, the Minister of Health signed an Interim Order to allow expedited access to COVID-19-related medical devices for use by healthcare providers, including diagnostic test kits. This is an important development in the fight against COVID-19. It will help ensure quicker and more flexible approval of the importation and sale of medical devices that are necessary for Canada's response to COVID-19, including test kits.

Q343. How will these new test kits help test more patients?

This Interim Order makes it easier and faster for certain medical devices, such as laboratory diagnostic test kits, to be imported and sold in Canada. This would help improve access to medical devices that could permit faster and more convenient testing of patients, which would avoid needing to send samples to the NML lab in Winnipeg, facilitating quicker test results.

Point-of-care diagnostic tests are in development and may become available through this Interim Order, which would permit quicker and more convenient testing of patients. Quicker test results would enable healthcare providers and patients to take appropriate actions more quickly in order to help reduce the spread of the disease.

Q344. How often are Interim Orders used?

Interim Orders have been needed a few times in recent years to permit access to health products quickly in exceptional circumstances to deal with a significant risk to health or safety.

The last use of an Interim Order was in August 2018 to facilitate the immediate importation and sale of AUVI-Q epinephrine auto-injectors as an emergency measure during a national critical shortage of EpiPens.

An Interim Order was also issued to allow immediate temporary access to naloxone nasal spray in July 2016 until a review for Canadian authorization was completed.

Q345. How will Health Canada ensure that these kits are safe and effective?

The Interim Order creates a tailored approval pathway for the importation and sale of medical devices that support Canada's response to COVID-19. This Interim Order, and the tailored approval pathway it creates, provides the Minister with flexibility to consider the urgent circumstances relating to the need for the medical device, authorizations granted by foreign regulatory authorities, or possible new indications of use for medical devices that are already approved in Canada.

As with all drugs and medical devices, Health Canada will assess and monitor the safety and effectiveness of all products authorized under this Interim Order, and will take immediate action if required to protect the health and safety of Canadians.

Manufacturers will still be required to follow strict post-market safety requirements such as mandatory problem reporting, recall procedures and complaint handling.

Q346. Is Canada guaranteed to receive adequate supply of diagnostic test kits?

We anticipate that there will be adequate supply of diagnostic tests. It would be at the company's discretion to allocate kits if demand exceeds supply.

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Q347. Why is the use of the Altona RealStar SARS-CoV-2 PCR kit in compliance with medical device regulations, if its actual use is related to actual diagnostic testing of COVID-19?

The *Medical Devices Regulations* apply only to the importation and sale of medical devices. The use of medical devices—including in laboratories—is regulated at the provincial level.

Q348. Why are tests labelled 'for research use only' exempt from medical devices regulations?

Tests labelled "for research use only", such as the Altona device, do not meet the definition of a medical device and are exempt from the Regulations. For more information, please consult Health Canada's Guidance for the Risk-based Classification System for In Vitro Diagnostic Devices (IVDDs).

National Emergency Strategic Stockpile (NESS)

Q349. Who is in charge of NESS? Where are NESS storage facilities located?

The Public Health Agency of Canada (PHAC) maintains the National Emergency Strategic Stockpile (NESS). NESS facilities consist of a central depot in the National Capital Region and warehouses strategically located across Canada. For security reasons, we don't disclose specific locations.

Q350. Is stockpiling of PPE's for the NESS part of PHAC's mandate?

Public health is a shared responsibility in Canada amongst local, provincial and federal levels of government. During a public health emergency, most needs will be addressed at local levels. The role of the federal National Emergency Strategic Stockpile (NESS) is premised on those two concepts.

The NESS provides surge capacity during an emergency when local and provincial or territorial resources have been exhausted, and is the sole provider of niche assets required for rare public health events. As a result, the NESS stocks a moderate supply of personal protective equipment. However, in response to COVID-19, the Public Health Agency of Canada (PHAC) has worked hard to secure additional supply, including by leveraging bulk procurement mechanisms and by working with domestic suppliers to bolster production. This includes playing a key coordination role as part of the Government of Canada's pandemic response efforts by organizing the distribution of incoming shipments to the provinces and territories for their immediate health care use. This work is being done in collaboration with a range of federal departments, including Public Services and Procurement Canada, Health Canada, Innovation, Science and Economic Development Canada and Indigenous Services Canada, as well as provinces and territories.

Q351. How large is the stockpile and how will the supplies be allocated and distributed?

The Public Health Agency of Canada (PHAC) does not disclose specifics related to National Emergency Strategic Stockpile (NESS) holdings.

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The NESS contains supplies of personal protective equipment and ventilators. In the current environment, the inventory numbers are consistently fluctuating as stock is released, at the request of provinces and territories, to provide surge support.

Bulk orders of PPE and medical supplies have been delivered, and the Government of Canada is rapidly allocating supplies to the provinces and territories as per the allocation formula agreed upon by federal, provincial and territorial Ministers of Health. In addition to responding to requests for assistance to National Emergency Strategic Stockpile (NESS), the Government of Canada supported the distribution of 6.8 million surgical masks from Medicom, which were shipped directly to provinces and territories. Ontario received its allocation on April 3. As well, 1.7 million nitrile gloves are in transit to provinces and territories.

In alignment with Health Canada's guidance on Optimizing the use of masks and respirators during the COVID-19 outbreak<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/masks-respirators-covid19.html>, the NESS has also shipped almost 300,000 expired N95 masks to provinces and territories.

Q352. Which provinces and territories have drawn on supplies from the NESS? What have they taken?

To address immediate short-term needs, PHAC deploys supplies from the NESS based on requests for assistance. As of April 6, 23 requests for assistance from provinces and territories have been received by the National Emergency Strategic Stockpile and completed. Items released from the NESS have included N95 masks, surgical masks, face shields, gloves, gowns and ventilators. To maintain NESS inventory, a portion of the federal, provincial and territorial collaborative procurement is retained at the NESS to provide surge support to meet the urgent needs of provinces and territories.

Q353. Alberta's modelling data indicated that Alberta expects 6 ventilators from the Public Health Agency of Canada. Are those coming from the NESS or some other source?

The Public Health Agency of Canada (PHAC) continues to deploy personal protective equipment and ventilators from the National Emergency Strategic Stockpile to provinces and territories in response to requests for assistance. In the context of this process, PHAC can confirm that Alberta was sent six ventilators.

Q354. How many surgical and N95 masks does Canada have now, and how many would be needed when the epidemic reaches its peak?

The National Emergency Strategic Stockpile (NESS) contains supplies of personal protective equipment (PPE), including N95 respirators, to provide surge capacity to provinces and territories.

Based on needs identified by provinces and territories, collaborative federal, provincial and territorial (FPT) procurement efforts are focused on procurement of large quantities of PPE, such as N95 respirators. PPE procurement orders are starting to arrive, and jurisdictions are discussing approaches for allocation to effectively support a health system response to COVID-19.

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Up to May 8, of the approximately 11.5 million N95 respirators and equivalents (e.g., KN95 respirators) received so far, approximately 1.5 million met the technical specifications for healthcare settings for COVID-19 response; approximately 8.5 million did not; and 1.5 million are currently undergoing testing.

N95 respirators and equivalents (e.g., KN95 respirators) that do not meet their technical specifications for healthcare settings for the COVID-19 response are not distributed to provinces and territories and are subsequently assessed for use in non-medical settings.

The safety of healthcare workers is a top priority. The Government of Canada continues to work with provincial and territorial partners to respond to the COVID-19 outbreak, including helping to ensure that healthcare workers have the PPE they need to be safe and to protect the health of patients.

Q355. How many other NESS warehouses and stockpiles were disposed of or shut down across Canada in recent years? How many remain?

In recent years, the NESS moved from nine warehouse locations across Canada to six. The independent assessment indicated that the six strategic locations would maintain the NESS' role as timely surge support.

Q356. Was the number of PPE supplies reduced because of the drop in NESS warehouses or was the same level of PPE supplies just consolidated in the smaller number of locations?

The amount of personal protective equipment supplies stored by the National Emergency Strategic Stockpile is not directly correlated to the number of warehouse locations across the country. When a warehouse was closed down, anything that was usable was moved to a new location, and anything that was damaged, expired, unusable or obsolete was disposed of in accordance with the Treasury Board Directive on Disposal of Surplus Materiel.

Q357. Why did the Regina NESS facility close and were the masks and gloves replaced?

The Regina warehouse was closed following an independent assessment of the federal warehouse network of the National Emergency Strategic Stockpile (NESS), which found that moving from nine warehouse locations across Canada to six would offer the most efficient distribution system without sacrificing response capacity. For example, since the creation of the NESS, Canada's transportation infrastructure has improved, making it easier to maintain the same 24-hour delivery target with fewer warehouses.

In addition to masks and gloves, other expired or outdated stock, such as dressings, sponges, IV giving sets and pads, was assessed as no longer appropriate for distribution or donation. Many of these products were over 20 years old and were disposed of in accordance with the Treasury Board Directive on Disposal of Surplus Materiel. We also considered the value of the stock compared with the costs of shipping it elsewhere.

Q358. How many masks and gloves were thrown away and why?

The National Emergency Strategic Stockpile (NESS) reviews its stock of equipment regularly and as part of the review, expired material is disposed of in accordance with the Treasury Board

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Directive on Disposal of Surplus Materiel. In 2019, approximately 2 million expired masks and 440,000 expired gloves were disposed of during the closure of the National Emergency Strategic Stockpile (NESS) warehouse in Regina. The masks and gloves had been purchased in 2009 and had passed the limit of five years for their use, as recommended by the manufacturer.

While the World Health Organization allows for the donation of personal protective equipment, it requires that any equipment be supported by the manufacturer for a minimum of two years. What this means is that equipment must be donated two years before its expiration.

The Public Health Agency of Canada (PHAC) follows strict guidelines when deploying materials. If the Agency cannot account for the quality of material, it will not deploy it. Even under the current circumstances of the COVID-19 pandemic, where Health Canada guidance allows for the deployment of expired personal protective equipment, the Agency would examine very closely any equipment that is five years old or more. This is in accordance with manufacturers' guidelines.

Q359. Why doesn't Ottawa have a plan to provide the NESS medical supplies to other users before they expire (i.e., provincial health care systems)?

The NESS mandate is to provide surge support to provinces and territories, as well as to federal populations such as Correctional Service Canada. The NESS contains supplies that provinces and territories can request in emergencies when their own resources are insufficient, such as during infectious disease outbreaks, natural disasters and other public health events.

Most supplies have a specified shelf life, after which they should be discarded. As part of normal life cycle management of supplies in the NESS, once products have expired, they may be disposed of in accordance with the Treasury Board Directive on Disposal of Surplus Materiel. The NESS will be looking at ways to optimize product life cycle management to minimize the disposal of expired stock, while continuing to prioritize end-user safety.

Q360. What is the process for personal protective equipment distribution and how are these prioritized?

The Government of Canada and provincial and territorial governments have agreed to a personal protective equipment (PPE) allocation strategy.

Based on needs identified by provinces and territories, collaborative federal, provincial and territorial (FPT) procurement efforts are focused on procurement of large quantities of PPE and medical supplies, including N95 respirators, surgical masks, face shields, nitrile gloves, gowns and other protective clothing, sanitizers, ventilators, and testing supplies. The allocation of these supplies is a collective FPT decision that will support Canada's health system response to COVID-19.

Additionally, to provide surge support to the provinces and territories, the Public Health Agency of Canada (PHAC) has released items from the National Emergency Strategic Stockpile (NESS). This has also included specific types of PPE, such as surgical masks, gloves and N95 respirators, as well as other items, such as ventilators, disinfectants and hand sanitizers.

To receive stock from the NESS, the provinces and territories submit Requests for Assistance (RFA). PHAC responds to RFA as they are received and allocates supplies to provide surge

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capacity to the provinces and territories while maintaining a conservative inventory at the NESS to ensure surge support. In this current environment, due to global high demand for PPE, provinces and territories are encouraged to submit RFA with shorter time frames (e.g., surge requirements for 1-2 weeks) with the option of following up with additional RFA as this event progresses.

Q361. Is it the Government of Canada's responsibility to maintain the NESS stockpile or is it a provincial or territorial responsibility?

The NESS mandate is to provide surge support to provinces and territories, as well as to federal populations such as Correctional Service Canada.

PHAC has been working with Public Services and Procurement Canada to advance bulk procurement orders of PPE to respond to the needs of provinces and territories, which are also actively working to ensure they have the necessary equipment to distribute to frontline health care workers.

Procurement orders are arriving and the majority is deployed to provinces and territories, with a conservative portion allocated to the NESS to maintain and replenish NESS inventory for surge support.

Q362. Has inventory been added to NESS since the outbreak of COVID19?

Orders for PPE and medical supplies were placed early on by federal, provincial and territorial governments to supplement their existing stocks.
On March 9, the Prime Minister and Deputy Prime Minister wrote to all Premiers announcing their intention to lead a bulk procurement effort on healthcare supplies responding to the COVID-19 outbreak.

PHAC has been working with Public Services and Procurement Canada to advance bulk procurement orders of PPE to respond to the needs of provinces and territories, which are also actively working to ensure they have the necessary equipment to deliver front line health care.

Procurement orders are arriving, and jurisdictions are working together to ensure an effective health system response to COVID-19 while maintaining and replenishing NESS inventory for surge support.

We continue to do our best to update the public on rapidly changing numbers with respect to PPE; however, our priority is getting this protective equipment and delivering to provinces so that front line health care workers who need it most have access.

Q363. Is NESS fully integrated with other repositories of medical equipment in Canada?

The NESS mandate is to provide surge support to provinces and territories, as well as to federal populations such as Correctional Service Canada. However, in support of COVID-19 response, PHAC is also accepting and deploying donations of medical supplies from other government departments, companies and countries.

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In addition, under Canada's Plan to Mobilize Industry to fight COVID-19, the Government of Canada is directly supporting businesses to rapidly scale up production or re-tool their manufacturing lines to develop products in Canada such as personal protective equipment and other critical medical supplies.

The Government of Canada has stood up the Strategic Innovation Fund that will allow for rapid support to Canadian companies that are working on large-scale and later-stage promising research and development projects aimed at providing medical countermeasures to COVID-19, including vaccines and critical medical supplies.

Q364. Was a recent notice on the Government Buy and Sell site a call out to identify additional suppliers for NESS?

The Government of Canada is exploring all avenues to secure medical supplies, including personal protective equipment (PPE), in order to prepare for and respond to the COVID-19 outbreak.

The Notice that went out on Buy and Sell to identify additional suppliers will benefit federal, provincial and territorial governments, including the National Emergency Strategic Stockpile (NESS).

More information on the Government of Canada's response can be found here.

Q365. Does PHAC have to go to tender to replenish NESS supplies or can it use the Emergency Rule to buy directly?

PHAC follows appropriate laws, policies and guidelines with respect to the procurement of supplies or assets for the NESS. Competitive procurement practices such as the use of established supply arrangements, or requests for proposal, are routinely utilized to access the supply chain.

On March 14, 2020, PHAC requested, and received, a National Security Exception for the Procurement of Goods and Services required by the Government of Canada to respond to the COVID-19 outbreak. With this authority, PHAC will not be required to go to tender to replenish NESS supplies and will work with Public Services and Procurement Canada to determine the best procurement strategy.

Q366. A 2010 audit found that PHAC did not have a complete up-to-date inventory of its emergency medical supply stockpile, designed for distribution to the provinces during public health emergencies like this one. Does the federal government now have a complete inventory of its emergency medical supply stockpile? Has it shared this inventory with the provinces or public? Can you provide evidence of the inventory?

Following the 2010 Audit, the Public Health Agency of Canada (PHAC) implemented an electronic inventory system to tracks the inventory of the National Emergency Strategic Stockpile (NESS). The provinces and territories are aware of NESS holdings; however, for security reasons, PHAC does not disclose the inventory of the NESS with the public.

Q367. What has changed since the 2011 evaluation report of the NESS?

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Since the 2011 evaluation, the NESS has evolved to better align with the ever-changing risk environment and is investing in strategic assets, such as medical counter-measures and mini-clinics, to enhance the Agency's ability to support surge requests during health emergencies. In addition, there has been increased engagement with provincial and territorial partners and other stakeholders to increase awareness of NESS capabilities.

Q368. Can you explain why the number of warehouses stocking supplies from the National Emergency Strategic Stockpile was reduced, and whether that led to a reduction in the amount of PPE that was stockpiled by the federal government?

Canada's National Emergency Strategic Stockpile (NESS) contains supplies that provinces and territories can request in emergencies when their own resources are insufficient, such as during infectious disease outbreaks, natural disasters and other public health events. The purpose of the NESS is to provide surge support to provinces and territories; it is not intended to replace supplies that provinces and territories hold or procure. Provinces and territories are responsible for preparing and maintaining their own supply capacities.

Over the past decade, we have reduced some of the materials included in the NESS. For example, blankets were previously part of the stockpile but are now available through other channels and no longer needed in large supplies through the NESS. As the NESS has modernized, the stockpile has focused on stockpiling strategic medical supplies that are typically not held by provinces and territories. This includes items such as medication and vaccines that require controlled environmental conditions.

Following an independent assessment of the federal warehouse network, the NESS moved from nine warehouse locations across Canada to six to offer the most efficient distribution system without sacrificing response capacity. For example, since the creation of the NESS, Canada's transportation infrastructure has improved, making it easier to maintain the same 24-hour delivery target with fewer warehouses.

The supplies in the NESS are regularly reviewed and supplies are purchased on a regular basis. In January, the Public Health Agency of Canada (PHAC) began monitoring the coronavirus outbreak in China and started assessing its NESS inventories and procuring supplies needed to respond to a possible outbreak in Canada.

Q369. In the early 2000s, NESS had 165 completely equipped portable hospitals. It had 33,000 beds (hospitals beds/cots) during 9/11 19,000 of them were deployed to NS and Nfld. What happened to those stocks?

The National Emergency Strategic Stockpile (NESS) was established during the Cold War era to provide medical and social service supplies in response to public health emergencies, specifically nuclear disasters. The portable field hospitals were a relic of that time and no longer met the standards of care currently utilized in Canada. Since 2013, the stock from those field hospitals was either re-purposed for continued use in the current mini-clinics, stockpiled for future emergencies, destroyed/recycled, or donated for historical reasons according to Treasury Board's Disposal of Surplus Moveable Crown Assets policy.

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Items retained include, but are not limited to, cots and blankets, which continue to be used when requested to support provincial or territorial responses to health emergencies. The NESS kept one entire field hospital as an artifact.

Q370. In the early 2000s, there were 10 regional warehouses, there are now five. On what basis was the decision made to rationalize the number of locations?

Until 2011, the NESS was a series of 11 warehouses in nine locations. A decision was made in 2013 to modernize and optimize the stockpile's warehouse presence. This was undertaken to reflect changes in the NESS operating environment, including enhanced capacity amongst partners (federal, provincial and territorial, and non-government organizations) and improvements in transportation infrastructure, which had reduced the time required to deliver assets across Canada. An independent assessment of the federal warehouse network of the NESS found that moving from nine warehouse locations across Canada to six warehouse locations would offer the most efficient distribution system without sacrificing response capacity.

As of 2019, all NESS holdings were consolidated into eight warehouses in six locations. In March 2020, an additional warehouse was leased in Ottawa, given the volume of supplies being donated to and purchased by the NESS as part of the federal government's COVID-19 response.

Q371. Has the NESS stockpile changed in the last 10 years? Has it diminished or deteriorated since 2015 and has there been any specific policy/funding changes through governments?

The National Emergency Strategic Stockpile (NESS) provides health emergency assets for surge capacity when local, provincial or territorial resources have been exhausted. The NESS is not intended to replace supplies that the provinces and territories hold or procure. Provinces and territories are responsible for preparing and maintaining their own supply capacities.

Since its establishment, the NESS has adapted to the changing risk environment in Canada. For example, in the 1980s and 1990s, the scope of the NESS expanded to include the capacity to respond to natural disasters and other emergencies by stockpiling supplies needed to support evacuations and care for displaced individuals - such as kits for reception centres. The 2000s was a period of dramatic change in the nature of international security and public health threats, marked by the September 11, 2001 terrorist attacks, the 2003 SARS outbreak, and the 2009 H1N1 influenza pandemic. During this period, the NESS stockpile of supplies expanded to include chemical, biological, radiological and nuclear threats. The NESS began to shift away from stockpiling social services supplies (beds and blankets) to increase its holdings of medical countermeasures and antiviral medications—a key treatment in response to viral outbreaks such as influenza pandemics. While the NESS mandate has always been to provide emergency supplies to the provinces and territories as surge capacity, it was during this time that its focus evolved to include the enhanced procurement of niche supplies. At the same time, the role of the NESS in procurement became better defined - as both a potential collaborative sourcing organization and clearinghouse, paving the way for potential bulk procurement.

The NESS is used to store critical life-saving medical countermeasures (vaccines and other therapies) in response to potential biological threats, as well as other consumables, such as generators, cots, blankets and mini clinics, which can be drawn upon by the federal government or the provinces and territories. The NESS has historically carried only small amounts of

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personal protective equipment (PPE), given that all jurisdictions have traditionally sourced PPE directly from known suppliers.

Since 2012-13, the annual base funding for the NESS has remained stable and been approximately $3 million a year. This funding is included in the overall funding identified for the Health Security Infrastructure Program area reported in Public Accounts. On top of the NESS core operating budget, there have been investments made for particular initiatives, stocks of supplies and medical countermeasures. Over the last 10 years, these investments have varied year over year, and have amounted to more than $79 million. This includes funding linked to specific purchases, such as a three-year investment in the smallpox vaccine that began in 2013-14 and the Ebola vaccine in 2014-15.

Q372. The rationalization of the NESS stockpile put more emphasis on pharmaceuticals than nuts and bolts medical equipment. Can you confirm that and explain the rationale?

That is correct. The NESS is intended to provide surge capacity in support of provincial and territorial emergency responses. The acquisition of NESS assets is guided by the evolving threat and risk landscape of emergency preparedness and response. The focus of the NESS is on its role as a primary supplier of medical countermeasures that are not normally stockpiled by provinces and territories. It also holds a supply of antivirals to support P/Ts with surge capacity in the event of an influenza pandemic.

Provincial and territorial governments are primarily responsible for the provision of supplies and equipment for health care services. Due to the unprecedented shortages of personal protective equipment due to COVID-19, the Government of Canada has taken steps to:

- order additional supplies as part of bulk procurement efforts with the provinces and territories,
- establish new logistical arrangements to enable delivery of supplies, and
- establish domestic production of certain supplies.

VACCINE AND TREATMENT

Q373. Is there a vaccine that protects against coronaviruses in humans? If none are currently approved, are there any that are in development or being tested?

Currently, there is no approved vaccine that protects against coronaviruses in humans.

The World Health Organization (WHO), along with the Coalition for Epidemic Preparedness Innovations, is coordinating an international collaboration to help advance research and vaccine development for the COVID-19.

The Public Health Agency of Canada and the Canadian Institutes of Health Research—in consultation with international partners, including the WHO and the Global Research Collaboration for Infectious Disease Preparedness — is assessing how scientists at our National Microbiology Laboratory, along with the broader Canadian research community, will participate in the global research efforts.

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Q374. Canada is spending millions to fund vaccine research. If a Canadian group successfully develops a vaccine, will early doses go to Canadians first? Is that an explicit condition of any Canadian funding?

The Government of Canada recognizes that access to the right tools and technologies to address COVID-19, including vaccines, will be critical to the response. Canada joined other G20 nations in committing to bolstering our coordination towards rapid development, manufacturing and distribution of vaccines, adhering to the objectives of efficacy, safety, equity, accessibility, and affordability.

Through investments of more than $1 billion in medical research, the federal government is supporting multiple organizations in working to develop candidate vaccines. There are currently over 100 vaccine candidates globally that are at different stages of development by academia, small and medium enterprises and large, multinational pharmaceutical organizations, including 10 in Canada. The Government's support for vaccine development will better position Canada to rapidly access a vaccine once it does become available.

Through the Canadian Institutes of Health Research (CIHR) and the Natural Sciences and Engineering Research Council of Canada (NSERC), the Government of Canada is providing grants to independent researchers working in external labs. The CIHR and NSERC do not own or control the commercialization of results of the research they fund, as this falls within the responsibility of the funded researcher and their organization. Therefore, the researcher and their institution would be the initial owner of the intellectual property.

Sharing a vaccine with Canadians first was not a condition of CIHR or NSERC funding . Conditions apply mainly to openly sharing research findings and data relevant to the COVID-19 outbreak, for example, in peer-reviewed journals, with other researchers, etc. The full conditions on the CIHR funding can be found on their website.

One of the conditions of NSERC funding was that applications demonstrated that there are benefits to Canada from the proposed research. Applicants needed to make that demonstration in relation to the specifics of each project that they proposed. In the context of COVID-19-related grants, researchers were advised that discoveries must be open access, and would be proactively shared with government authorities so that they can be utilized as appropriate to rapidly generate impact for Canada.

The Human Health Therapeutics Research Centre at the National Research Council of Canada (NRC) also undertakes vaccine research. Where this work is done in collaboration with external partners, our technology transfer and collaborative agreements favour benefits to Canadians. Should a successful vaccine candidate or new analytical tests result from NRC-supported activities, specific distribution plans would be established in consultation with the Public Health Agency of Canada as appropriate.

Q375. Would Canada impose any exports limits on vaccine doses to ensure material manufactured in Canada is available to Canadians?

Canada has not implemented new export restrictions in response to COVID-19 at this time, and has sought to facilitate trade with temporary relief of duties and taxes to support the import of critical supplies for public health authorities, centres for health care (e.g., hospitals, testing sites), and first response organizations for use in responding to the COVID-19 crisis.

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Canada is leading work with likeminded nations and in multilateral institutions to maintain open supply chains ensuring people in Canada and around the world have access to the essential medicine, medical supplies and other critical goods they need, especially at this crucial time, and as reflected in the joint ministerial statement and the G20 Trade and Investment Ministerial Statement.

To ensure a stable supply of medical equipment and supplies for Canadians, Canada is:

- taking action to increase domestic supply by funding the University of Saskatchewan's Vaccine and Infectious Disease Organization – International Vaccine Centre (VIDO-InterVac);
- supporting the National Research Council of Canada to upgrade its Human Health Therapeutics facility to develop, test and scale-up promising vaccine candidates to be ready for industrial production;
- providing Strategic Innovation Fund support for Medicago, a company that has identified a viable plant-based vaccine candidate currently at the pre-clinical testing phase, to rapidly move forward on clinical trials and then quickly shift to scaling up production for pandemic response; and
- purchasing items from other countries, and, only if necessary, implementing targeted, proportionate, transparent and temporary import and export measures.

Q376. Has Canada made a commitment to donate 10% of the stockpile to the WHO? What is Canada doing to ensure vaccines are accessible where they are needed most?

In addition to domestic efforts, Canada is also a significant contributor to international vaccine development initiatives. Through contributions to the Coalition for Epidemic Preparedness Innovation (CEPI), which is working in close collaboration with the World Health Organization on COVID vaccine candidates, Canada is committed to supporting the global effort to develop and manufacture COVID vaccines that will be available to all, on an equitable basis.

A founding principle of CEPI is enabling equitable access to the vaccines for all affected populations during outbreaks. In the context of the COVID pandemic, that will mean that appropriate vaccines developed trough CEPI-funded initiatives would be made available first to populations when and where they are most needed to curtail an epidemic, regardless of geography or ability to pay.

The Government of Canada is a signatory to the Pandemic Influenza Preparedness (PIP) Framework. Under this framework, manufacturers of vaccines and/or antivirals commit to at least two of six options in exchange for biological materials that are required to develop and test vaccines and antivirals. One of these options is to donate at least 10% of real-time pandemic vaccine production to the WHO.

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Q377. Does Canada already have in place a contract for a pandemic vaccine from a supplier able to produce large quantities when the time comes?

There is currently no vaccine for COVID-19. Consequently Canada cannot put in place a procurement contract for supply of COVID-19 vaccine. Through investments of more than $1 billion in medical research, the federal government is supporting multiple organizations in working to develop candidate vaccines. There are currently over 100 vaccine candidates globally that are at different stages of development by academia, small and medium enterprises and large, multinational pharmaceutical organizations, including 10 in Canada. It is still to be determined which of these candidates will be successful. The Government's support for vaccine development will better position Canada to rapidly access a vaccine once it does become available.

Canada does have a 10-year contract with GlaxoSmithKline to provide domestically produced pandemic **influenza** vaccine to respond to a declared influenza pandemic; however, this contract and the production facility involved are specific for egg-based influenza vaccine production.

Q378. How long will it take to develop a vaccine?

Coronaviruses are a group of viruses that can cause a wide range of illness, ranging from the common cold to Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS-CoV). The challenge of developing a vaccine that protects against coronaviruses is that infection by human coronaviruses does not provide long-lasting immunity, meaning someone can be re-infected in the future following recovery from an initial infection.

Although a vaccine that provides long-term immunity remains a challenge, an outbreak vaccine aimed to provide short-term protection (similar to a pandemic influenza vaccine) to respond to a novel coronavirus outbreak could potentially be developed.

In the case of a vaccine for a specific coronavirus, it could take years for researchers to develop a vaccine.

For example, there are currently no licensed vaccines or specific treatments for Middle East Respiratory Syndrome coronavirus (MERS-CoV)—a particular coronavirus that was first identified in 2012. We are aware of work being conducted elsewhere to better understand how MERS-CoV infections might be prevented and to develop a MERS-CoV vaccine. This includes vaccine development efforts being coordinated by WHO and the Coalition for Epidemic Preparedness (CEPI).

Q379. How will Canada secure a Canadian supply of an eventual COVID-19 vaccine in an open market against other countries also seeking to secure their own supplies?

There are currently several candidate vaccines in research and development and it is not possible to determine which one(s) will be successful in preventing COVID-19 infection at this time. As such, the Government of Canada is supporting multiple organizations who are working at unprecedented speed to develop candidate vaccines. The Government's support for vaccine research and development, bio-manufacturing requirements to support large-scale production, enhancing capacity and access for clinical trials, and seeking solutions for domestic capacity, will all help to better position Canada to rapidly access a vaccine, once it becomes available.

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The Government of Canada is closely monitoring the vaccine development efforts, both domestically and internationally, and will work quickly to negotiate purchase agreements with vaccine manufacturer(s) to secure supply for all Canadians as soon as it is feasible.

Q380. Once a COVID-19 vaccine is available, how will Canada produce or obtain enough doses required for Canada?

The Government of Canada is investing in promising projects to advance the development of vaccines and treatments, and facilitate access to them for Canadians. At the same time, the Government is working to secure the supply of an eventual vaccine and other promising treatments. While Canada has existing biomanufacturing industrial capabilities, a comprehensive process is underway to build up domestic capacity and plan for the eventual global discovery of a proven vaccine through the massive global efforts underway that will protect us from COVID-19.

Q381. Is the PVC13 vaccine, used against pneumonia, useful as a therapy against COVID-19?

There are currently no vaccines or other health products authorized specifically for the prevention or treatment of COVID-19, as it is still a relatively new virus.

For vaccines or other health products that show early promise in treating COVID-19 including secondary infections that may be associated with the illness, clinical trials are the most appropriate means to pursue as they provide a way for the healthcare community to systematically collect information on the effectiveness of the treatments and what the associated risks may be. To date, Health Canada has not received any application for clinical trials for pneumonia vaccines used in the treatment of COVID-19-related infections.

Health Canada is working closely with many potential clinical trial sponsors to support access to clinical trials for COVID-19 for Canadians. To facilitate earlier access to needed therapeutic products to treat or prevent COVID-19, Health Canada will expedite its regulatory process for any COVID-19-related health products, including the review of submissions and the authorization of clinical trial applications, while continuing to protect the safety of trial participants. In addition to work done by professional societies, clinical trials are being coordinated across the Health Portfolio in Canada and globally.

Q382. How are people being treated for this illness?

At present there is no specific drug or medication treatment for people who have COVID-19. Researchers are looking at the effectiveness of existing antiviral treatments.

World Health Organization has provided advice to health professionals that includes recommendations for early supportive therapy, management of symptoms and prevention of complications.

The novel coronavirus causes a range of illness from mild to severe for some individuals. Therefore, if you have travelled outside Canada, it is important to monitor your health when you return to Canada. While abroad, you may have come in contact with the novel

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coronavirus. PHAC asks that you monitor your health for fever, cough and difficulty breathing for 14 days after you arrive in Canada. If you develop fever, cough, or difficulty breathing, call your health care professional or local public health authority to inform them about your symptoms. They will provide advice on what you should do.

Q383. Is Health Canada investigating these reports and is there any current direction regarding the use of Vitamin C as a defence or treatment against the coronavirus?

Since the outbreak of COVID-19, Health Canada has taken actions to support Canadians in accessing health products they need to either treat or prevent COVID-19. Currently, there are no drugs specifically authorized to treat COVID-19 since it is still a relatively new virus. Much effort is being placed to investigate potential new therapies including drugs that may have been authorized for the treatment of illnesses other than COVID-19. For drugs that show an early promise in treating COVID-19, the best way to access therapies through clinical trials which provides way for the healthcare community to systematically collect information on the effectiveness of the treatments and what the associated risks may be.

Health Canada recently authorized a clinical trial application to investigate the use of intravenous Vitamin C in COVID-19 patients to help improve the functioning of some of the body's organs that is associated with severe cases of COVID-19 and closely monitoring its progress.

To facilitate earlier access to needed therapeutic products to treat or prevent COVID-19, Health Canada will expedite its regulatory process for any COVID-19 related health products, including the review of submissions and the authorization of clinical trial applications. In addition to work done by professional societies, clinical trials are being coordinated across the health portfolio in Canada and globally. This is a rapidly evolving landscape and the health portfolio is working to adapt to shifting needs.

Q384. Are there safety issues with the use of ibuprofen in COVID-19 cases?

There is no scientific evidence that establishes a link between ibuprofen, or other non-steroidal anti-inflammatory drugs (NSAIDs), and the worsening of COVID-19 symptoms.

If you have symptoms of COVID-19, speak with your healthcare provider regarding the most appropriate health products for the treatment of fever or pain. If you are currently taking ibuprofen, especially for a chronic illness, do not stop taking your medication.

Q385. Can Hydroxychloroquine and azithromycin be used to treat any patient who is infected with COVID-19? Will they be effective for everyone?

Hydroxychloroquine is an antiparasitic drug that is indicated for the treatment of malaria, as well as autoimmune diseases such as rheumatoid arthritis and lupus. Azithromycin is an antibiotic used in the treatment of pneumonia and other bacterial infections.

There is some evidence to suggest that these drugs may be effective for some patients; however, these are preliminary findings from a few, very small studies. There are also some known significant safety risks associated with both drugs, such as QT prolongation, which is a serious heart rhythm condition. A healthcare practitioner may choose to use these medications

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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

In Canada, a doctor's decision to prescribe a particular drug to a patient, whether it's to be used for a labelled indication or off label, is part of the practice of medicine. While Health Canada regulates drugs, it is the responsibility of healthcare professionals to consider information from medical journals, reports, and peer-reviewed studies when prescribing medication.

Q386. Does Health Canada have an official position on Hydroxychloroquine and chloroquine for treating COVID-19?

Health Canada recognizes that Canadians who are ill with COVID-19 need access to safe and effective medicines and treatments. Hydroxychloroquine and chloroquine are available on the Canadian market for treating other illnesses, but they have not been approved for the treatment of COVID-19.

International reports have suggested hydroxychloroquine and chloroquine to be promising drugs for the treatment of COVID-19, but this remains to be confirmed. For medicines that show an early promise in treating COVID-19, the best way to offer them to Canadians is through clinical trials. Clinical trials provide a way for the healthcare community to systematically collect information on the effectiveness of the treatments and what the associated risks may be. Therefore, Health Canada encourages manufacturers to work with researchers so that these medicines can be offered to COVID-19 patients in the context of clinical trials.

As of April 8, 2020, Health Canada has approved two clinical trials for the use of hydroxychloroquine in treating COVID-19. Health Canada has also approved 9 other clinical trials using other potential therapies. A list of clinical trials approved for the prevention or treatment of COVID-19 as well as associated complications can be found in Health Canada's Clinical Trials Database. One can search this database by entering "COVID" in the medical condition box.

Q387. What is Health Canada doing about products claiming to prevent, treat or cure COVID-19?

At this time, there is no vaccine for COVID-19 or any natural health products—including traditional Chinese medicines—that are authorized to treat or protect against COVID-19.

Selling unauthorized health products or making false or misleading claims to prevent, treat or cure COVID-19 is illegal in Canada. The Department takes this matter very seriously and will take action to stop this activity. To date, Health Canada has not approved any product to treat or cure COVID-19. Health products that have been authorized for sale by Health Canada will have an eight-digit Drug Identification Number (DIN), Natural Product Number (NPN) or Homeopathic Drug Number (DIN-HM). The Department is taking action to address complaints regarding unauthorized products on the Canadian market making false or misleading claims for the treatment, prevention or cure of COVID-19.

The Department encourages anyone who has information regarding potential non-compliant sale or advertising of any health product claiming to treat, prevent or cure COVID-19, to report it using the online complaint form.

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When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its associated Regulations, it takes steps to confirm whether non-compliance has occurred and takes action based on the risk to the health of Canadians. A number of compliance and enforcement options are available to correct non-compliance or mitigate a risk to Canadians, including site visits, public communications, recalls, and the seizure of products and advertising materials. The primary objective of the Department's compliance and enforcement approach is to manage the risks to Canadians using the most appropriate level of intervention, in accordance with Health Canada's Compliance and Enforcement Policy.

Q388. What actions will Health Canada take in case of non-compliance related to health products claiming they can cure, treat or prevent COVID-19?

Under the *Food and Drugs Act*, distributing a health product for free is considered advertising. If Health Canada becomes aware of companies distributing free samples of unauthorized products or free samples of authorized products making false and misleading claims, it will ask the parties involved to immediately stop this distribution and will take all required compliance and enforcement actions to achieve compliance, which may include seizing the product.
As mentioned previously, Health Canada has not approved any products for the treatment or cure of COVID-19, including any traditional Chinese medicines. Selling unauthorized health products or making false or misleading claims to, prevent, treat or cure COVID-19 is illegal in Canada.

The distribution of free samples of authorized products making false and misleading claims or any other form of advertising making this claim is illegal and considered to be false and misleading. The Department takes this issue seriously and will not hesitate to use all tools at its disposal to stop these activities.
Health Canada is assessing this advertising issue and will take all required compliance enforcement actions if non-compliance with the legislation or regulations is identified.
The Department encourages anyone who has information regarding potential non-compliant sale or advertising of any health product claiming to treat, prevent or cure COVID-19, to report it using the online complaint form.

Q389. Are there any natural health products, including traditional Chinese medicines, Ayurvedic medicines and homeopathic products to protect against or treat this virus?

No natural health products are authorized to protect against, or treat COVID-19. This includes traditional Chinese medicines, Ayurvedic medicines and homeopathic products.

Q390. Is Favipiravir or Avigan approved in Canada? Is Canada taking any steps to get them approved?

Avigan is the brand name for favipiravir. It has been approved in Japan and China for the treatment of influenza. There are currently no favipiravar-containing products approved in Canada.

Since the outbreak of COVID-19, Health Canada has taken actions to support Canadians in accessing health products they need to either treat or prevent COVID-19. To facilitate earlier access to a vaccine or therapeutic product for COVID-19, Health Canada will expedite its

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regulatory process for any COVID-19 related health products, including the review of submissions and the authorization of clinical trial applications.

Health Canada initiated conversations with companies whose products have shown potential in fighting COVID-19, including the company that manufactures favipiravir. However, to date, Health Canada has not received a submission for a favipiravir-containing product. It is ultimately up to the manufacturer to decide whether they choose to seek market authorization for their product in Canada.

For medications that show early promise in treating COVID-19, such as favipiravir, Health Canada encourages sponsors to work with researchers and offer medicines to patients in the context of clinical trials. This would ensure that there is informed consent for patients, and the healthcare community would be able to learn whether the treatments are effective, and what the associated risks are.

Q391. Will Health Canada or Public Health Agency of Canada be issuing treatment guidelines if drugs like favipiravir or other antivirals, or any other drug, is found effective in another country/jurisdiction at treating COVID-19?

At present, there is insufficient evidence to recommend any specific anti-COVID-19 treatment for patients with confirmed COVID-19 outside of clinical trials. There are many ongoing clinical trials testing various potential antivirals registered on https://clinicaltrials.gov/ or on the Chinese Clinical Trial Registry (http://www.chictr.org.cn/abouten.aspx). Clinical care guidance for COVID-19 is presently being developed in conjunction with Association of Medical Microbiology and Infectious Disease Canada and the Canadian Critical Care Society.

Drugs not available in Canada can be accessed through clinical trials or the Special Access Program. Should there be data available to support a submission to Health Canada concerning the effectiveness of a drug in treating COVID-19, if approved, directions for use would be included in the product monograph. Other organizations may provide additional guidelines for off-label use of products shown to be effective.

Q392. What additional regulatory flexibilities is Health Canada considering in addition to the rolling review model?

Companies interested in filing a drug submission to treat or prevent COVID-19 are encouraged to contact Health Canada to discuss the specifics of their submissions and whether there are other flexibilities Health Canada should consider with their submission in response to the COVID-19 pandemic.

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

Q393. Will Fluzone HD protect against seniors getting COVID-19?

No. At present there is no vaccine for COVID-19. However, protecting our senior population living in long term care facilities against the flu ensures that this vulnerable group stays as healthy as possible, and that our health care system is available to treat those who need it most.

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Q394. Will provinces and territories be allowed to use the Fluzone® HD purchased on their behalf for other groups within their jurisdiction?

The doses of Fluzone® HD that will be purchased will be equitably allocated amongst all interested provinces and territories for use in their long-term care facilities. The residents of long-term care facilities are bearing a significant burden of the illness and death that is occurring due to the COVID-19 pandemic. Given the concern that the spread of influenza in the fall and winter will significantly add to this burden, the one-time initiative to secure supplies of Fluzone® HD is focused on ensuring that residents of long-term care facilities are as protected as possible.

Should there be surplus doses available during the flu season, only then will provinces and territories be free to use those surplus doses to vaccinate other eligible recipients in a manner that they deem best in accordance with the objectives of their vaccination program.

Q395. Given the additional protection that Fluzone® HD provides to vulnerable seniors in long-term care facilities, will the government provide annual funding to provinces and territories for the purchase of this vaccine?

This is a one-time federal contribution that is intended to assist provinces and territories in managing the health care system capacity during the next influenza season in the context of an ongoing COVID-19 pandemic. Provinces and territories are responsible for the delivery of influenza vaccination programs and are best placed to make decisions on which vaccine products should be used in their programs and what populations should be covered.

Q396. Will there still be an allotment of Fluzone HD available to the provinces and territories to purchase for other Canadians aged 65 and older who do not live in long-term care facilities?

The residents of long-term care facilities are bearing a significant burden of the illness and death that is occurring due to the COVID-19 pandemic. Given the concern that the spread of influenza in the fall and winter will significantly add to this burden, the one-time initiative to secure supplies of Fluzone® HD is focused on ensuring that residents of LTC care facilities are as protected as possible against influenza this fall and winter. As such, the allotment of Fluzone® HD that the Government of Canada is purchasing will be equitably allocated amongst all interested PTs for use in their LTC facilities as the primary goal.

Each PT determines which populations will be covered by its public vaccine program. As such, PTs that wish to offer Fluzone HD to Canadians aged 65 and older who do not reside in long-term facilities would be responsible for obtaining their own additional doses. Each province and territory should be contacted directly for more information on the scope of its influenza vaccination program.

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Should there be surplus doses available in a PT, however, then that PT will be free to usfacilities
e those surplus doses to vaccinate other eligible recipients in a manner that they deem best in accordance with the objectives of their vaccination program.

Clinical Trials

Q397. Are there clinical trials underway to determine whether Hydroxychloroquine and azithromycin are effective?

Yes, Health Canada has authorized clinical trials on the use of hydroxychloroquine to treat COVID-19 in Canada and is aware of other ongoing clinical trials across the world. Health Canada is closely monitoring their developments.

Any company or healthcare practitioner treating patients with COVID-19 who wishes to conduct a clinical trial to evaluate the effectiveness of these or other drugs is encouraged to contact Health Canada.

A list of clinical trials approved for the prevention or treatment of COVID-19 or its complications can be found in Health Canada's Clinical Trials Database by entering "COVID" in the medical condition box.

Q398. Are Hydroxychloroquine or chloroquine being used in Canadian hospitals for either trials or treatment?

Two clinical trials approved in Canada are being conducted in multiple locations in Canada.

As both hydroxychloroquine and chloroquine have been approved in Canada for the treatment of other illnesses, physicians may prescribe these medicines outside of their approved indications (off-label use). Off-label use of medicines falls under the practice of medicine and is regulated at the provincial level.

Q399. Are there times when "human challenge trials" are authorized by Health Canada? Is this WHO document one of the reference tools that Health Canada is using developing its regulations for "human challenge trials"? Or is there anything more recent from the WHO about this?

In the context of COVID-19, no vaccine trials are currently under way in Canada yet, and Health Canada has not received any applications for challenge studies. The list of clinical trials authorized by Health Canada for COVID-19 is available on line.

Under the *Food and Drug Regulations*, a clinical trial must be conducted in keeping with good clinical practice, with the approval of a research ethics board, with informed consent and with thorough safety monitoring in order to protect the participant. If it is carefully controlled, it may be possible to conduct a challenge study to assess a vaccine's effectiveness. Health Canada's approach would generally be consistent with international best practices, such as guidelines from the World Health Organization and other major regulatory agencies.

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Q400. Can you provide any details on how plasma therapy for COVID-19 works and how before it gets approved?

Health Canada has worked closely with clinical trial sponsors and the blood operators—Canadian Blood Services and Héma-Québec—to provide regulatory and scientific advice to support the development of this blood plasma trial protocol. Health Canada recently received a clinical trial application for the use of blood plasma from COVID-19 patients who have recovered from their illness to treat other patients. As with other clinical trial applications for COVID-19, the review of this application has been prioritized and is being expedited. Usual timelines for clinical trial authorizations depend on the information submitted in support of the trial and are up to 30 days. Priority review timelines vary but it is expected that they may be completed in 1 to 2 weeks. The purpose of Health Canada's review is to protect the health of the study participants or other persons, ensure that the trial is in the best interests of the study participant, and whether the objectives of the study will be achieved.

Q401. What is the plasma donation criteria for men who have had sex with men (MSM) within the last three months? Will they be allowed to donate plasma or is it status quo?

To conduct a clinical trial in Canada—including one using convalescent plasma obtained from individuals who have recovered from COVID-19—a sponsor must submit a Clinical Trial Application (CTA) to Health Canada for review and authorization. The purpose of Health Canada's review is to assess whether the trial could endanger the health of the study participant or other persons, whether the trial is in the best interests of the study participant, and whether the objectives of the study will be achieved. Separate from the Health Canada review, the trial must also be approved by research ethics boards associated with the trial sites before patients can be enrolled. Accordingly, it is the CTA sponsor who must identify the protocols for conducting the trial in their application. For trials involving plasma or blood products, this would include the criteria for selecting donors.

To date, Health Canada has authorized one clinical trial of convalescent plasma for the treatment of COVID-19. This multicentre trial is designed to determine the safety and efficacy of COVID-19 convalescent plasma, collected from donors who have recovered from COVID-19 infection in reducing the risk of intubation or death in adults who are admitted to hospital with COVID-19 respiratory illness. Canadian Blood Services and Héma-Québec will be responsible for providing the donor plasma for use in this clinical trial and the plasma will be collected and processed according to the protocols already in place under their Health Canada authorizations, which include the current donor deferral for men who have had sex with another man in the past three months.

Q402. Is Canada taking part in the Solidarity II project lead by WHO?

As part of the World Health Organization (WHO) R&D Blueprint and COVID-19 response, the WHO has launched a multi-national clinical trial to study possible treatments for COVID-19.

Countries that have signed up to date include Canada, Argentina, Bahrain, France, Iran, Norway, South Africa, Spain, Switzerland and Thailand. Additional countries may join at a later time.

The goal is to generate robust data with the same study protocol applied to multiple sites to obtain statistically sound results from a sufficient number of patients.

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The Principal Investigator in Canada is Dr. Srinivas Murthy from British Columbia. There are currently 31 hospitals across Canada in various phases of activation to set up this trial.

Dr. Murthy has received a Canadian Institutes of Health Research grant for $954,936 to study treatments through observational studies and randomized controlled trials.

The initial interventions to be included are 1) lopinavir/ritonavir combination currently marketed for HIV in comparison to standard of care; and 2) hydroxychloroquine, currently marketed for malaria, which will be added to the protocol later.

Q403. Are there human challenge trials (people who are volunteering for live vaccine trials on COVID-19?

Health Canada has not received any applications for human challenge studies for vaccines for COVID-19. The list of clinical trials authorized by Health Canada for COVID-19 is available online.

Under the *Food and Drug Regulations*, a clinical trial must be conducted under good clinical practices, with approval from a research ethics board, with informed consent, and with extensive safety monitoring to protect the participants. If carefully controlled, it could be possible to conduct a challenge study to assess the efficacy of a vaccine. However, before doing so, we need to have sufficient information about the potential risks of the virus and how to mitigate them. Global scientific and clinical knowledge of this new virus including its impact on people is still evolving. Health Canada is closely monitoring global vaccine development and working collaboratively with our international counterparts to share scientific knowledge. If an application is submitted to Health Canada on a human challenge trial, part of the considerations that would go into the assessment would also include international best practices.

Lianhua Qingwen capsules

Q404. Have Lianhua Qingwen Capsules been approved for sale in Canada? If so, why?

Lianhua Qingwen Capsules have been licensed by Health Canada with the recommended use: "Traditionally used in Chinese medicine to help remove heat-toxin invasion of the lung, including symptoms such as fever, aversion to cold, muscular soreness, stuffy and runny nose, dry and sore throat, red tongue with yellow and greasy coating."

All natural health products sold in Canada must meet the requirements of the *Food and Drugs Act* and the *Natural Health Products Regulations*. Health Canada assesses the safety, efficacy and quality of natural health products based on the ingredients and health claims made. An eight-digit Drug Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) is issued after all the regulatory requirements are met and before the product can be sold in the Canadian market.

Detailed information on Lianhua Qingwen Capsules (NPN 80033781) is available on Health Canada's publicly accessible Licensed Natural Health Products Database.

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Q405. Are the Lianhua Qingwen capsules effective in curing COVID-19, as claimed by the manufacturer?

At this time, there are no health products—including traditional Chinese medicines—that have been authorized by Health Canada to specifically treat or protect against COVID-19.

Selling unauthorized health products or making false or misleading claims to, prevent, treat or cure COVID-19 is illegal in Canada. The Department takes this matter very seriously and will take action to stop this activity. To date, Health Canada has not approved any product to treat, prevent or cure COVID-19. The Department is taking action to address complaints regarding unauthorized products on the Canadian market making false or misleading claims for the treatment, prevention or cure of COVID-19.

Health Canada is assessing this advertising issue and will take all required compliance enforcement actions if non-compliance with the legislation or regulations is identified.

The Department encourages anyone who has information regarding the potential non-compliant sale or advertising of any health product claiming to treat, prevent or cure COVID-19, to report it using the online complaint form.

Q406. Is it true that Ephedra is one of the ingredients used in the Lianhua Qingwen capsules and is banned by Health Canada?

The medicinal ingredient Ephedra (Ephedra sinica) is not banned by Health Canada. The Ephedra monograph provides detailed information on the requirements that need to be met to ensure the safety of this ingredient in natural health products. All natural health products—including products containing Ephedra—must be authorized by Health Canada and have a valid 8-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) to be legally sold in Canada.

Q407. Has Health Canada received any complaints regarding Lianhua Qingwen capsules?

As of April 21, 2020, Health Canada has received two complaints regarding Lianhua Qingwen capsules. As a result of these complaints, Health Canada has opened cases and is taking actions to verify if any non-compliance has occurred. Given that these are active, ongoing files, the Department is not in a position to provide details regarding compliance and enforcement actions it may be considering.

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its associated Regulations, it takes steps to confirm whether non-compliance has occurred and takes action based on the risk to the health of Canadians. A number of compliance and enforcement options are available to correct non-compliance or mitigate a risk to Canadians, including site visits, public communications, recalls, and the seizure of products and advertising materials.

The Department encourages anyone who has information regarding potential non-compliant advertising of any health product claiming to treat, prevent or cure COVID-19, to report it by sending us an email at drug-device-marketing@canada.ca or using the online complaint form.

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Temporary Exemption Under The Controlled Drugs And Substances Act For Medical Treatments

Q408. Was this exemption requested by provinces and territories?

Health Canada received inquiries from a few jurisdictions regarding measures that would facilitate access to certain medical treatments during the pandemic. The Department has taken quick action to respond to their concerns and to prevent potential issues related to accessing medical treatment during the pandemic.

Q409. How soon will pharmacists and practitioners be able to begin doing these new activities?

In response to the COVID-19 outbreak, Health Canada has temporarily exempted certain new activities that apply to pharmacists who are registered and entitled to practice pharmacy under the laws of their province or territory and are entitled to conduct activities with controlled substances. The availability of these new activities depends on the province or territory and licensing authority adopting these measures. Health Canada recommends contacting the provincial and territorial licensing authorities for more information.

Given the seriousness of the COVID-19 outbreak, Health Canada is working quickly to help jurisdictions maintain access to medications for Canadians.

Q410. What activities are currently authorized for pharmacists?

Pharmacists are medication experts and play a significant role in monitoring patients and medication to ensure safe and optimal use while contributing to outcome-focused patient care. Regulations under the *Controlled Drugs and Substances Act* state that a pharmacist is authorized to sell or provide a controlled substance to a person if they have received a prescription or a written order from a practitioner.

While these regulations do not permit pharmacists to prescribe, other related activities that are included in the meaning of *sell or provide* are permitted as long as the quantity dispensed does not exceed the amount originally authorized. These activities include, but are not limited to:

- **Adjusting the formulation**: adjusting the dosage form in which the drug is prescribed
    - e.g., change from pill to liquid formulations;
- **Adjusting the dose and regimen**: a structured plan that specifies the frequency in which a dose of medication should be ingested
    - e.g., change from 20mg per day for 5 weeks to 10mg per day for 10 weeks;
- **De-prescribing**: the planned and supervised process of reducing or stopping a medication; and
- **Part-filling**: dispensing a quantity of a medication that is less than the total amount of the drug specified by a practitioner
    - For greater clarity, this includes part-fills requested by a patient, when a pharmacy is dealing with an inventory shortage or other situations where the nature of the part-fill is a matter of discussion between the pharmacist and patient.

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With the goal of supporting better medication management and protecting the health and safety of Canadians, Health Canada has shared with pharmacists an interpretive guide related to prescribing activities with substances regulated under the *Narcotic Control Regulations*, Benzodiazepines and Other Targeted Substances and Part G of the *Food and Drug Regulations*.

Q411. If a patient doesn't have a prescription, can a pharmacist now prescribe new medications for patients?

With this exemption, pharmacists can be authorized to renew or extend prescriptions in order to maintain a patient on a medication. Pharmacists are not authorized to initiate a new medical treatment with controlled substances (e.g., narcotics).

Q412. Will this exemption apply to other healthcare professionals?

This exemption will apply to other healthcare professionals, including nurse practitioners, dentists and veterinarians, allowing them to verbally prescribe narcotics (depending on the prescriber's scope of practice and provincial and territorial authorization).

Q413. Has there been any consideration of permanently giving pharmacists extended authorities?

Pharmacists are medication experts and play a significant role in monitoring patients and medication to ensure safe and optimal use in patient care.

With the goal of supporting better medication management and protecting the health and safety of Canadians, in March 2019, Health Canada launched an official consultation seeking comments on ways to modernize pharmacists' role in the healthcare system. The Department is currently analyzing all feedback received. There will be another opportunity to comment on any draft regulations that are developed in *Canada Gazette* Part I. Health Canada encourages everyone to participate in the consultation.

Q414. Are there any special provisions being made to assist supervised consumption sites during the COVID-19 pandemic?

Health Canada recognizes that local pandemic precautions may impact the operations of supervised consumption sites and services. The Department continues to work directly with site operators to assess each individual situation and develop appropriate modifications to their protocols and practices. Operators are encouraged to contact the Office of Controlled Substances' Exemptions Section at hc.exemption.sc@canada.ca.

VIRUS TRANSMISSION

Q415. How is COVID-19 transmitted?

Current evidence suggests that COVID-19 is most commonly spread from an infected person through:

- respiratory droplets generated when they cough or sneeze,
- close personal contact, such as touching or shaking hands, or

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- touching something with the virus on it, then touching your mouth, nose or eyes before washing your hands.

In general, coronaviruses are a large family of viruses, some that causes illness in people and others that circulate among animals, including camels, cats and bats.

Q416. Can COVID-19 be transmitted when a person is not showing symptoms?

Now that more countries have had large numbers of cases and have analysed transmission patterns, recent studies provide evidence that transmission of the virus can happen from infected people—before they develop symptoms. We refer to this as *pre-symptomatic transmission*.

There is also evidence that some infected people who never develop symptoms are also able to transmit the virus. This is called *asymptomatic transmission*. We do not know how much of a role pre-symptomatic and asymptomatic transmission play in driving this epidemic at this time—but we know that it is occurring among those with close contact or in close physical settings.

While the primary driver of the global pandemic of COVID-19 has been individuals with visible symptoms (coughing and respiratory droplets are key ways the virus is spread), evidence of asymptomatic or pre-symptomatic transmission points to the importance of everyone, even those who feel fine, following the proven methods of preventing transmission.

To prevent transmission of COVID-19 the following measures are our best defence:

- Staying home and away from others if you are sick
- Washing your hands frequently
- Covering your cough with tissues or your sleeve
- Practicing physical distancing
- Cleaning and disinfecting surfaces and objects
- Protecting those most at risk from the virus

Q417. What are the statistics on asymptomatic cases in Canada?

The Public Health Agency of Canada (PHAC), as well as provincial and territorial public health authorities, are working collaboratively to provide the best available and most accurate information to Canadians. All efforts are made to have timely reporting but, as for any disease surveillance, there are some delays in reporting some of the data.

Provinces and territories report data using the national case report form for COVID-19. Based on 22,217 case report forms received as of April 22, 11:00 AM (EDT), PHAC is aware of 220 cases that were classified as asymptomatic, representing 2.7% of cases for instances where the symptom status was known (n=7,879). Note that the presence of symptoms was unknown for 65% of the cases reported to PHAC.

This is not a true representation of asymptomatic cases because of incomplete data and the fact that COVID-19 testing focuses on symptomatic people. In addition, the case report form data for these cases are preliminary and may have missing values for characteristics of interest. Provinces and territories may not routinely update detailed data. Although the status of the patient may change with illness progression, PHAC does not receive routine updates on patient status.

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Q418. What should you do if you have been exposed to an individual who has a confirmed case of COVID-19?

If you **do not have symptoms**, but believe you were exposed to a source of COVID-19, the Public Health Agency of Canada asks that you, for the next 14 days:

- monitor your health for **fever, cough and difficulty breathing**; and,
- avoid places where you cannot easily separate yourself from others if you become ill.

To further protect those around you, wash your hands often and cover your mouth and nose with your arm when coughing or sneezing.

If you develop symptoms of COVID-19, isolate yourself from others as quickly as possible. Immediately call a health care professional or the public health authority in the province or territory where you are located. Describe your symptoms and travel history. They will provide advice on what you should do.

Q419. Are Canadians at risk for contracting COVID-19 if they touch a surface that could potentially be contaminated?

It is not yet known how long the virus causing COVID-19 lives on surfaces, however, early evidence suggests it can live on objects and surfaces from a few hours to days.

Surfaces frequently touched with hands are most likely to be contaminated. These include doorknobs, handrails, elevator buttons, light switches, cabinet handles, faucet handles, tables, countertops and electronics.

The best way to prevent COVID-19 and other respiratory illnesses is to:

- avoid touching the eyes, nose and mouth;
- consistently use good hand hygiene measures, which includes frequent handwashing with soap under warm running water for at least 20 seconds, or using an alcohol-based or non-alcohol based hand sanitizer approved by Health Canada if soap and water are not available;
- maintain good respiratory etiquette, such as covering your mouth and nose with your arm or sleeve when coughing and sneezing, disposing of any used tissues as soon as possible, and following with handwashing or use of alcohol-based hand sanitizers where soap and water are not available;
- regularly clean and disinfect surfaces that people touch frequently such as toilets, bedside tables, doorknobs, phones and television remotes with a product that cleans and disinfects.

Q420. Are Canadians at risk for contracting COVID-19 from products shipped within or from outside of Canada?

It is not yet known how long the virus causing COVID-19 lives on surfaces, however, early evidence suggests it can live on objects and surfaces from a few hours to days depending on different conditions, such as:

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- Temperature
- type of surface
- humidity of the environment.

Products shipped within or from outside of Canada could be contaminated. However, because parcels generally take days or weeks to be delivered, and are shipped at room temperature, the risk of spread is **low**. There is no known risk of coronaviruses entering Canada on parcels or packages.

To protect yourself from COVID-19, make sure to do the following when handling products shipped within or outside of Canada:

- use good hygiene measures
- regularly clean and disinfect surfaces
- do not touch your eyes, nose and mouth

Q421. Can COVID-19 be transmitted through food, food products or water?

There is currently no evidence to suggest that food is a likely source or route of transmission of the virus and there are currently no reported cases of COVID 19 transmission through food. People are unlikely to be infected with the virus through food. People are unlikely to be infected with the virus through food.

Scientists and food safety authorities across the world are closely monitoring the spread of COVID-19.

The Corona virus has not been identified as a foodborne pathogen.

Coronaviruses are killed by common cleaning and disinfection methods and by cooking food to safe internal temperatures.

If the CFIA becomes aware of a potential food safety risk, appropriate actions will be taken to ensure the safety of Canada's food supply.

Animals

Q422. Can I get this virus from animals in Canada?

The current spread of COVID-19 is a result of human-to-human transmission. There is no evidence to suggest that pets or other animals play a role in transmitting the disease to humans. Scientists are still trying to understand if and how it affects animals.

Q423. Can my pet or other animals get sick from this virus?

It is possible that some types of animals may be able to get infected with COVID-19 virus but it is not yet clear whether they would get sick.

As a precautionary measure, if you have COVID-19 symptoms or are self-isolating due to contact with a COVID-19 case, you should follow similar recommendations around animals, as you would around people in these circumstances:

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- avoid close contact with animals during your illness
    - practise good handwashing and avoid coughing and sneezing on your animals
    - do not visit farms or have contact with livestock
- if possible, have another member of your household care for your animals
    - if this is not possible, always wash your hands before and after touching animals, their food and supplies and practise good cough and sneezing etiquette
- limit your animal's contact with other people and animals outside the household until your illness is resolved

These measures are recommended as a precaution, and are basic practices to prevent transmission of diseases between humans and animals. If you have concerns, seek professional advice from your veterinarian or a public health professional who can help to answer your questions.

The Canadian Food Inspection Agency website has more information about animals and COVID-19.

Q424. Am I at risk of getting COVID-19 if I have contact with an animal recently imported from an affected area (e.g. a dog imported by a rescue organization)?

All animals entering Canada must meet import requirements set out by the Canadian Food Inspection Agency. There are currently no specific requirements in place in Canada restricting animal importation related to the COVID-19 outbreak as there is no evidence that pets or other domestic animals can spread the virus. However, until we know more, importers, rescue organizations and adoptive families should consider limiting or postponing importing animals from affected areas.

Any animals that are imported from an affected area should be closely monitored for signs of illness. If an animal becomes sick, contact your veterinarian and inform them of the situation. Call ahead to ensure they are aware of the circumstances.

Animals imported from other countries can carry a variety of diseases that we don't have in Canada, and that can spread between animals and people. Therefore, it is always a good idea to have a recently imported animal examined by a veterinarian so that they can advise you on appropriate treatments and vaccinations to keep them and your family healthy.
Take these precautions to prevent infectious diseases from spreading between animals and people:

- Always wash your hands after touching animals, their food/supplies, or cleaning up after them;
- Do not kiss animals, share food, or let them lick your face; and
- Regularly clean and disinfect areas where animals live.

Further information on animals and COVID-19 can be found at:

- https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/COV-19/COVID19_21Feb.pdf

- https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters

Q425. What is pediatric multi-system inflammatory syndrome?

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Pediatric multi-system inflammatory syndrome is a rare acute inflammatory illness that primarily affects children.

Q426. What are the symptoms of pediatric multi-system inflammatory syndrome?

Reported symptoms of pediatric multi-system inflammatory include persistent fever, inflammation, poor function in one or more organs, and other clinical and laboratory features.

Q427. What causes pediatric multi-system inflammatory syndrome?

Pediatric multi-system inflammatory syndrome is observed in children after a viral or bacterial infection.

Q428. What is the treatment for pediatric multi-system inflammatory syndrome?

In Canada, the treatment for pediatric multi-system inflammatory syndrome is determined based on the severity of the disease. Some treatments include, and are not limited to, corticosteroids, intravenous immune globulin treatments and anti-inflammatory medications.

Treatment for pediatric multi-system inflammatory syndrome requires the consultation of specialists from infectious diseases, rheumatology, immunology, cardiology and intensive care to determine the best course of action for each patient.

Q429. How common is pediatric multi-system inflammatory syndrome in Canada?

Pediatric multi-system inflammatory syndrome is rare in Canada.

Q430. Does PHAC have current numbers or the rate of incidence across Canada?

PHAC does not have this information at this time. For more information, contact local provincial and territorial public health authorities.

Q431. What is the link between COVID-19 and pediatric multi-system inflammatory syndrome in Canada?

Many children with this inflammatory syndrome did not test positive for COVID-19. Globally, nose swab tests for the COVID-19 virus were often negative, and tests for antibodies were sometimes but not always positive. The fact that patients who tested negative for COVID-19 virus sometimes tested positive for antibodies suggests that inflammatory complications were delayed, occurring when the virus was no longer detectable on nasal swabs.

To date, most children affected have done well and recovered. Some children have required ICU admissions.

Why these cases are emerging only now, and what is causing them, is unknown at this time. It is suspected an immune response to COVID-19 activates an inflammatory process in genetically susceptible children. However, other mechanisms are possible. The global pediatric medical community is rapidly studying this issue.

Health care providers in Canada are aware of this potential syndrome and are on alert to identify cases.

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So far, there have been fewer cases of COVID-19 among children than in adults. Even young people can have serious outcomes or potentially death, so it is important that everyone take precautions to prevent infection.

Q432. Why is Canada doing a review on the COVID-19 evidence on transmission in children?

Monitoring how disease transmission varies across different segments of our population is important for understanding the dynamics of disease transmission. Children have been shown to be important drivers of other respiratory diseases (e.g., influenza). As such, examining whether there is evidence that SARS-COV-2 is spread more or less by children than other age groups is of interest.

Q433. Is there a timeline for the review on transmission in children to be published?

The Public Health Agency of Canada is conducting literature reviews and evidence syntheses on various topics relevant to the COVID-19 response, including a recent rapid review of evidence on transmission in children. The Agency will provide the details of literature review results through reputable scientific publications and websites. The process for these publications is already underway.

Q434. Is the information being reviewed or is the Government working with any facilities?

These rapid reviews are conducted by individuals with a variety of backgrounds—including synthesis research, infectious diseases and epidemiology—with the purpose of providing a summary of the existing evidence that can be used in decision-making. The Agency is working with the National Collaborating Centres and other external partners in collating evidence to guide Canada's response to COVID-19.

PREVENTION AND RISKS

Q435. How can I protect myself from this virus?

You can stay healthy and prevent the spread of infections by:

- washing your hands often with soap under warm running water for at least 20 seconds;
- using alcohol-based or non-alcohol based hand sanitizer approved by Health Canada only if soap and water are not available;
- avoiding touching your eyes, nose or mouth with unwashed hands;
- avoiding contact with sick people, especially if they have fever, cough, or difficulty breathing;
- covering your mouth and nose with your arm to reduce the spread of germs;
- staying home if you become sick to avoid spreading illness to others.

Q436. Should the general population in Canada wear masks to protect themselves from this virus?

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To prevent transmission of COVID-19 the following measures are our best defence:

Staying home and away from others if you are sick

- Washing your hands frequently
- Covering your cough with tissues or your sleeve
- Practicing physical distancing
- Cleaning and disinfecting surfaces and objects
- Protecting those most at risk from the virus

Healthcare workers need medical masks, including surgical, medical procedure masks and respirators such as N95 masks. It is extremely important that we keep the supply of medical masks for healthcare workers where it is urgently needed for medical procedures and to care for individuals who have COVID-19.

Wearing a non-medical mask or face covering (i.e. constructed to completely cover the nose and mouth without gaping, and secured to the head by ties or ear loops) in the community has not been proven to protect the person wearing it. However, the use of a non-medical mask or facial covering can be an additional measure you can take to protect others around you.

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

For short periods of time when physical distancing is not possible in public settings (e.g., grocery shopping, in close settings such as public transit), wearing a non-medical mask is one way to protect those around you.

Non-medical masks or facial coverings should not be placed on young children under age 2, anyone who has trouble breathing, or is unconscious, incapacitated or otherwise unable to remove the mask without assistance.

Q437. What was the thinking behind the change of advice for wearing masks? What informed that advice?

Canadian public health guidance related to COVID-19 has been evolving as the evidence base and understanding of the new virus grows. We are continually reviewing the latest scientific evidence as it develops and working with our partners across the country and around the world to learn more. From the beginning of the COVID-19 outbreak, masks were recommended for symptomatic people suspected of or confirmed to have COVID-19 when they were within two metres of other people or if they were leaving their home for essential reasons (i.e., to seek medical care). Masks were not recommended for widespread use by healthy people in the community.

Thinking about the use of masks has evolved with emerging evidence that the virus can be transmitted by infected people before they develop symptoms (pre-symptomatic transmission). There is also evidence that some infected people who never develop symptoms are also able to transmit the virus (asymptomatic transmission). It is not known how much of a role pre-

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symptomatic and asymptomatic transmission plays in driving the COVID-19 epidemic at this time—but that it is occurring among those with close contact or in close physical settings. This evidence has led to advice by the Council of Chief Medical Officers of Health that people could wear non-medical masks and face coverings as an additional layer of protection in settings where physical distancing might not be possible.

Health care workers working on the frontline of the COVID-19 pandemic need medical masks, including surgical, medical procedure masks, and respirators such as N95 masks and it is extremely important that we keep the supply of medical masks for them. While wearing a non-medical mask/face covering in the community has not been proven to protect the person wearing it, it is an additional measure individuals can take to protect others around them.

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

It is important to note that wearing a non-medical mask does not replace the proven methods of transmission prevention, including:

- Staying home when ill
- Physical distancing
- Hand hygiene
- Protecting the most vulnerable from infection and exposure to others
- Covering your cough with non-medical mask, tissues or sleeve

Q438. Has Health Canada seen an increase in calls from people reporting illnesses related to cleaning products and disinfectants during the COVID-19 pandemic? Have there been more cases of people misusing cleaning products, such as not properly using bleach or mixing products together since the COVID-19 outbreak?

Health Canada and the five regional poison centres from across Canada have been working together to analyze numbers of poison centre calls related to exposures to cleaning products. Data are collected by the poison centres and have been shared with Health Canada for compilation in order to obtain a pan-Canadian overview.

The assessment compared numbers of reported exposures in 2019 and 2020. Data from January 2019 was not included because information from one poison centre was not available. In addition, data from April 2020 is not yet available.

Comparing reports in February and March 2019 to data from the same months in 2020, poison centres saw a 58% increase in the number of reported exposures that were related to cleaning products, bleaches, disinfectants, hand sanitizers, and chlorine and chloramine gases (i.e., those cases generated when cleaners are combined with bleach).

The increase in reports may be due to a variety of factors, including:

- individuals—including children—spending more time at home;
- increased volume of cleaning products available in households because of increased purchases as preparedness measure; and

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- increased availability of products because of increased cleaning and disinfection practices at home and elsewhere.

Health Canada is monitoring this evolving situation closely and has taken action to inform Canadians on the safe use and storage of cleaning and disinfectant products through regular social media postings and its website.

Q439. Can vaping/smoking/doing drugs damage the lungs - making someone more vulnerable to COVID-19?

No direct evidence has been published on vaping or drug use and associations with COVID-19 disease outcomes.

Studies which have looked at the association between smoking and COVID-19 disease severity indicate that smokers may be more susceptible than non-smokers.

Q440. In the US, people under age 44 make up a large proportion of hospitalizations. What are we seeing with younger people in Canada?

In Canada, people under the age of 40 make up 31% of cases. Compared to other age groups, people under the age of 40 have milder illness with only 9% of hospitalizations and 4% of ICU admissions being reported from this age group. (These numbers are subject to change as new cases are identified and the situation evolves.)

Q441. What is your message to young people (especially those who smoke/vape/do drugs) who think they are immune to COVID-19?

Everyone is susceptible to this virus – you are not immune. Vaping can increase your exposure to chemicals that could harm your health (e.g., cause lung damage). It is also important to remember that vaping or drug use equipment should never be shared with others. At this time it is particularly important to maintain a healthy lifestyle.

Q442. PHAC assessed the public health risk within Canada to Covid-19 as "low" as recently as Feb. 22. When did that risk assessment change? What is the current public health risk assessment for the virus within Canada?

The public health risk assessments reported in the Health Portfolio Situation Reports were based on the risk of COVID-19 to Canadians in Canada at that time. On February 22, 2020, the risk to the public within Canada was low, as there was no evidence that COVID-19 was circulating within the Canadian population. On March 5, an updated risk assessment was reported that measured the current risk as low for the general population, and moderate for the elderly and those with underlying medical conditions.

The appearance of community spread of COVID-19 within the Canadian population prompted an increase in the risk level. The current public health risk assessment for the virus within Canada, in place since March 16, is considered high for the full population.

5G TECHNOLOGY AND COVID-19

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Q443. What is the Government of Canada's role with respect to wireless communication technology?

The Government of Canada's approach to radiofrequency exposure safety is among the most stringent in the world. Health Canada's mandate regarding human exposure to radiofrequency electromagnetic fields is to carry out research into possible health effects, monitor the relevant scientific literature, and develop recommended human exposure limits in a guideline commonly referred to as Safety Code 6. We continuously monitor the research and scientific literature on the health effects of radiofrequency exposure to ensure that the recommended limits in Safety Code 6 are consistent with the current scientific consensus to prevent potential adverse health effects.

Innovation, Science and Economic Development Canada (ISED) is responsible for the deployment of 5G wireless technology. To help protect Canadians, ISED has adopted the limits in Health Canada's Safety Code 6 for wireless devices and their associated infrastructure.

Safety Code 6 has always maintained an exposure limit below the threshold for the occurrence of all established adverse health effects. The Government of Canada continues to monitor the best available evidence, and will take appropriate action should new scientific evidence emerge.

Q444. What is Safety Code 6?

Safety Code 6 is Canada's radiofrequency exposure guidelines. Safety Code 6 covers all frequencies (and combinations thereof) in the range from 3 kHz to 300 GHz. This range includes the frequencies used by existing communications devices, as well as those that may be used by devices employing 5G technology (i.e., above 6 GHz).

Q445. How does Safety Code 6 protect Canadians' health?

The recommended limits in Safety Code 6 are designed to protect all Canadians from all scientifically established adverse health effects from exposure to radiofrequency electromagnetic fields. These effects are tissue heating (like the warming of your skin) and nerve stimulation (a tingling sensation in the skin). This means that if anyone, including a small child, were exposed to radiofrequency energy from multiple sources within the Safety Code 6 limits for 24 hours a day, 365 days a year, they would not experience adverse health effects.

Q446. Are radiofrequency exposures from cell phone towers and antenna installations safe?

Yes, radiofrequency exposures from cell phone towers and antenna installations are safe. There is no scientific basis for the recent suggestion linking the deployment of 5G networks and the spread of COVID-19. The World Health Organization and the International Commission for Non-Ionizing Radiation Protection have also recently communicated this message on their websites. ISED manages the use of the radio spectrum and requires that all antenna systems meet the limits in Safety Code 6 in order to protect the public from overexposure. Additional information on antenna towers can be found at www.ic.gc.ca/towers.

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Q447. How does Canada compare to other countries in regulating radiofrequency emissions?

The exposure limits in Safety Code 6 are consistent with the science-based standards used in other parts of the world, including the United States, the European Union, Japan, Australia and New Zealand. Internationally, while a few jurisdictions have applied more restrictive limits for exposure to radiofrequency electromagnetic fields from cell towers, scientific evidence does not support the need for limits that are more restrictive than those in Safety Code 6.

The exposure limits in Safety Code 6, and the conclusions of Health Canada, are similar to those of the International Commission on Non-Ionizing Radiation Protection, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks, and the World Health Organization.

SAFETY OF EMPLOYEES

Q448. What is Health Canada doing to ensure federal employees are taking the appropriate precautions?

Health Canada's Public Service Occupational Health Program (PSOHP) provides occupational health services and occupational hygiene consultative services to Government of Canada departments.

As per usual protocols for these types of situations, PSOHP issued a general Occupational Health Advisory to departments and agencies which provided information on novel coronavirus and recommended precautions for employees such as: frequent hand hygiene, proper cough and sneeze etiquette, and self-monitoring for symptoms.

The advice and information is based on the science and risk level as assessed by the Public Health Agency of Canada and the World Health Organization.

In addition, given the variety of federal work settings, PSOHP developed supplemental advice for specific workplaces. The first priority was advice for employees based at airports who interact with travelers, for example, what personal protective equipment should be used when searching luggage or escorting an ill traveller. Health Canada Occupational health nurses are also supported our departmental partners with information sessions for personnel at airports and CFB Trenton.

The department is also working with Global Affairs Canada to ensure that departments and agencies with employees in affected countries have all of the occupational health information they require.

Health Canada's occupational health experts will continue to work closely with departments to ensure the health and safety of employees in the federal public service.

Q449. What protocols did Health Canada follow after receiving confirmation that an employee tested positive for COVID-19?

A Health Canada employee who works at Tunney's Pasture has tested positive for COVID-19. The employee is in self-isolation and is following the direction of local public health authorities.

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The Department followed established protocols:

- The area where the employee works, including common areas, has been properly cleaned, according to Public Services and Procurement Canada standards. This was done in collaboration with Statistics Canada as the two departments share common work space.

In addition, local public health authorities have been in contact with the employee for any relevant contact tracing. This involved contacting certain colleagues who have also been advised to self-isolate by local public health authorities.

The Government of Canada has asked teleworking to be used whenever and wherever possible, subject to each department's operating requirements. Departments and agencies are actively exercising this flexibility. We are constantly re-assessing the situation and striving to balance both our duty to Canadians and the health and safety of all public servants.

The government is working on a means to centralize information on confirmed cases within the public service. Treasury Board Secretariat has been working closely with Health Canada and the Public Health Agency of Canada to provide workplace-related information and advice to departments and agencies so they can manage their workforce accordingly.

Q450. Can you confirm that a number of employees who work at Canada's National Microbiology Laboratory in Winnipeg have tested positive for COVID-19?

Two employees who work at Canada's National Microbiology Laboratory in Winnipeg have tested positive for COVID-19. The employees are in self-isolation and are following the direction of the local public health authority. Contact tracing is underway by local public health who will implement all follow-up procedures necessary to prevent the spread of the virus.

Consistent with usual laboratory protocol, procedures for cleaning and disinfection of work areas and common spaces have been followed. Our employees continue to practice effective public health measures, including social distancing, hand-washing, and respiratory etiquette.
It is not unexpected that we would see cases amongst our workforce as COVID-19 infection is circulating in our community. We are prepared for such circumstances through business continuity plans that ensure that the NML's essential operations continue in circumstances where employees are ill or absent. For those employees whose duties allow them to work from home, this arrangement is supported as part of the Government of Canada's policy for all federal workers during the COVID-19 pandemic. We wish our employees a speedy recovery and are thinking of them and their families during this difficult time.

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