Sunnybrook
RESEARCH INSTITUTE

Research team has isolated the COVID-19 virus

March 12, 2020

Pictured left to right: Dr. Robert Kozak, Dr. Samira Mubareka, Dr. Arinjay Banerjee

A team of researchers from Sunnybrook, McMaster University and the University of Toronto has isolated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the agent responsible for the ongoing outbreak of COVID-19.

Thanks to nimble collaboration, the team was able to culture the virus from two clinical specimens in a Level 3 containment facility.

“We need key tools to develop solutions to this pandemic. While the immediate response is crucial, longer-term solutions come from essential research into this novel virus,” said Dr. Samira Mubareka, microbiologist and infectious diseases physician at Sunnybrook.

The isolated virus will help researchers in Canada and across the world develop better diagnostic testing, treatments and vaccines, and gain a better understanding of SARS-CoV-2 biology, evolution and clinical shedding.

“Researchers from these world-class institutions came together in a grassroots way to successfully isolate the virus in just a few short weeks,” said Dr. Rob Kozak, clinical microbiologist at Sunnybrook. “It demonstrates the amazing things that can happen when we collaborate.”

Dr. Arinjay Banerjee, NSERC post-doctoral fellow at McMaster University, said he knows the collaboration won’t stop there.

“Now that we have isolated the SARS-CoV-2 virus, we can share this with other researchers and continue this teamwork,” he said. “The more viruses that are made available in this way, the more we can learn, collaborate and share.”

Congratulations to the researchers from these three Canadian institutions: Dr. Samira Mubareka and Dr. Rob Kozak of Sunnybrook and University of Toronto; Dr. Arinjay Banerjee and Dr. Karen Mossman of McMaster University.

With gratitude to the CL3 team and Biosafety O. cers.

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Two Canadian teams of scientists isolate coronavirus to speed research effort

IVAN SEMENIUK › SCIENCE REPORTER

PUBLISHED MARCH 13, 2020
UPDATED MARCH 15, 2020

PUBLISHED MARCH 13, 2020

This article was published more than 1 year ago. Some information in it may no longer be current.

The researchers involved in isolating the virus: Dr. Rob Kozak and Dr. Samira Mubareka of the University of Toronto, and Dr. Arinjay Banerjee of McMaster University.

HANDOUT/SUNNYBROOK HOSPITAL

Two teams of Canadian scientists have isolated the coronavirus that causes COVID-19 and successfully reproduced it in the laboratory.

The accomplishment means that researchers who are looking to test screening methods, therapies and vaccines now have Canadian sources that can provide access to the global pathogen without them having to undertake the complicating step of shipping live virus across international borders.

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"The significance for us is that it serves as a tool," said Samira Mubareka, a microbiologist at Sunnybrook Health Sciences Centre in Toronto and member of one of the teams. "Now that we have this virus in hand it means that we have material for a number of things."

Dr. Mubareka and her colleagues at McMaster University in Hamilton and the University of Toronto worked in a facility in the Toronto area with the appropriate containment level to handle the new coronavirus safely. They announced their feat on Thursday.

On Friday, Paul Hodgson, associate director of business development at the Vaccine and Infectious Disease Organization-International Vaccine Centre in Saskatoon, confirmed to The Globe and Mail that the joint federal-provincial facility had quietly reached the same milestone a few weeks earlier and is now using its version of the virus for a vaccine development effort.

Samples of the Saskatoon-derived version of the coronavirus are now available for approved research groups through the National Microbiological Laboratory in Winnipeg. The Ontario group also plans to generate its version for distribution.

The spread of the novel coronavirus that causes COVID-19 continues, with more cases diagnosed in Canada. The Globe offers the dos and don'ts to help slow or stop the spread of the virus in your community.

In both cases, the virus was isolated from clinical samples obtained from patients at Sunnybrook, the first hospital in Canada to treat someone with COVID-19. However, the Toronto and Saskatoon isolates are from different

patients and so may vary in ways that will be important for scientists looking to detect or target the virus.

They are also different from a version of the virus isolated by the U.S. Centers for Disease Control and Prevention and documented in a paper posted online last week. That version is intended to be the reference strain for scientists working in the United States.

“I think having multiple virus isolates is incredibly valuable,” Dr. Hodgson said. “We can see whether one vaccine or therapy works across all the virus strains ... if there are known [genetic] variations.”

Dr. Mubareka said that for the Ontario-based team, the process of isolating the virus began with a relatively standard procedure that did not work the first time. Hurdles along the way had to be surmounted with some additional scientific tricks. The group ultimately succeeded in getting the virus to reproduce in animal cells that were engineered to have no immune response and specially treated to enhance the likelihood of infection.

The first sign that the method was working surfaced when the group spotted “plaques” in their cell cultures –patches of dead cells that were destroyed by the virus.

“We did the infection from clinical specimens on a Friday,” said Arinjay Banerjee, a postdoctoral researcher at McMaster University’s Institute for Infection Disease Research. “Then to go back on Monday and see all [the] cells dead – that was pretty exciting. That was step one.”

Dr. Mubareka said that one of the first uses for the isolate would be to act as a control to make sure that tests used by health-care workers to identify

the virus are performing as expected. It could also serve as a “challenge” strain for antiviral drugs and vaccines currently in development.

Karen Mossman, a professor of pathology and molecular medicine at McMaster, said that researchers there would be working with the isolates to better understand details about the biology of COVID-19, including how the virus works to counteract the human immune response.

She added that there was a certain irony in trying so hard to create a virus that “everyone else is trying to get rid of.”

Dr. Hodgson said the virus isolated in Saskatoon has now been used to establish the virus in ferrets that can be used to test the efficacy of vaccines in living organisms before human clinical trials commence.

Last week, the western facility received a $1-million grant to advance its work as part of a funding competition organized by the Canadian Institutes for Health Research, which selected 47 teams working on various aspects of the COVID-19 outbreak.

The Ontario collaboration was not among the winners and, until now, a lack of funding has been the team’s biggest challenge, Dr. Mubareka said.

On Friday, the federal agency said it would be able to support 49 additional projects with a portion of the $1.1-billion COVID-19 response package announced earlier in the week by Prime Minister Justin Trudeau. Among them is a proposal by Dr. Mossman’s group at McMaster to study the biology of how the virus interacts with its hosts and to model this interaction in laboratory experiments

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THE CONVERSATION

Academic rigour, journalistic flair

I study viruses: How our team isolated the new coronavirus to fight the global pandemic

March 25, 2020 3.10pm EDT

Coronaviruses get their name from the crown, or corona, of spikes that adorn the outer surface of the virus, as seen on this illustration of a highly magnified virus. (U.S. Centers for Disease Control and Prevention)

Author

Karen Mossman
Professor of Pathology and Molecular Medicine and Acting Vice President, Research, McMaster University

As most people rush to distance themselves from COVID-19, Canadian researchers have been waiting eagerly to get our (gloved) hands on the hated virus.

We want to learn everything we can about how it works, how it changes and how it interacts with the human immune system, so we can test drugs that may treat it, develop vaccines and diagnostics and prevent future pandemics.

This is what researchers live to do. Much of our everyday work is incremental. It’s important and it moves the field forward, but to have a chance to contribute to fighting a pandemic is especially inspiring and exciting.

The secret lives of viruses

Viruses are fascinating. They are inert microscopic entities that can either hide out, innocuous and undetected, or wreak pandemic havoc.

They are simultaneously complex and simplistic, which is what makes them so interesting — especially new, emerging viruses with unique characteristics. Researching viruses teaches us not only about the viruses we study, but also about our own immune systems.

Read more: ***Coronavirus weekly: expert analysis from The Conversation global network***

The emergence of a new coronavirus in a market in Wuhan, China, in December 2019 set in motion the pandemic we are now witnessing in 160 countries around the world. In just three months, the virus has infected more than 360,000 people and killed more than 16,000.

A health-care worker arrives at a walk-in COVID-19 test clinic in Montréal on March 23, 2020. Paul Chiasson/THE CANADIAN PRESS

Viral isolation

The outbreak sent researchers around the world racing to isolate laboratory specimens of the virus that causes COVID-19. The virus was later named severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2.

In countries that experienced earlier outbreaks, including China, Australia, Germany and the United States, researchers were able to isolate the virus and develop their own inventories of SARS-CoV-2, but logistical and legal barriers prevented them from readily sharing their materials with researchers beyond their borders.

What Canadian researchers needed to join the fight in earnest was a domestic supply of clean copies of the virus — preferably from multiple Canadian COVID-19 cases. Even in a pandemic, developing such a supply is not as easy as it might sound, and multiple teams in Canada set out to isolate and develop pure cultures of the virus, not knowing which would be successful, or when.

Ultimately two teams in Canada would isolate the virus for study: one at the University of Saskatchewan and one that featured researchers from McMaster University, Sunnybrook Health Sciences Centre and the University of Toronto.

Arinjay Banerjee, a postdoctoral research fellow at McMaster who typically works in my virology lab, volunteered his special expertise. We were proud to have him share his talent with the team in Toronto, where he set to work with physicians and researchers Samira Mubareka, Lily Yip, Patryk Aftanas and Rob Kozak.

For Banerjee, it was like a batter being called to the plate with the score tied in the bottom of the ninth. He had come to work at McMaster because of its Institute for Infectious Disease Research and its Immunology Research Centre, and because the university maintains a research colony of bats.

Banerjee's PhD work at the University of Saskatchewan, and now at McMaster, has focused on bats and how their viruses, including coronaviruses, interact with bat and human antiviral responses. Over the past few years, studies have shown that bat coronaviruses have the capacity to infect human cells. Multiple researchers had predicted a coronavirus that would evolve and jump into humans.

Read more: It's wrong to blame bats for the coronavirus epidemic

Ideal viral conditions

Isolating a virus requires collecting specimens from patients and culturing, or growing, any viruses that occur in the samples. These viruses are obligate intracellular parasites, which means that they can only replicate and multiply in cells. To isolate a particular virus, researchers need to provide it with an opportunity to infect live mammalian cells, in tiny flasks or on tissue culture plates.

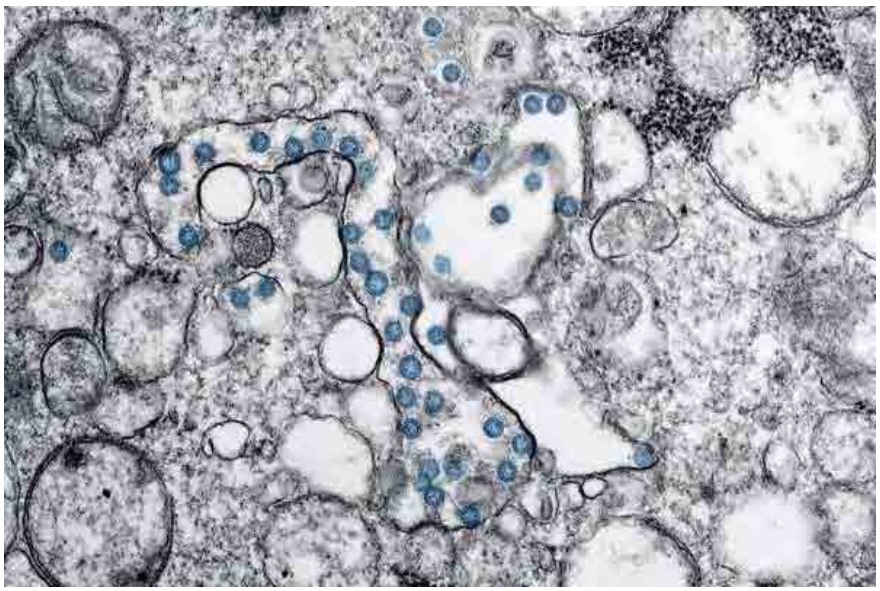
Viruses adapt to their hosts and evolve to survive and replicate efficiently within their particular environment. When a new virus such as SARS-CoV-2 emerges, it isn't obvious what particular environment that virus has adapted to, so it can be hard to grow it successfully in the lab.

We can use tricks to draw out a virus. Sometimes the tricks work and sometimes they don't. In this case, the researchers tried a method Banerjee and the team had previously used while working on the coronavirus that causes Middle Eastern Respiratory Syndrome: culturing the virus on immunodeficient cells that would allow the virus to multiply unchecked. It worked.

Since specimens from patients are also likely to contain other viruses, it is critical to determine if a virus growing in the culture is really the target coronavirus. Researchers confirm the source of infection by extracting genetic material from the virus in culture and sequencing its genome.

They compare the sequence to known coronavirus sequences to identify it precisely. Once a culture is confirmed, researchers can make copies to share with colleagues.

All this work must be done in secure, high-containment laboratories that mitigate the risk of accidental virus release into the environment and also protect scientists from accidental exposure. The more versions of a virus that can be isolated, the better. Having multiple virus isolates allows us to monitor how the virus is evolving in humans as the pandemic progresses. It also allows researchers to test the efficacy of vaccines and drugs against multiple mutations of the virus.



Transmission electron microscopic image of an isolate from the first U.S. case of COVID-19. The spherical viral particles, colourized blue, contain cross-sections through the viral genome, seen as black dots. (U.S. CDC)

Canadian viral strains

Both the Saskatchewan and Ontario teams are now able to make and share research samples with other Canadian scientists, enabling important work to proceed, using a robust domestic supply that reflects the evolving virus in its most relevant mutations.

That in turn gives Canadian researchers a fighting chance to deliver a meaningful blow to COVID-19 while there is still time. I'm glad our colleagues at other Canadian institutions will also have versions of the virus to use in their research.

There is still so much work for all of us to do.

Pandemic Canada Coronavirus Viruses Middle East Respiratory Syndrome (MERS) COVID-19 SARS-CoV-2

Isolation, Sequence, Infectivity, and Replication Kinetics of Severe Acute Respiratory Syndrome Coronavirus 2

Arinjay Banerjee, Jalees A. Nasir,[1] Patrick Budylowski,[1] Lily Yip, Patryk Aftanas, Natasha Christie, Ayoob Ghalami, Kaushal Baid, Amogelang R. Raphenya, Jeremy A. Hirota, Matthew S. Miller, Allison J. McGeer, Mario Ostrowski, Robert A. Kozak, Andrew G. McArthur, Karen Mossman, Samira Mubareka

Since its emergence in Wuhan, China, in December 2019, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has infected ≈6 million persons worldwide. As SARS-CoV-2 spreads across the planet, we explored the range of human cells that can be infected by this virus. We isolated SARS-CoV-2 from 2 infected patients in Toronto, Canada; determined the genomic sequences; and identified single-nucleotide changes in representative populations of our virus stocks. We also tested a wide range of human immune cells for productive infection with SARS-CoV-2. We confirm that human primary peripheral blood mononuclear cells are not permissive for SARS-CoV-2. As SARS-CoV-2 continues to spread globally, it is essential to monitor single-nucleotide polymorphisms in the virus and to continue to isolate circulating viruses to determine viral genotype and phenotype by using in vitro and in vivo infection models.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged in December 2019 in Wuhan, China (*1*). SARS-CoV-2 has since spread to ≈185 countries and infected ≈6 million persons, among whom ≈380,000 have died (*2*). On January 23, 2020, a case of coronavirus disease (COVID-19) was detected in Toronto, Canada (*3*); since then, multiple cases have been identified across Canada. As SARS-CoV-2 spreads globally, the virus is likely to adapt and evolve. It is critical to isolate SARS-CoV-2 viruses to characterize their ability to infect and replicate in multiple human cell types and to determine if the virus is evolving in its ability to infect human cells and cause severe disease. Isolating the virus also provides the opportunity to share the virus with other researchers for development and testing of diagnostics, drugs, and vaccines.

We isolated SARS-CoV-2 from 2 patients with COVID-19 and determined the genomic sequence of each isolate (SARS-CoV-2/SB2 and SARS-CoV-2/SB3-TYAGNC). In addition, we studied the replication kinetics of SARS-CoV-2/SB3-TYAGNC in human fibroblast, epithelial, and immune cells.

Methods

Cells

We maintained Vero E6 cells (African green monkey cells; American Type Culture Collection [ATCC], https://www.atcc.org) in Dulbecco's modified Eagle medium (DMEM) supplemented with 10% fetal bovine serum (FBS) (Sigma-Aldrich, https://www.sigmaaldrich.com) and 1× L-glutamine and penicillin/streptomycin (Pen/Strep; Corning, https://ca.vwr.com). Calu-3 cells (human lung adenocarcinoma derived; ATCC) were cultured as previously mentioned (*4*), as were THF cells (human telomerase life-extended cells) (*5*). THP-1 cells (monocytes; ATCC) were cultured in RPMI medium (Gibco Laboratories, https://www.thermofisher.com) supplemented with 10% FBS, 2mM L-glutamine, 1× penicillin/

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DOI: https://doi.org/10.3201/eid2609.201495

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streptomycin, and 0.05 mM β-mercaptoethanol. THP-1 cells (monocytes and differentiated macrophages and dendritic cells) were differentiated into macrophages by using 50 ng/mL lymphocyte/granulocyte/macrophage–colony stimulating factor (LGM-CSF; R&D Systems, https://www.rndsystems.com) plus 50 ng/mL macrophage–colony stimulating factor (R&D Systems) and into dendritic cells by using 50 ng/mL granulocyte/macrophage-colony stimulating factor (GM-CSF; R&D Systems) plus 500 U/mL interleukin-4 (BioLegend, https://www.biolegend.com). We purified peripheral blood mononuclear cells (PBMCs) from 2 healthy donors (OM8066 and OM8067) into CD4+, CD8+, CD19+, monocytes, and other cells (CD4–, CD8–, CD19–) by using a CD4+ selection kit that uses immunomagnetic negative selection, a CD8+ selection kit, a phycoerythrin-positive selection kit, and a monocyte-negative selection kit, all by STEMCELL Technologies (https://www.stemcell.com; Appendix Figure 1, https://wwwnc.cdc.gov/EID/article/26/9/20-1495-App1.pdf). We resuspended CD4+, CD8+, CD19+ and CD4–, CD8–, CD19– cells in R-10 media (RPMI + 2 mM L-glutamine + 10% FBS + penicillin/streptomycin) plus 20 U/mL interleukin-2. Primary monocytes were resuspended in R-10 media. This work was approved by the Sunnybrook Research Institute Research Ethics Board (149–1994) and the Research Ethics Boards of St. Michael's Hospital and the University of Toronto (REB 20–044; for PBMCs).

Isolation and Quantification

We seeded Vero E6 cells at a concentration of 3×10^5 cells/well in a 6-well plate. The next day, we collected 200 μL of mid-turbinate swab samples from 2 COVID-19 patients, mixed it with 200 μL of DMEM containing 16 μg/mL TPCK-treated trypsin and inoculated the cells. After 1 h, the inoculum was replaced with DMEM containing 2% FBS and 6 μg/mL TPCK-treated trypsin. We observed the cells daily under a light microscope. Supernatant from the cells was used to determine virus titers (50% tissue culture infectious dose [$TCID_{50}$]/mL) according to the Spearman and Karber method (*6*,*7*) as outlined previously (*8*).

Quantitative Real-Time PCR

To detect SARS-CoV-2 in cell culture supernatant, we removed 140 μL of supernatant and performed detection of viral nucleic acids by reverse transcription PCR (RT-PCR), following an adaptation of the Corman et al. protocol (*9*). In brief, we extracted viral RNA from infected cells by using a QIAamp viral RNA kit (QIAGEN, https://www.qiagen.com) according to the manufacturer's instructions. The RT-PCR reactions were conducted by using Luna Universal qPCR Master Mix (New England Biolabs, https://www.neb.ca) according to the manufacturer's instructions. Two separate gene targets were used for detection, the 5′ untranslated region (UTR) and the envelope (E) gene. Primers and probes used were 5′ UTR forward GTTGCAGCCGATCATCAGC, 5′ UTR reverse GACAAGGCTCTCCATCTTACC, and 5′ UTR probe FAM-CGGTCACACCCGGAC-GAAACCTAG-BHQ-1; and E-gene forward CAG-GTACGTTAATAGTTAATAGCGT, E-gene reverse ATATTGCAGCAGTACGCACACA, and E-gene probe CAL Fluor Orange 560-ACACTAGCCATCCT-TACTGCGCTTCG-BHQ-1. The cycling conditions were 1 cycle of denaturation at 60°C for 10 min, then 95°C for 2 min, followed by 44 amplification cycles at 95°C for 10 s and 60°C for 15 s. Analysis was performed by using Rotor-Gene Q software (QIAGEN) to determine cycle threshold (C_t).

Electron Microscopy

Samples were fixed in 10% neutral buffered formalin (Sigma-Aldrich), for 1 h. Pellets were washed with 0.1 M phosphate buffer (pH 7.0) and postfixed with 1% osmium tetroxide in 0.1 M phosphate buffer (pH 7.0) for 1 h. Pellets were washed with distilled water and en-bloc stained with 2% uranyl acetate in distilled water for 2 h. Pellets were washed with distilled water and dehydrated in a series of ethanol concentrations. Pellets were infiltrated with Araldite Embed 812 resin (VWR, https://us.vwr.com) and cured at 65°C for 48 h. Resin blocks were trimmed, polished, and 9 nm thin sections were ultramicrotomed (Leica Reichert Ultracut E, https://www.leica-microsystems.com) and mounted on transmission electron microscopy grids. Thin sections were stained with 5% uranyl acetate and 5% lead citrate. Sections were imaged by using transmission electron microscopy (Talos L120C; ThermoFisher Scientific, https://www.thermofisher.com) and an LaB6 (lanthanum hexaboride) filament at 120 kV. We scanned 10 fields per cell type, each at a different magnification level: 2,600×, 8,500×, 17,500×, and 36,000×.

Immunofluorescence

To detect SARS-CoV-2 proteins in Vero E6 and CD4+ T lymphocytes, we infected cells with SARS-CoV-2 at a 0.1 multiplicity of infection (MOI) for 24 h. After 24 h, we fixed the cells in 10% neutral buffered formalin (Sigma-Aldrich). After fixation, cells were permeabilized and blocked as previously described (*10*). Cells were stained in suspension by using a

previously described protocol (*10*). For primary antibody staining, we used a combination of 6.6 μg/mL rabbit anti-SARS-CoV-2 N (BioVision, https://www.biovision.com) plus 10 μg/mL recombinant human anti-SARS-CoV-2 spike S1 (GenScript, https://www.genscript.com) and 1:100 diluted serum from a recovered COVID-19 patient (OM8073) (Figure 1, panels A, B). To confirm SARS-CoV-2 staining in CD4+ T cells, we used 10 μg/mL recombinant human SARS-CoV-2 spike S1 antibody as primary staining antibody (GenScript) alone (Figure 1, panel C). For secondary antibodies, we used 1 μg/mL mouse anti-human FITC (BioLegend) and 4 μg/mL goat anti-rabbit Alexa Fluor 488 (abcam, https://www.abcam.com). After staining, cells were spun at 500 × *g* for 5 min in a 96-well plate. The cells were observed under an EVOS FL digital microscope (VWR).

Flow Cytometry

To prepare cells for flow cytometry, we washed 100 μL (400,000 cells) of primary CD4+, CD8+, and CD19+ cells and monocytes with 1 mL of phosphate-buffered saline (PBS) and spun the cells at 500 *g* for 5 min. The cells were resuspended in 100 μL of Live/Dead

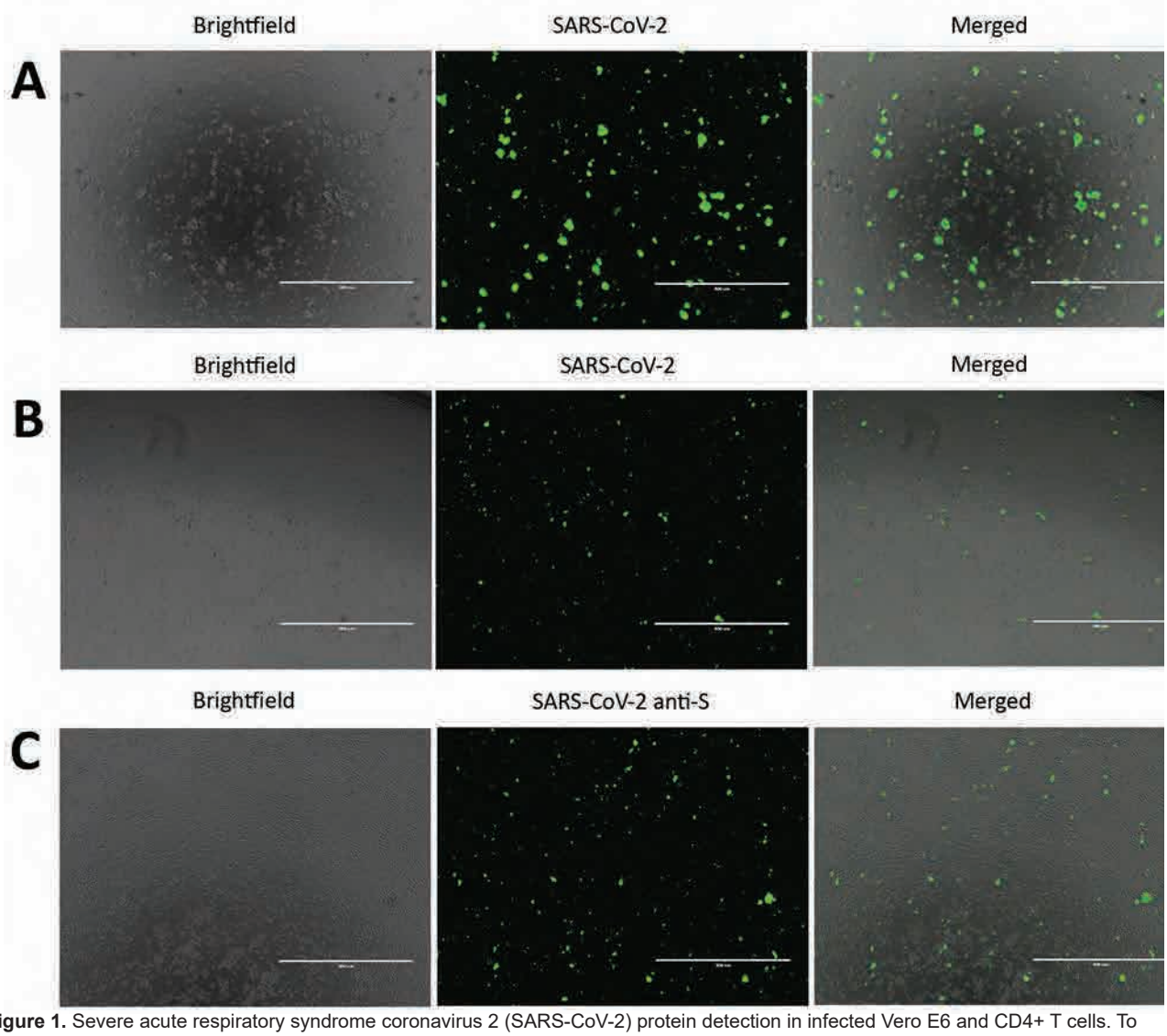

Figure 1. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) protein detection in infected Vero E6 and CD4+ T cells. To detect SARS-CoV-2 protein expression, we infected Vero E6 and CD4+ T cells with SARS-CoV-2 at a multiplicity of infection of 0.1 for 24 h. We immunostained these cells and observed them by using fluorescent microscopy. A) SARS-CoV-2–infected and immunostained Vero E6 cells. B) SARS-CoV-2–infected and immunostained CD4+ T cells. For panels A and B, cells were stained by using an antibody cocktail consisting of SARS-CoV-2 S1 antibody, SARS-CoV-2 N antibody, and diluted serum from a recovered coronavirus disease patient. C) SARS-CoV-2 infected CD4+ T cells immunostained with SARS-CoV-2 S1 antibody (anti-S). Scale bars indicate 400 μm; original magnification ×10.

Violet stain (ThermoFisher Scientific) according to the manufacturer's recommendation and diluted 1:1,000 in PBS. Cells were incubated at 4°C for 30 min. Next, cells were washed with 1 mL of fluorescence-activated cell sorting buffer (in-house reagent) and spun at 500 × *g* for 5 min. Cells were then stained with 100 µL of their respective stains (αCD4-FITC, αCD8-FITC, αCD19-FITC, αCD14-APC; BioLegend) at a concentration of 1 µg/mL for 30 min at 4°C. After staining, the cells were washed with 1 mL of fluorescence-activated cell sorting buffer and spun at 500 × *g* for 5 min. Extra aliquots of cells were left unstained and also spun at 500 × *g* for 5 min. The pellets were resuspended in 100 µL of 1% paraformaldehyde (ThermoFisher Scientific) and analyzed. Samples were run on the BD LSRFortessa X-20 (BD, https://www.bdbiosciences.com). To exclude debris and dead cells, we stained the cells with Live/Dead Violet stain, which stains dead cells brightly. Cells were then analyzed on a flow cytometer, and brightly stained cells were excluded. The remaining cells were then analyzed for the expression of their respective cell surface markers to assess purity.

Sequencing and Phylogenetic Relationship

RNA was extracted from the supernatant of Vero E6 cells after 1 passage by using the QIAamp Viral RNA Mini kit (QIAGEN) without addition of carrier RNA. We synthesized double-stranded DNA for sequencing library preparation by using the Liverpool SARS-CoV-2 amplification protocol (*11*). Two 100-µM primer pools were prepared by combining primer pairs in an alternating fashion to prevent amplification of overlapping regions in a single reaction. In a PCR tube, we added 1 µL Random Primer Mix (ProtoScript II First Strand cDNA Synthesis Kit; New England Biolabs) to 7 µL extracted RNA and denatured it on a SimpliAmp Thermal Cycler (ThermoFisher Scientific) at 65°C for 5 min and then incubated it on ice. We then added 10 µL 2X ProtoScript II Reaction Mix and 2 µL 10X ProtoScript II Enzyme Mix to the denatured sample and performed cDNA synthesis under the following conditions: 25°C for 5 min, 48°C for 15 min, and 80°C for 5 min. After cDNA synthesis, in a new PCR tube we combined 2.5 µL cDNA with 12.5 µL Q5 High-Fidelity 2X Master Mix (New England Biolabs), 8.8 µL nuclease-free water (ThermoFisher Scientific), and 1.125 µL of 100 µM primer pool 1 or 2. PCR cycling was then performed as follows: 98°C for 30 s, followed by 40 cycles of 98°C for 15 s and 65°C for 5 min.

All PCRs were purified by using RNAClean XP (Beckman Coulter, https://www.beckmancoulter.com) at a 1.8× bead-to-amplicon ratio and eluted in 30 µL of RNase-free water (AmericanBio, https://www.americanbio.com). We quantified 2 µL of amplified material by using a Qubit 1X dsDNA assay (ThermoFisher Scientific) according to the manufacturer's instructions. Illumina sequencing libraries were prepared by using a Nextera DNA Flex Library Prep Kit and Nextera DNA CD Indexes (Illumina, https://www.illumina.com) according to the manufacturer's instructions. Paired-end 150-bp sequencing was performed for each library on a MiniSeq with a 300-cycle mid-output reagent kit (Illumina), multiplexed with targeted sampling of ≈40,000 clusters per library. Sequencing reads from pools 1 and 2 were combined (as R1 and R2), amplification primer sequences were removed by using Cutadapt version 1.18 (*12*), and Illumina adaptor sequences were removed and low-quality sequences trimmed or removed by using Trimmomatic (version 0.36) (*13*). Final sequence quality and confirmation of adaptor/primer trimming were confirmed by using FASTQC version 0.11.5 (*14*). SARS-CoV-2 genome sequences were assembled by using UniCycler version 0.4.8 (default settings, except for conservative mode) (*15*) and assembly statistics were generated by QUAST (version 5.0.2) (*16*). Sequencing depth and completeness of coverage of the assembled genomes was additionally assessed by using Bowtie2 version 2.3.4.1 (*17*) alignment of the sequencing reads against the assembled contigs, and statistics were generated by ngsCAT (version 0.1) (*18*). Sequence variation in the assembled genomes was assessed by comparing sequences in BLASTN (http://blast.ncbi.nlm.nih.gov//Blast.cgi) with SARS-CoV-2 genomes available in GenBank as well as BreSeq version 0.35.0 (*19*) analysis relative to GenBank entry MN908947.3 (first genome sequence reported from the original outbreak in Wuhan). We constructed a phylogenetic tree (Appendix Figure 2) by using maximum-likelihood based on a multiple sequence alignment and RAxML-HPC BlackBox with the general time-reversible plus gamma plus invariate sites model for among-site rate variation (*20*).

Results

For virus isolation, we inoculated Vero E6 cells with aliquots of mid-turbinate swab samples and monitored the cells for cytopathic effects (CPE) daily. Relative to mock-inoculated cells, cells inoculated with both samples (SARS-CoV-2/SB2 and SARS-CoV-2/SB3-TYAGNC) displayed extensive CPE 72 h after infection (Figure 2, panel A). We collected 200 µL of cell culture supernatant and re-infected a fresh layer of Vero E6 cells. After 24 hours, both wells containing

cells that were reinoculated displayed extensive CPE (Figure 2, panel B). We extracted viral RNA from the supernatant and confirmed the presence of SARS-CoV-2 by using a diagnostic quantitative real-time PCR (Figure 2, panel C). We also confirmed the presence of coronavirus-like particles in infected Vero E6 cells by electron microscopy (Figure 2, panel D).

Next, we performed genome sequencing of both isolates, generating genome sequences with 7,500-8,000–fold coverage and ≈94% completeness, with only ≈260 bp and ≈200 bp at the 5′ and 3′ termini undetermined (Table; Appendix Figure 2). SARS-CoV-2/SB2 and SARS-CoV-2/SB3-TYAGNC shared synonymous and nonsynonymous substitutions with those

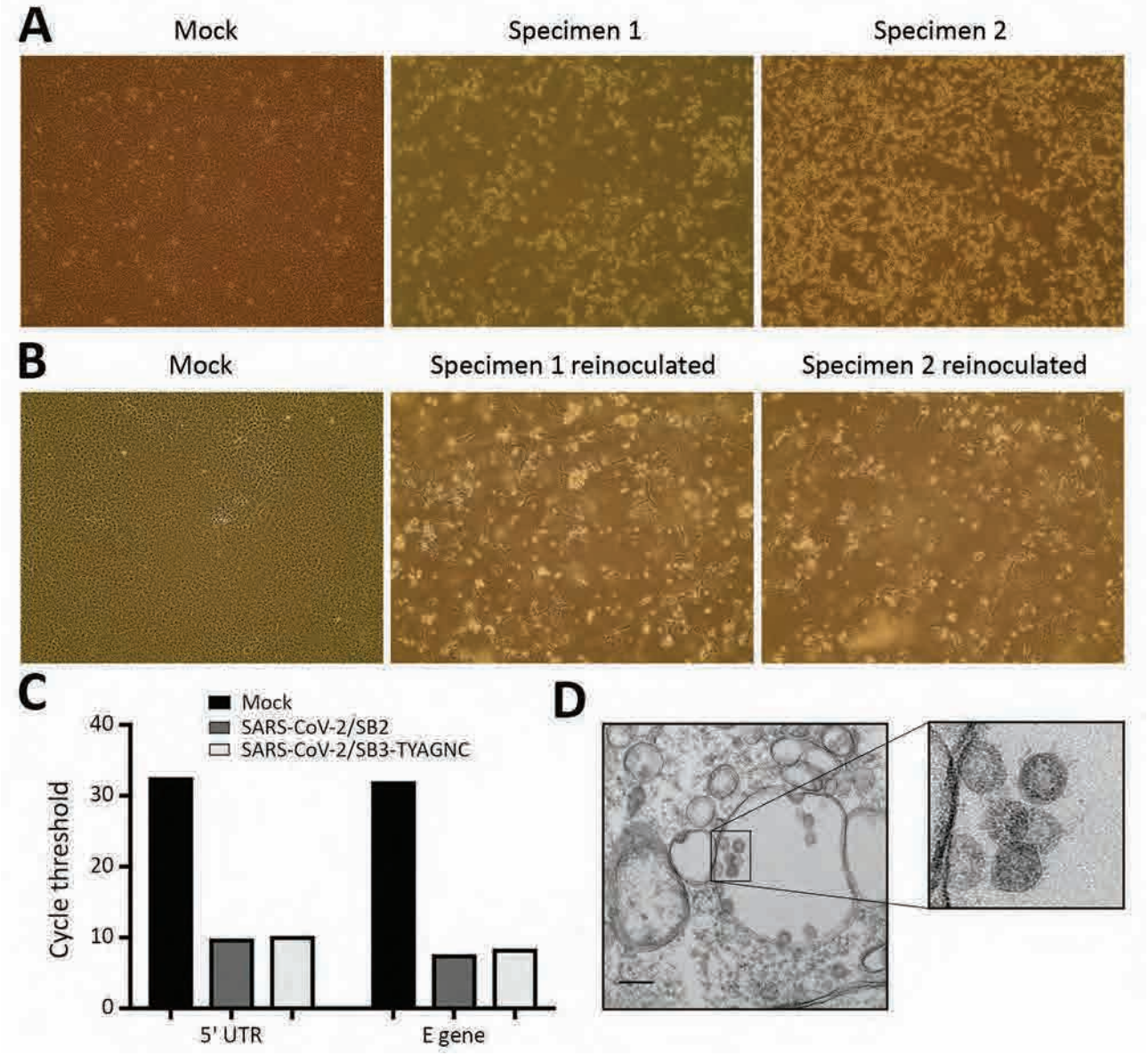

Figure 2. Isolating severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from patients with coronavirus disease (COVID-19). A) Vero E6 cells were mock inoculated or inoculated with midturbinate clinical specimens from COVID-19 patients. Cells were incubated for 72 h and observed for cytopathic effect (CPE) under a light microscope. Original magnification ×10. B) To determine if supernatant from Vero E6 cells that were mock inoculated or inoculated with clinical specimens contained replication competent virus, we reinoculated a fresh monolayer of Vero E6 cells and observed cells under a light microscope for CPE after 24 h. Original magnification ×10. C) Quantitative real-time PCR was used to detect SARS-CoV-2 5′-UTR and E gene in RNA extracted from supernatant that was collected from Vero E6 cells that were mock infected or infected with clinical specimens from COVID-19 patients for 72 h. D) Electron micrograph of Vero E6 cells that were reinfected for 48 h with supernatant that was collected from Vero E6 cells infected with clinical specimens. Original magnification ×36,000. Inset, zoomed and cropped from the original electron micrograph, shows coronavirus-like particles. M, mock specimen; specimen 1, SARS-CoV-2/SB2; specimen 2, SARS-CoV-2/SB3-TYAGNC. E, envelope; UTR, untranslated region.

Table. Sequencing read and genome assembly statistics used in study of isolation, sequence, infectivity, and replication kinetics of SARS-CoV-2*

Metric or mutation	SARS-CoV-2/SB2	SARS-CoV-2/SB3_TYAGNC
Number of paired reads	730,137 bp	690,167 bp
Reads from SARS-CoV-2	94.0%	94.4%
Number of assembly contigs	1	1
Assembly N50	29,494 bp	29,369 bp
Average depth of coverage of reads	7940.0-fold	7550.1-fold
Total assembly length	29,494 bp	29,369 bp
SARS-CoV-2 assembly completeness	98.6%	98.2%
Unresolved 5′ sequence	262 bp	272 bp
Unresolved 3′ sequence	200 bp	205 bp
Pos. 884 (orf1ab polyprotein)		**R207C (CGT→TGT)**
Pos. 1397 (orf1ab polyprotein)	**V378I (GTA→ATA)**	**V378I (GTA→ATA)**
Pos. 2832 (orf1ab polyprotein)	K856R (AAG→AGG)	
Pos. 3040 (orf1ab polyprotein)		Y925Y (TAC→TAT)
Pos. 8327 (or1ab polyprotein)	18.1% of reads suggest L2688F (CTT→TTT)	
Pos. 8653 (orf1ab polyprotein)		**M2796I (ATG→ATT)**
Pos. 10353 (orf1ab polyprotein)	5.6% of reads suggest K3363T (AAG→ACG)	
Pos. 11074 (orf1ab polyprotein)	10.2% of reads suggest +TTT and a deletion between positions 10809 and 13203	
Pos. 11083 (orf1ab polyprotein)	**L3606F (TTG→TTT)**	**L3606F (TTG→TTT)**
Pos. 25413 (orf3a protein)		36.7% of reads suggest I7I (ATC→ATT)
Pos. 28688 (nucleocapsid phosphoprotein)	**L139L (TTG→CTG)**	**L139L (TTG→CTG)**

*Predicted mutations are relative to the MN908947.3 SARS-CoV-2 genome (29,903 bp). Mutations within codons are underlined. All mutations were predicted by 100% of sequencing reads mapping to that position, unless otherwise noted. None of the mutations with support from <100% of sequencing reads appeared in the final assembled genome consensus sequences. Substitutions in boldface have been observed in direct sequencing of patient isolates (S. Mubareka, A.G.McArthur, unpub. data). orf1ab, open reading frame 1ab; pos., position; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

independently observed in direct sequencing of clinical isolates (Table; S. Mubareka and A.G. McArthur, unpub. data). SARS-CoV-2/SB2 also contained a nonsynonymous substitution at position 2832 (K856R in open reading frame [ORF] 1ab polyprotein) and 3 regions with mutations or a deletion supported by a minority of sequencing reads, but SARS-CoV-2/SB3-TYAGNC had only an additional synonymous substitution in ORF1ab polyprotein (Y925Y) plus a minority of sequencing reads supporting another synonymous substitution in the ORF3a protein (Table). Furthermore, maximum-likelihood phylogenetic analysis including >1,900 SARS-CoV-2 isolates from GISAID (https://www.gisaid.org) placed both SARS-CoV-2/SB2 and SARS-CoV-2/SB3-TYAGNC within a clade of isolates from patients around the globe but with evidence of travel history associated with the COVID-19 outbreak in Iran (Appendix Figure 2). As such, SARS-CoV-2/SB3-TYAGNC was used for subsequent studies as the best representative of a clinical viral isolate. Raw sequencing reads for each isolate are available in the National Center for Biotechnology Information under BioProject PRJNA624792. Only sequencing reads that aligned by Bowtie2 to the MN908947.3 SARS-CoV-2 genome were included in the deposited sequence files.

To determine the replication kinetics of SARS-CoV-2 in human structural and immune cells, we infected Calu-3 cells, THF cells, Vero E6 cells (African green monkey kidney epithelial), THP-1 cells, and primary PBMCs from healthy human donors (CD4+, CD8+, CD19+, monocytes, and other PBMCs; Appendix Figure 1) with an MOI of 0.01. We monitored virus replication in the cell lines for 72 h (Figure 3). We also determined virus replication in PBMCs from healthy donors for 48 h (Figure 3). SARS-CoV-2 propagated to high titers in Vero E6 and Calu-3 cells (Figure 3). SARS-CoV-2 did not replicate efficiently in THF cells (Figure 3). Of note, human immune cell lines and primary PBMCs from healthy donors did not support SARS-CoV-2 replication (Figure 3).

To further support virus replication data, we imaged infected human epithelial, fibroblast, and immune cells by using electron microscopy after 48 h of infection with SARS-CoV-2 at an MOI of 0.01 (Figure 4). We scanned 10 different fields per cell type, each using 4 different magnifications—2,600×, 8,500×, 17,500×, and 36,000×—to determine if the cell populations contained virus-like particles. Virus-like particles were detected in 7/10 fields in Vero E6 cells and 8/10 fields in Calu-3 cells (Figure 4, panels A, B). We also detected virus-like particles in 2/10 fields in primary CD4+ T cells (Figure 4, panel C). We did not observe any virus-like particles in other human immune cells that were experimentally infected with

SARS-CoV-2 (Figure 4, panels D–J). To determine if virus-like particles can be detected in Vero E6 cells and PBMCs at earlier time points, we infected these cell populations with SARS-CoV-2 at an MOI of 0.01 and imaged the cells with electron microscopy at 6 h and 12 h after infection (Appendix Figures 3, 4). We observed virus-like particles in 9/10 fields at 6 h after infection and 10/10 fields at 12 h after infection in Vero E6 cells (Appendix Figure 3, panel A, Figure 4, panel A). We also observed virus-like particles in 1/10 fields at 6 h and 1/10 fields at 12 h after infection in CD4+ T cells (Appendix Figure 3, panel B, and Figure 4, panel B). None of the other infected PBMC populations contained detectable virus-like particles (Appendix Figure 3, panels C–F, and Figure 4, panels C–F).

To confirm SARS-CoV-2 infection and protein expression in CD4+ T cells, we infected Vero E6 and CD4+ T cells with SARS-CoV-2 at an MOI of 0.1 for 24 h. We immunostained these cells and observed them by using fluorescent microscopy. To enhance our ability to detect SARS-CoV-2 proteins in these cells, we immunostained the cells by using a cocktail of antibodies that included SARS-CoV-2 S1 antibody, SARS-CoV-2 N antibody, and diluted serum from a recovered COVID-19 patient (Figure 1, panels A and B). We were able to detect SARS-CoV-2 infected Vero E6 and CD4+ T cells by using this antibody cocktail (Figure 1, panels A, B). Furthermore, to confirm SARS-CoV-2 infection of CD4+ T cells by using a single antibody, we immunostained infected CD4+ T cells with anti-SARS-CoV-2 S1 antibody and were able to detect infected cells in the population (Figure 1, panel C).

Discussion

We report the isolation of 2 replication competent SARS-CoV-2 virus samples from COVID-19 patients in Canada. We used TPCK-treated trypsin to facilitate virus isolation from clinical specimens (Figure 2, panel A). Exogenous trypsin activates SARS-CoV spike proteins more efficiently and facilitates cellular entry (*21*). Exogenous trypsin treatment also enhances infectivity of other zoonotic batborne coronaviruses (*22*). Furthermore, TPCK-treated trypsin has been used to successfully isolate SARS-CoV-2 in China (*1*). In our study, subsequent infection and virus replication did not require any additional TPCK-treated trypsin (Figure 2, panel B). The presence of CPE alone does not indicate successful isolation of a coronavirus. Mid-turbinate samples from adults with acute respiratory distress may often contain other microbes, including viruses (*23*). Thus, to identify our cell culture isolates, we sequenced them to confirm that they were reflective of the SARS-CoV-2 infecting patients worldwide, selecting SARS-CoV-2/SB3-TYAGNC for experimental

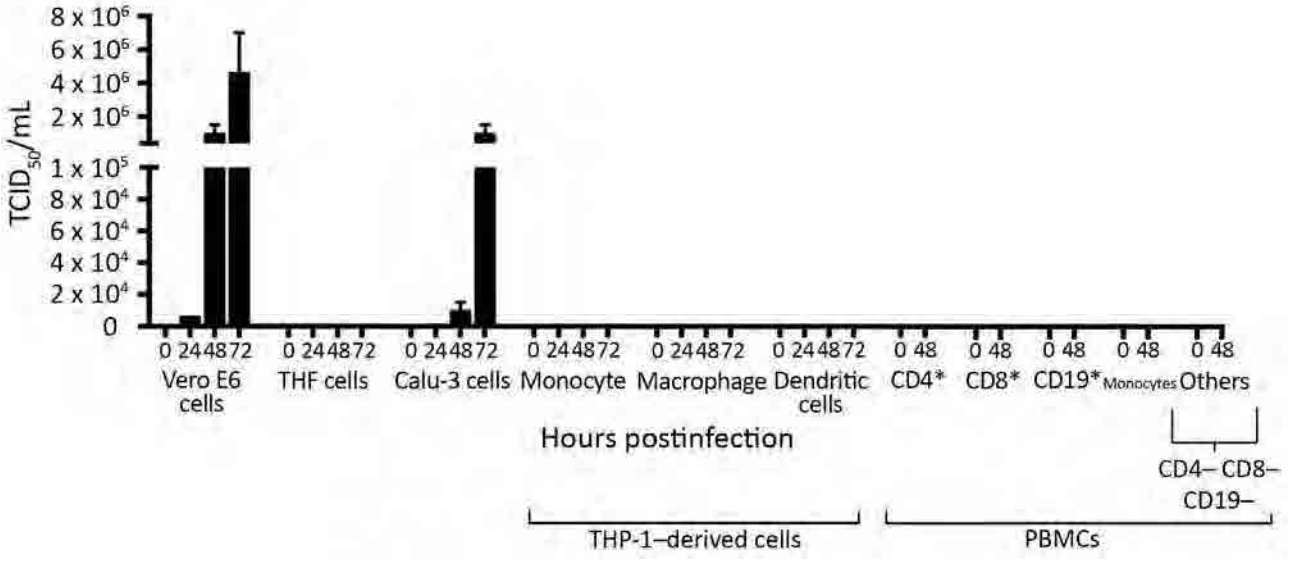

Figure 3. Replication of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in human structural and immune cells. To identify human cells that support SARS-CoV-2 replication, we infected human cell lines and primary cells at a multiplicity of infection of 0.01 (n = 2 independent experiments; supernatant from each experiment was titrated in triplicate). We infected Vero E6 cells as a control. THF (human telomerase life-extended cells) and Calu-3 cells (human lung adenocarcinoma–derived) cells represent human structural cells. THP-1 is a monocyte cell line that was used to derive macrophages and dendritic cells. PBMCs from 2 healthy human donors were used to generate CD4+, CD8+, CD19+, monocytes, and other (CD4–, CD8–, CD19–) cell populations. Supernatant from infected cells was collected at various times and titrated on Vero E6 cells to determine virus titers ($TCID_{50}$). PBMC, peripheral blood mononuclear cell; $TCID_{50}$, 50% tissue culture infectious dose.

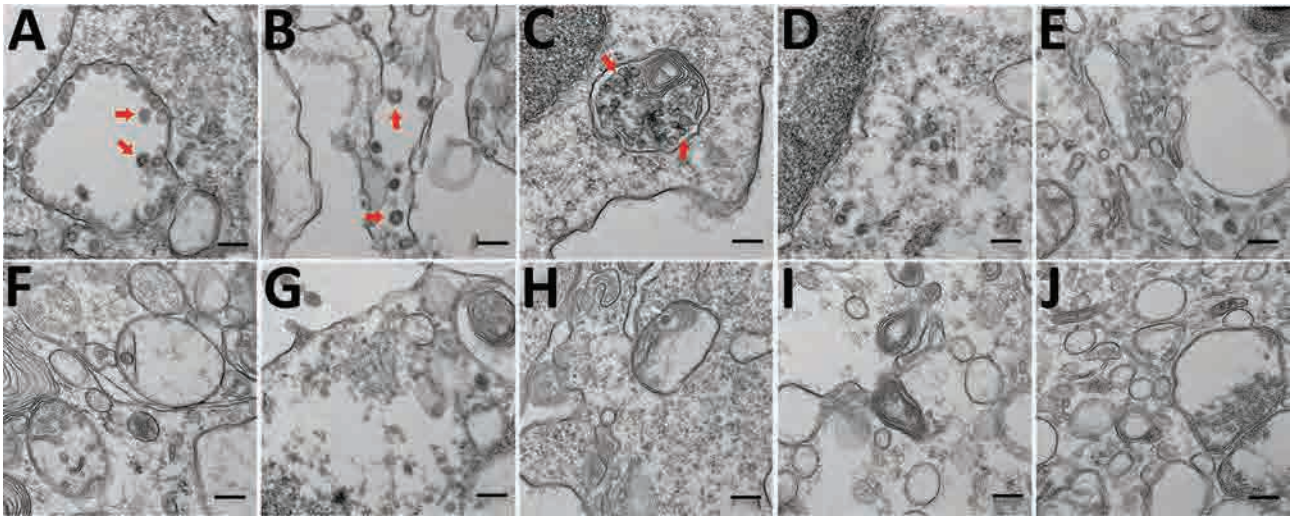

Figure 4. Electron micrographs of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)–infected cells. To detect coronavirus-like particles in experimentally infected human structural and immune cells, we infected a range of cells with SARS-CoV-2 at a multiplicity of infection of 0.01 for 48 h. The cells were fixed, processed, and imaged by using a transmission electron microscope (10 fields/cell type). A representative image of each cell type is shown. Virus-like particles are indicated by red arrows. A) Vero E6 cells. B) Calu-3 cells. C) CD4+ PBMCs. D) CD8+ PBMCs. E) CD19+ PBMCs. F) Monocytes from PBMCs. G) Other cells from PBMCs (CD4–, CD8–, CD19– cell populations). H) THP-1 monocyte. I) THP-1-derived macrophage. J) THP-1-derived dendritic cell. PBMC, peripheral blood mononuclear cell. Scale bars indicate 200 nm.

investigation because this isolate produced fewer minority sequencing reads (Table).

SARS-CoV caused the 2003–2004 outbreak of severe acute respiratory syndrome. SARS-CoV can infect structural (*24*) and immune cell lines (*25*) from humans in vitro. To identify cell types that can support productive infection of SARS-CoV-2, we infected a range of human cell populations with SARS-CoV-2/SB3-TYAGNC. Both Vero E6 and Calu-3 cells supported SARS-CoV-2 replication to high titers (Figure 3), as reported in other recent studies (*26*,*27*). Previously, SARS-CoV was also shown to replicate efficiently in Vero E6 cells (*24*). Vero E6 cells are immunodeficient, with deficiencies in innate antiviral interferon signaling, which makes them ideal candidates for virus isolation (*28*). However, to enable studies on SARS-CoV-2–host interactions, it is important to identify human lung epithelial cells with intact immune responses that can support SARS-CoV-2 replication. We and others have previously shown that SARS-CoV and Middle East respiratory syndrome coronavirus (MERS-CoV) replicate efficiently in Calu-3 cells (*8*,*29*,*30*). In addition, SARS-CoV–induced and MERS-CoV–induced immune responses have been studied in Calu-3 cells (*30*,*31*). The ability to infect Calu-3 cells with SARS-CoV-2 (Figure 3) will facilitate in vitro studies of virus–host interactions using SARS-CoV-2. Other commonly used human lung cells, such as A549, do not support efficient replication of SARS-CoV-2 (*26*). Furthermore, hTERT (human telomerase reverse transcriptase) THF cells also did not support virus replication (Figure 3).

Previous studies have shown that human immune cells, such as THP-1 cells, are susceptible to SARS-CoV infection (*25*). In our study, human immune cell populations, including THP-1–derived cell lines and primary cells (PBMCs) did not support productive SARS-CoV-2 replication (Figure 3). Although primary CD4+ T cells did not support productive virus replication, we observed virus-like particles in these cells by electron microscopy (Figure 4, panel C). We also detected SARS-CoV-2 proteins in infected CD4+ T cells by using fluorescent microscopy (Figure 1, panels B, C). This finding is consistent with that recently reported by Wang et al. when they demonstrated that SARS-CoV-2 and pseudotyped viruses could enter human T-cell lines (MT-2) (*32*). Those authors also noted that SARS-CoV-2 replication was abortive in MT-2 cells. SARS-CoV-2 transcript levels in infected MT-2 cells increased at 6 h after infection but remained steady at later time points, indicating a lack of virus replication in these cells (*32*). This finding is similar to abortive replication observed in MERS-CoV–infected T lymphocytes (*33*). However, the study by Wang et al. did not quantify virus titers in the supernatant from infected cells. In our study, we could not detect any replication-competent virus in the supernatant that was collected from SARS-CoV-2–infected CD4+ T cells (Figure 3). Human

immune cells lack expression of angiotensin-converting enzyme 2 (*34*) (https://www.proteinatlas.org), the functional receptor of SARS-CoV-2 (*1*,*35*). Emerging data indicate that there could be other receptors, such as CD147, that may facilitate cellular entry of SARS-CoV-2 (K. Wang et al., unpub. data, https://www.biorxiv.org/content/10.1101/2020.03.14.988345v1). Additional studies are needed to determine the full breadth of cellular receptors and coreceptors that may facilitate entry of SARS-CoV-2. Thus, although it is intriguing that CD4+ T cells may be susceptible to SARS-CoV-2, our data show that these cells are not permissive to SARS-CoV-2 replication in vitro. More studies are required to fully identify the effects of SARS-CoV-2 entry in CD4+ T lymphocytes.

In conclusion, we report that although a human lung cell line supported replication of SARS-CoV-2, the virus did not propagate in any of the tested immune cell lines or primary human immune cells. Although we did not observe a productive infection in CD4+ primary T lymphocytes, we observed virus-like particles in these cells by electron microscopy. Thus, SARS-CoV-2 can enter CD4+ primary T lymphocytes but is unable to replicate efficiently. Our data shed light on a wider range of human cells that may or may not be permissive for SARS-CoV-2 replication, and our study strongly suggests that the human immune cells tested do not support a productive infection with SARS-CoV-2.

Acknowledgments

We acknowledge Lindsey Fiddes' help with electron microscopy. SARS-CoV-2 Liverpool protocol genome amplification primer sequences were generously shared by Public Health England.

This study was supported by a Canadian Institutes of Health Research (CIHR) COVID-19 rapid response grant to principal applicant K.M. and co-applicants A.B., A.G.M., M.S.M., and S.M. A.B. was funded by the Natural Sciences and Engineering Research Council of Canada. J.A.N. was supported by funds from the Comprehensive Antibiotic Resistance Database. B.P.A. and A.R.R. were supported by CIHR funding (PJT-156214 to A.G.M.). Computer resources were supplied by the McMaster Service Lab and Repository computing cluster, funded in part by grants to A.G.M. from the Canadian Foundation for Innovation. Additional cloud computing needs were funded by the Comprehensive Antibiotic Resistance Database. J.A.H. is supported by the Canada Research Chairs Program and an Ontario Early Career Researcher Award. M.S.M. is supported by a CIHR COVID-19 rapid response grant, a CIHR New Investigator Award, and an Ontario Early Researcher Award.

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Dr. Banerjee is a postdoctoral research fellow at McMaster University, Hamilton. His research interests include coronavirus–host interactions in humans and bats as well as the evolution of antiviral immune responses in bats.

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CANADA

With strong controls, Canada could see 11,000 to 22,000 coronavirus deaths: officials

By **Amanda Connolly** • **Global News**

Posted April 9, 2020 7:40 am

Speaking to reporters outside Rideau Cottage in Ottawa on Thursday, Canadian Prime Minister Justin Trudeau said even under the best-case projections released earlier in the day by his government, it's likely the "first wave" of COVID-19 peak infection will likely not end until the summer – Apr 9, 2020

The coronavirus could cost 11,000 to 22,000 Canadian lives over the course of the pandemic — and that's the best case scenario with the strongest control measures.

If those controls are weak, those deaths could spike to more than 100,000.

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That's according to modelling released by federal public health officials for the first time on Thursday in Ottawa, which lays out three different potential scenarios based on strong, weak and no responses to containing the virus.

Coronavirus outbreak: Canada’s “best case” COVID-19 projection sees 11,000 to 22,000 deaths – Apr 9, 2020

It’s important to note that projections are not carved in stone. They are estimates based on the best available data so far, and that data can and does change regularly.

“Data and models can help Canadians see how our collective efforts … can determine the trajectory of Canada’s COVID-19 pandemic,” said Dr. Theresa Tam, chief public health officer of Canada.

“Models are not a crystal ball.”

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But they offer a glimpse into where the data suggests the

country could be heading, and the emerging picture is grim: 22,580 to 31,850 cases by April 16 with 500 to 700 potential deaths by the same time.

The modelling lays out three possible scenarios: one with strong control measures such as high rates of social distancing and testing, one with weaker response measures, and one with no measures taken.

Tam said the objective for Canada is to be in the strong control measure camp, which the modelling suggests would result in roughly 11,000 deaths if 2.5 per cent of the population is infected and 22,000 deaths if that infection rate rises to five per cent.

Under that scenario, total hospitalizations would be around 73,000 if 934,000 people were infected under the forecast for a 2.5 per cent infection rate, while there would be 146,000 hospitalizations and 1,879,000 total cases if five per cent are infected.

2:26

Coronavirus outbreak: COVID-19 projection...

Coronavirus outbreak: COVID-19 projection shows Canada still has opportunity to 'control epidemic' – Apr 9, 2020

If the infection rate hits 25 per cent under the weaker control measures scenario, those deaths could spike to more than 100,000 or 250,000 if 50 per cent of the population is

100,000 or 250,000 if 50 per cent of the population is infected.

[Sign up for our Health IQ newsletter for the latest coronavirus updates]

“These stark numbers tell us we must do everything in our power to stay in the control model,” Tam said.

TRENDING STORIES

Canada-U.S. border closure extended again, until July 21

Broadway show off limits to those who got AstraZeneca COVID-19 vaccine

> **“We cannot prevent every death, but we must prevent every death that we can.”**
>
> **TWEET THIS**

Tam continued, adding that it is not clear yet where Canada is on those models.

“All I can tell you is we stand a really good chance of staying in that green [strong measure] zone if we try and continue everything we’re doing now.”

2:26

Coronavirus outbreak: COVID-19 projection...

Coronavirus outbreak: COVID-19 projection shows Canada still has opportunity to ‘control epidemic’ – Apr 9, 2020

Even if the country is successful in getting the epidemic under control, measures like physical distancing, restrictions on international and domestic travel, and contact tracing will need to remain, Tam said.

“It is too early to know how close we are to the peak from a

"It is too early to know how close we are to the peak from a national perspective," she added, saying that officials won't know when the peak occurs until they start seeing downward numbers.

And even after the peak, control measures will not be able to be lifted, she said.

"We can't give up after the peak."

Premier grants Easter Bunny special 'eggs-emption' as holidays shift under COVID-19 – Apr 8, 2020

The modelling for the best case scenario with the strongest responses suggests it's possible the cases in Canada could peak in the coming months and then subside into the fall.

Under the weaker response model, that peak might not come until the fall with infections subsiding over the winter and spring of 2021.

READ MORE: No return to 'normality' until coronavirus vaccine is available, Trudeau says

"We expect subsequent smaller waves. That's why it's difficult to say nationally that at such-and-such a date, we'll be able to set aside these measures," said Dr. Howard Njoo, deputy chief public health officer, when asked whether the restrictive measures in place could last until December 2020, for example.

"It's up to each province and territory to monitor their

epidemics very closely. If it becomes clear that we are on the downward side of the curve, we may be able to relax some measures but it will be up to the provinces and territories."

He added that officials know the coming Easter weekend and similar upcoming celebrations will be challenging for people given many are used to being with family and friends.

READ MORE: **Canada lost 1 million jobs in March**

But he and Tam noted that it is crucial to maintain physical distancing and not loosen up any of the measures in place so far if the country wants to continue to try to control the spread.

"It is a matter of life and death," said Tam.

"When I say we're authors of our fate, this is something that's really serious."

Prime Minister Justin Trudeau noted in his daily briefing shortly after the release of those numbers that it will likely be months before the measures in place can begin to be rolled back.

"Normality as it was before will not come back until we get a vaccine for this and as you say, that will be

a very long way off," he said. "For a year, 18 months there will be things we just aren't able to do."

Officials have been under pressure to release national coronavirus scenarios for weeks.

Canada's two most populous provinces have already done so, along with Alberta and B.C.

Ontario projections released last week predicted the province could see 1,600 deaths by the end of April even with the current social distancing and shutdown measures in place.

READ MORE: Ontario projects just under 1,600 COVID-19 deaths, 80,000 cases by end of April

But that's compared to the projected 6,000 deaths by the end

But that's compared to the projected 3,000 deaths by the end of the month if nothing was done at all.

Ontario's modelling also predicted the pandemic could last for two years, with total death tolls in the province of between 3,000 and 15,000.

Quebec projected it could see between 1,263 and 8,860 deaths by the end of the month as well.

That province predicted it will see its peak in cases around April 18, while Alberta estimates are that its residents won't see the peak in infections until May.

The federal modelling comes at the same time as the federal government released sobering new job numbers showing Canada lost one million jobs in March, leading to the biggest one-month jump in unemployment since 1976.

Canadian cases

CONFIRMED	DEATHS	RECOVERED	VACCINE DOSES
1,407,269	26,023	1,368,449	31,399,702
(today: +1,016)	(today: +11)	(today: +1,652)	(today: +648,839)

Source: Esri Canada

Check out our Coronavirus Tracker for more details and maps Last Updated: June 18, 2021, at 11:00:00 am EST

JOURNALISTIC STANDARDS REPORT AN ERROR

COVID-19 Coronavirus covid-19 canada Coronavirus Cases +7

COMMENTS

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HEALTH

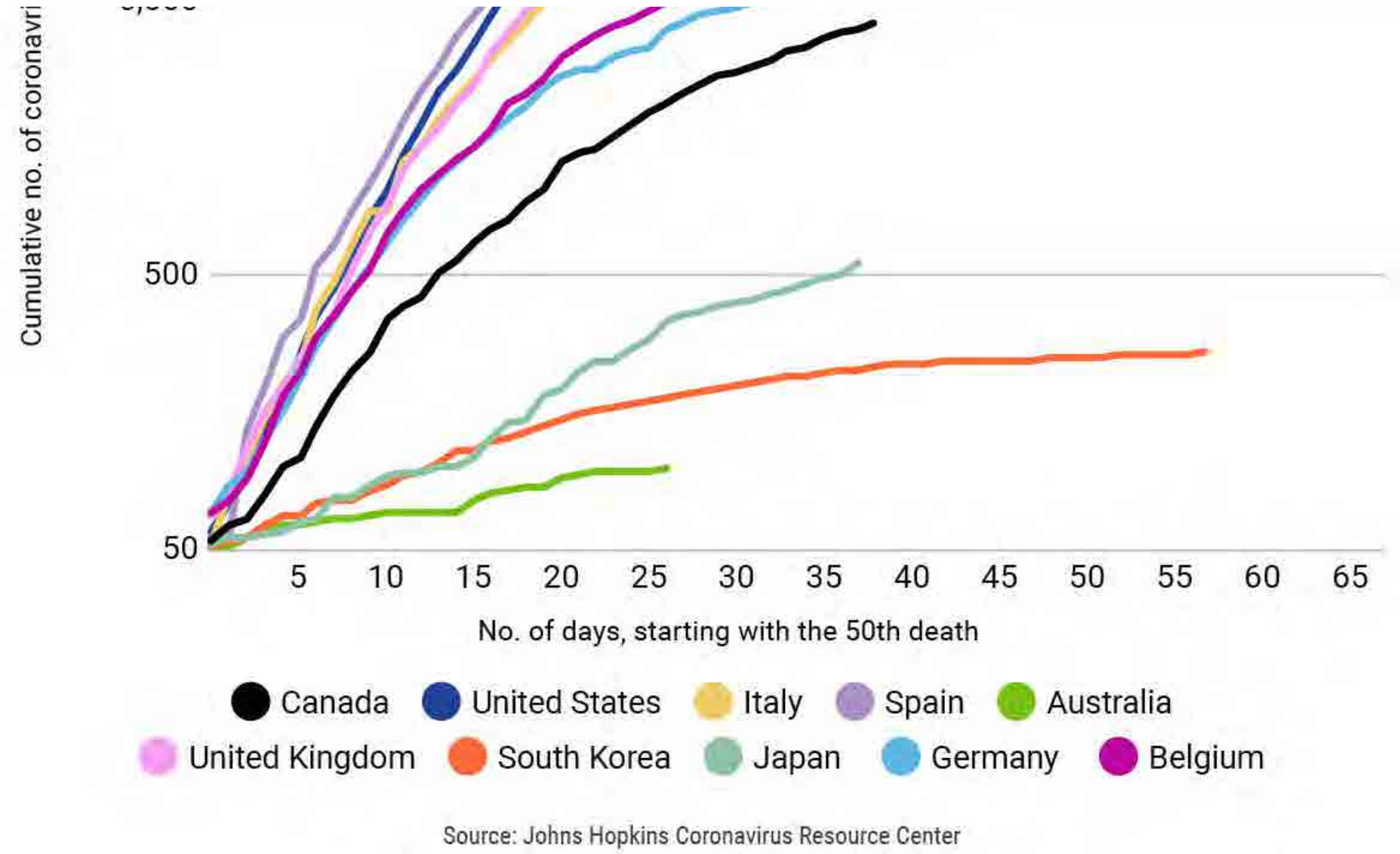
Coronavirus deaths: These charts show how Canada compares with the world

When you adjust for population, we're doing a little worse than Germany—and only a bit better than the United States

By Patricia Treble
May 5, 2020

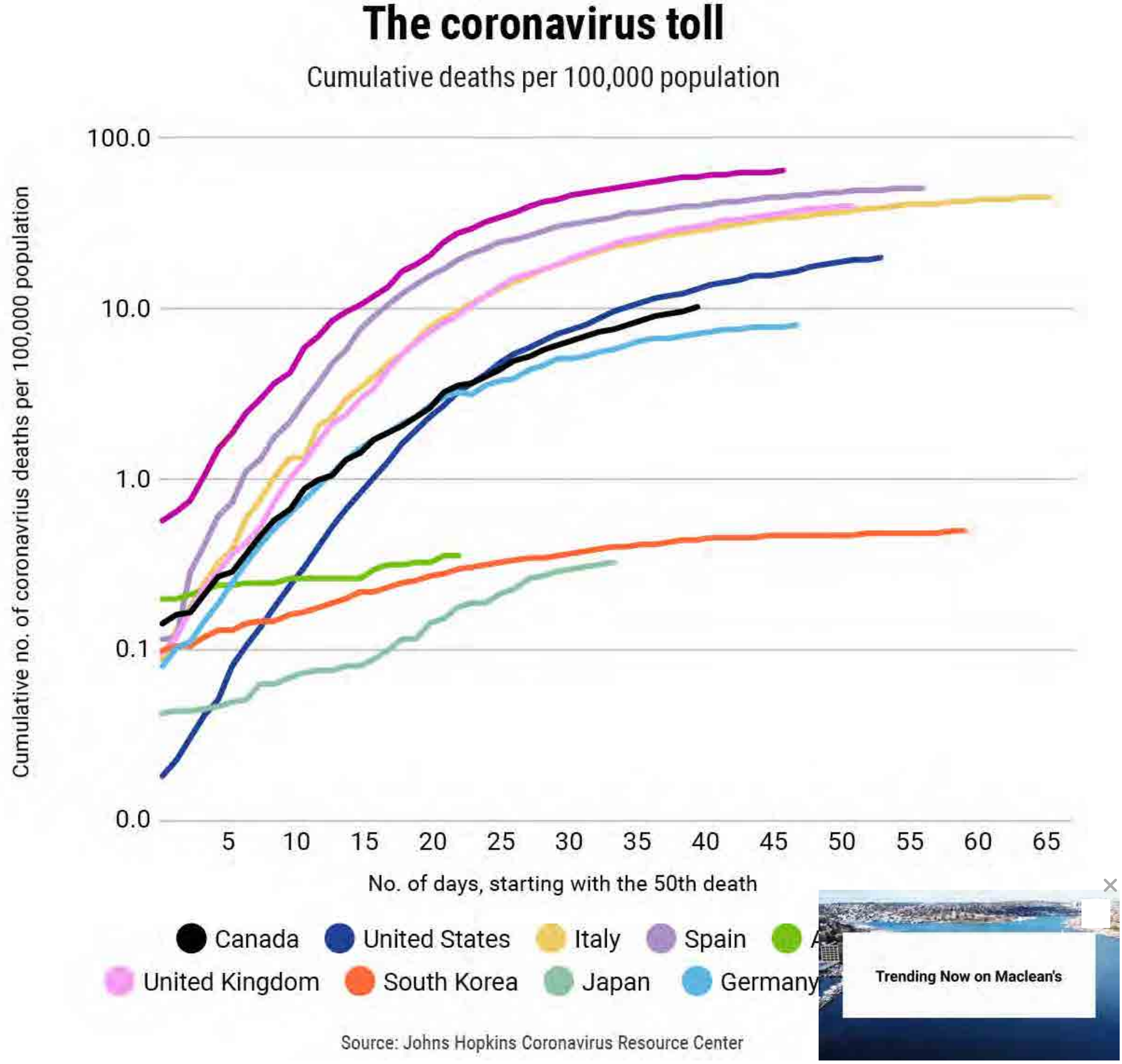
As the number of people who have died from COVID-19 passes 250,000 in the world, the relentless climb of infections and deaths can be almost too much for people to comprehend. For instance, it took roughly a decade for 58,220 Americans to die in the Vietnam War, yet COVID-19 killed at least that number in two months.

Canada is in its ninth week of self-isolation. Since the nation's first death was recorded in British Columbia on March 8, roughly 4,000 people in this country have died of COVID-19. In the beginning, the numbers were shooting up by more than 100 per cent weekly. But in the last two weeks, those increases have slowed. The week of April 19 to 25 saw a 22 per cent increase to 1,025 dead for the week from 838 in the previous week. The next week, April 26 to May 5, another 1,102 deaths were recorded. While the numbers are brutally high, they have largely stabilized, at least for the moment.



(Patricia Treble and Lauren Cattermole)

That overall death toll as of May 5—4,000 have died in Canada—may look small compared to the 70,000 dead in the United States, but that huge gap narrows significantly when the cumulative number of deaths for those two nations are plotted in a logarithmic chart, along with those of selected nations that have their own stories to tell. Such charts are good for identifying trends when dealing with the exponential growth of the virus, and its deaths, especially among jurisdictions of varying population sizes. As well, by picking the same starting point in the epidemic for every nation, the charts allow comparisons between countries further along in their outbreaks, such as Italy and Spain, with countries that could see what was happening in those nations and shut down earlier.



(Patricia Treble and Lauren Cattermole)

That dichotomy suggests that the death toll of COVID-19 may be far higher than currently acknowledged. (Canada doesn't provide up-to-date death data.)

Then, there is Belgium, which is presented in these two logarithmic death charts. Its death rate per capita is the highest in the world. The small European nation (pop. 11.6 million) has been very hard-hit by the virus, yet part of the explanation for its high death rate may be because its authorities are including more COVID-19 deaths in its statistics than other nations, in particular, those outside hospitals.

The speed at which COVID-19 has changed the world is breathtaking. Yet, death is always with us, though not from such a pernicious infection. While comparing the two-month COVID-19 death toll to the Vietnam War helps put its toll into perspective, the *Washington Post* notes that heart disease and cancer each claim around 100,000 American lives in those same two months.

Related

Israel is the world leader in vaccinations. What can Canada learn from them?

Canada is likely to exceed the U.S. infection rate in the coming days

How quickly will the COVID-19 vaccines start curbing the pandemic in Canada?

How many people a day could Canada vaccinate when going full-tilt?

When are more COVID vaccine doses coming to Canada?

FILED UNDER: **CHARTS** **CORONAVIRUS** **COVID DEATHS** **COVID-19** **EDITOR'S PICKS**

Politics

Even with strict containment measures, COVID-19 could claim 22,000 lives, federal officials project

PM says physical distancing, quarantines are 'new normal' until vaccine is developed

Kathleen Harris · CBC News · Posted: Apr 09, 2020 8:52 AM ET | Last Updated: April 9, 2020

Chief public health officer Theresa Tam gestures explains the pandemic curve during a news conference in Ottawa earlier this week. (Adrian Wyld/Canadian Press)

comments

Federal health officials are saying there could be nearly 32,000 cases of COVID-19 and between 500 and 700 deaths in Canada by April 16 — and anywhere from 11,000 to 22,000 deaths over the course of the pandemic, even with relatively strong control measures in place.

That projection emerged Thursday morning as officials released modelling on how the COVID-19 crisis could unfold in the country, and suggested that containment measures, such as physical distancing and quarantines, could be in place for months to come.

Prime Minister Justin Trudeau conceded that it won't be easy to continue those measures because the first wave of the virus could last until the summer, with other outbreaks erupting after that.

Trudeau said he could not predict how long those measures will be required, but said some experts estimate it will take six to eight months to develop a vaccine, while others suggest it could take a year to 18 months.

He pleaded with Canadians to step up to meet what he called the "challenge of the generation" and said Canada is at a "fork in the road" between the best and worst outcomes.

"This will be the new normal until a vaccine is developed," he said.

Watch: 'This will be the new normal until a vaccine is developed': Trudeau:

'This will be the new normal until a vaccine is developed': Trudeau

1 year ago | 1:55

Prime Minister Justin Trudeau says it will take months of Canadians' "continued, determined effort" to follow pandemic measures such as physical distancing to overcome COVID-19. 1:55

Longer-term projections look at scenarios involving strong controls (one to 10 per cent of the population infected, called the "green zone" scenario), weaker controls (25 to 50 per cent of the population infected, the "blue zone") and no controls at all (70-80 per cent infected, the "red zone").

If about 2.5 to five per cent of the population became infected, that would mean between 934,000 and 1.9 million cases. That would also mean up to 22,000 deaths and between 23,000 and 46,000 ICU admissions.

- **LIVE BLOG RECAP** **COVID-19 April 9 update: Trudeau addresses Canadians | Special coverage**

If no containment measures had been taken (which was not the case in Canada), officials said there could have been about 300,000 deaths.

Officials said the caseload in Canada is doubling every three to five days, which is considered a relatively positive trajectory compared to other countries. Chief Public Health Officer Theresa Tam said that is in large part because of lessons learned from other countries about how strong control measures can limit the spread of the virus.

Tam said she is hopeful that Canada can stay in the green zone and keep infections and deaths relatively low.

'Prevent every death that we can'

She warned that measures that can create "hardships" are critical to keeping ICU admissions and deaths as low as possible.

"We can't prevent every death, but we must prevent every death that we can," she said.

So far in Canada, there have been about 20,000 cases and close to 500 deaths.

Tam said it's too early to know how close Canada is nationally to seeing a "peak" in transmission. But she cautioned that even as we start to see a decline in transmissions, Canadians will have to stay the course with preventative measures to keep the pandemic from re-igniting.

- **LIVE BLOG RECAP** **COVID-19 update: Health Canada releases COVID-19 modelling**
- **ANALYSIS** **What national COVID-19 modelling can tell us — and what it can't**

"What we do together now will buy us more time to further understand the virus and to develop treatments and vaccines," she said.

"We are the authors of our fate. Together we can plank the epidemic curve."

Tam said that if 2.5 per cent of the population were infected, it would inflict strains on the health care system.

Watch: Canada's chief public health officer Dr. Theresa Tam says: 'Models are not a crystal ball.':

'Models are not a crystal ball': Dr. Tam

1 year ago | 1:03

Canada's chief public health officer Dr. Theresa Tam says models are "imperfect" but that they can help understand the state and trajectory of the pandemic and the effect of public health measures to combat the spread of COVID-19. 1:03

Tam said officials will monitor the evolution of the outbreak and its trajectory, and "recalibrate" guidance for Canadians based on how the curve is bending.

"It is a pretty dynamic process," she said.

Officials are working to improve testing and lab capacity to detect and trace cases.

Conservative health critic Matt Jeneroux said Trudeau had no choice but to release the numbers after several provinces released their own projections and models, and said he has many concerns about the government's "reactive approach" to COVID-19.

"We heard today the peak may come in late spring, and from what I'm hearing, hospitals and front line workers are not equipped to handle this," he said.

"We need to ensure our front line workers have the personal protection equipment (PPE) they need. We need to ensure that patients have beds and ventilators, if required."

NDP health critic Don Davies said he's troubled by the projections outlined today, especially in light of evidence heard by the House of Commons

health committee earlier this week.

The heads of organizations representing Canada's doctors and nurses told MPs there is a critical lack of personal protective equipment for front line workers, and called the situation "outrageous and unacceptable."

They warned that lives are at stake and asked for more transparency and urgent federal action to keep health professionals safe.

"There is insufficient national coordination and inconsistent and incomplete data. We are behind in testing, contact tracing and isolating," Davies said.

"The shortage of PPE increases risk not only for health care workers but for those working with the public generally. Our border controls still are not as vigorous as they could be."

All of those elements present challenges to Canada's efforts to contain transmission and stay in the "green zone," he said.

Watch: 'We don't know if we've reached the peak anywhere': Tam:

'We don't know if we've reached the peak anywhere': Tam

1 year ago | 2:15

Canada's chief public health officer Dr. Theresa Tam was asked by CBC's Julie Van Dusen to say when she thinks the tightest restriction of public health measures will be lifted and how that could be possible if not all Canadians were tested for COVID-19. 2:15

The analysis of how many people could become infected, get sick or die from the virus comes just before the long holiday weekend. Tam urged people not to let down their guard, even as they mark important religious occasions such as Passover, Easter and Ramadan.

"That means dinners and celebrations need to be strictly limited to your existing household members only," she said.

"The plan for your holidays is a staycation for the nation."

Tam said the models are "imperfect" but they can help people understand the state of the pandemic and where it might go, along with the effect of public health measures on the transmission of the virus.

Several provinces have already released projections. Ontario estimates the number of deaths in the province could hit 3,000 to 15,000 over the course of the pandemic, which could last up to two years.

Watch: Prime Minister Justin Trudeau says Canadians must 'remain vigilant.':

'We will need to remain vigilant': Trudeau

1 year ago | 2:32

Prime Minister Justin Trudeau said normal life for Canadians will not return until a COVID-19 vaccine is developed 2:32

Repeated advice

Trudeau has told Canadians repeatedly that how fast and far the virus spreads will depend largely on how closely they follow public health advice, including physical distancing, hand-washing and staying home whenever possible.

His remarks come as Statistics Canada reported Thursday that Canada's economy lost more than one million jobs in March, pushing the jobless rate up to 7.8 per cent.

"Obviously, this is difficult news. This is news that reflects, particularly in the job numbers, a reality that millions of Canadians have been feeling over the past weeks, that the real impact, not just on our economy, but on the lives of Canadians, of workers, of families, of communities, is significant and real," he said.

"But what we're also seeing in numbers from different parts of the country is that there is a light at the end of this tunnel, that if we keep doing the things that we're doing, as we've been doing, as we've seen in other countries, we are able to minimize the level of the impact of this wave of COVID19."

Asked when measures such as border closures might be eased, Deputy Prime Minister Chrystia Freeland said it would be "foolhardy in the extreme" to offer a guess at this point, given the uncertainties surrounding the pandemic.

She said the crisis can't end until a vaccine is available.

"In terms of what that means about the border, we just can't say," she said.

Tam and Freeland explain how closing the US Border helped fight COVID-19

1 year ago | 2:12

Dr Theresa Tam Canada's Chief Public Health officer and Deputy Prime Minister Chrystia Freeland spoke with reporters on Thursday 2:12

Ontario and Canada Mask Exemptions

Discrimination Penalties and fines – December 03, 2020

Other criminal charges within the Criminal Code of Canada

- Offences against children — 718.01 When a court imposes a sentence for an offence that involved the abuse of a person under the age of eighteen years, it shall give primary consideration to the objectives of denunciation and deterrence of such conduct. 2005, c. 32, s. 24.

- Offence against vulnerable person — 718.04 When a court imposes a sentence for an offence that involved the abuse of a person who is vulnerable because of personal circumstances — including because the person is Aboriginal and female — the court shall give primary consideration to the objectives of denunciation and deterrence of the conduct that forms the basis of the offence. 2019, c. 25, s. 292.1.

Corporate Policies or practice do not override National, Provincial and International Human Rights of Canadians

Mask exemptions neglected by corporate policies: discrimination and refusal or lack of accommodation resulting in civil tort litigation resulting of criminal offenses against Canadians by the provinces, Municipalities and by public and private service health care and Business Corporations and retailors, etc.

1. Canadian Charter of Rights and Freedoms
2. Canadian Human Rights Act
3. Genetic Non-Discrimination Act
4. Criminal Code of Canada Act
5. Canada Labour Code Act
6. Human Rights Code, R.S.O. 1990, c. H.19
7. Accessibility for Ontarians with Disabilities Act

Discrimination Protection Laws: civil and criminal liability under the Acts

- Accessibility for Ontarians with Disabilities Act, 2005

PART I
INTERPRETATION

Purpose

1. Recognizing the history of discrimination against persons with disabilities in Ontario, the purpose of this Act is to benefit all Ontarians by,

(a) developing, implementing and enforcing accessibility standards in order to achieve accessibility for Ontarians with disabilities with respect to goods, services, facilities, accommodation, employment, buildings, structures and premises on or before January 1, 2025; and

(b) providing for the involvement of persons with disabilities, of the Government of Ontario and of representatives of industries and of various sectors of the economy in the development of the accessibility standards. 2005, c. 11, s. 1.

Definitions

2. In this Act,

"accessibility standard" means an accessibility standard made by regulation under section 6; ("norme d'accessibilité")

"barrier" means anything that prevents a person with a disability from fully participating in all aspects of society because of his or her disability, including a physical barrier, an architectural barrier, an information or communications barrier, an attitudinal barrier, a technological barrier, a policy or a practice; ("obstacle")

"director" means a director appointed under section 30; ("directeur")

"**disability" means**,

(a) any degree of physical disability, infirmity, malformation or disfigurement that is caused by bodily injury, birth defect or illness and, without limiting the generality of the foregoing, includes diabetes mellitus, epilepsy, a brain injury, any degree of paralysis, amputation, lack of physical co-ordination, blindness or visual impediment, deafness or hearing impediment, muteness or speech impediment, or physical reliance on a guide dog or other animal or on a wheelchair or other remedial appliance or device,

(b) a condition of mental impairment or a developmental disability,

© a learning disability, or a dysfunction in one or more of the processes involved in understanding or using symbols or spoken language,

(d) a mental disorder, or

© an injury or disability for which benefits were claimed or received under the insurance plan established under the *Workplace Safety and Insurance Act, 1997*; (“handicap”)

“Minister” means the Minister of Citizenship and Immigration or whatever other member of the Executive Council to whom the administration of this Act is assigned under the *Executive Council Act*; (“ rescrip”)

“organization” means any organization in the public or private sector and includes,

(a) the Government of Ontario and any board, commission, authority or other agency of the Government of Ontario,

(b) any agency, board, commission, authority, corporation or other entity established under an Act,

© a municipality, an association, a partnership and a trade union, or

(d) any other prescribed type of entity; (“organisation”)

“prescribed” means prescribed by regulation; (“ rescript”)

“regulations” means the regulations made under this Act, unless the context indicates or requires otherwise; (“règlements”)

“Tribunal” means, with respect to an appeal of an order made by a director under this Act, the tribunal designated by the Lieutenant Governor in Council under section 26 for the purposes of hearing that appeal. (“Tribunal”) 2005, c. 11, s. 2; 2009, c. 33, Sched. 8, s. 1.

Section Amendments with date in force (d/m/y)

Recognition of existing legal obligations

3. Nothing in this Act or in the regulations diminishes in any way the legal obligations of the Government of Ontario or of any person or organization with respect to persons with disabilities that are imposed under any other Act or otherwise imposed by law. 2005, c. 11, s. 3.

PART II
APPLICATION

Application

4. This Act applies to every person or organization in the public and private sectors of the Province of Ontario, including the Legislative Assembly of Ontario. 2005, c. 11, s. 4.

Crown bound

5. This Act binds the Crown. 2005, c. 11, s. 5.

Several applicable standards

(5) A person or organization may be subject to more than one accessibility standard. 2005, c. 11, s. 6 (5).

Content of standards

(6) An accessibility standard shall,

(a) set out measures, policies, practices or other requirements for the identification and removal of barriers with respect to goods, services, facilities, accommodation, employment, buildings, structures, premises or such other things as may be prescribed, and for the prevention of the erection of such barriers; and

(b) require the persons or organizations named or described in the standard to implement those measures, policies, practices or other requirements within the time periods specified in the standard. 2005, c. 11, s. 6 (6).

Classes

(7) An accessibility standard may create different classes of persons or organizations or of buildings, structures or premises and, without limiting the generality of this power, may create classes with respect to any attribute, quality or characteristic or any combination of those items, including,

(a) the number of persons employed by persons or organizations or their annual revenue;

(b) the type of industry in which persons or organizations are engaged or the sector of the economy of which persons or organizations are a part;

(c) the size of buildings, structures or premises. 2005, c. 11, s. 6 (7).

Penalties

(3) Every person who is guilty of an offence under this Act is liable on conviction,

(a) to a fine of not more than $50,000 for each day or part of a day on which the offence occurs or continues to occur; or

(b) if the person is a corporation, to a fine of not more than $100,000 for each day or part of a day on which the offence occurs or continues to occur. 2005, c. 11, s. 37 (3).

Duty of director or officer

(4) Every director or officer of a corporation has a duty to take all reasonable care to prevent the corporation from committing an offence under this section. 2005, c. 11, s. 37 (4).

Offence

(5) Every director or officer of a corporation who has a duty under subsection (4) and who fails to carry out that duty is guilty of an offence and on conviction is liable to a fine of not more than

$50,000 for each day or part of a day on which the offence occurs or continues to occur. 2005, c. 11, s. 37 (5).

Conflict

38. If a provision of this Act, of an accessibility standard or of any other regulation conflicts with a provision of any other Act or regulation, the provision that provides the highest level of accessibility for persons with disabilities with respect to goods, services, facilities, employment, accommodation, buildings, structures or premises shall prevail. 2005, c. 11, s. 38.

See:

https://www.ontario.ca/laws/statute/90h19#BK19

https://www.ontario.ca/laws/statute/05a11

https://laws-lois.justice.gc.ca/eng/acts/h-6/page-1.html

https://laws-lois.justice.gc.ca/eng/acts/G-2.5/page-1.html#h-247344

https://laws-lois.justice.gc.ca/eng/acts/C-46/index.html

https://laws-lois.justice.gc.ca/eng/acts/h-6/index.html

https://laws-lois.justice.gc.ca/eng/Const/page-15.html

https://www.genome.gov/about-genomics/fact-sheets/Polymerase-Chain-Reaction-Fact-Sheet

Genetic Non-Discrimination Act (S.C. (Statutes of Canada) 2017, c. 3)
Act current to 2020-11-17

Genetic Non-Discrimination Act

S.C. (Statutes of Canada) 2017, c. 3

Assented to 2017-05-04

An Act to prohibit and prevent genetic discrimination

Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

Short Title

Short title

1 This Act may be cited as the *Genetic Non-Discrimination Act*.

Interpretation

Definitions

2 The following definitions apply in this Act.

disclose includes to authorize disclosure. (*communiquer*)

genetic test means a test that analyzes DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (*test génétique*)

health care practitioner means a person lawfully entitled under the law of a province to provide health services in the place in which the services are provided by that person. (*professionnel de la santé*)

Prohibitions

Genetic test

3 (1) It is prohibited for any person to require an individual to undergo a genetic test as a condition of

(a) providing goods or services to that individual;

(b) entering into or continuing a contract or agreement with that individual; or

(c) offering or continuing specific terms or conditions in a contract or agreement with that individual.

Refusal to undergo genetic test

(2) It is prohibited for any person to refuse to engage in an activity described in any of paragraphs (1)(a) to (c) in respect of an individual on the grounds that the individual has refused to undergo a genetic test.

Disclosure of results

4 (1) It is prohibited for any person to require an individual to disclose the results of a genetic test as a condition of engaging in an activity described in any of paragraphs 3(1)(a) to (c).

Refusal to disclose results

(2) It is prohibited for any person to refuse to engage in an activity described in any of paragraphs 3(1)(a) to (c) in respect of an individual on the grounds that the individual has refused to disclose the results of a genetic test.

Written consent

5 It is prohibited for any person who is engaged in an activity described in any of paragraphs 3(1)(a) to (c) in respect of an individual to collect, use or disclose the results of a genetic test of the individual without the individual's written consent.

Exceptions: health care practitioners and researchers

6 Sections 3 to 5 do not apply to

(a) a physician, a pharmacist or any other health care practitioner in respect of an individual to whom they are providing health services; or

(b) a person who is conducting medical, pharmaceutical or scientific research in respect of an individual who is a participant in the research.

Offences and Punishment

Contravention of sections 3 to 5

7 Every person who contravenes any of sections 3 to 5 is guilty of an offence and is liable

(a) on conviction on indictment, to a fine not exceeding $1,000,000 or to imprisonment for a term not exceeding five years, or to both; or

(b) on summary conviction, to a fine not exceeding $300,000 or to imprisonment for a term not exceeding twelve months, or to both.

Canada Labour Code

8 [Amendment]

Canadian Human Rights Act

9 [Amendment]

10 [Amendments]

Coordinating Amendments

11 [Amendments]

Date modified:

2020-11-27

Interpretation

Definitions

2 The following definitions apply in this Act.
disclose includes to authorize disclosure. (communiquer) genetic test means a test that analyzes DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (test génétique)
health care practitioner means a person lawfully entitled under the law of a province to provide health services in the place in which the services are provided by that person. (professionnel de la santé)

https://laws-lois.justice.gc.ca/PDF/G-2.5.pdf

Polymerase Chain Reaction (PCR) Fact Sheet

Polymerase chain reaction (PCR) is a technique used to "amplify" small segments of DNA.

What is PCR?

Sometimes called "molecular photocopying," the polymerase chain reaction (PCR) is a fast and inexpensive technique used to "amplify" - copy - small segments of DNA. Because significant amounts of a sample of DNA are necessary for molecular and genetic analyses, studies of isolated pieces of DNA are nearly impossible without PCR amplification.

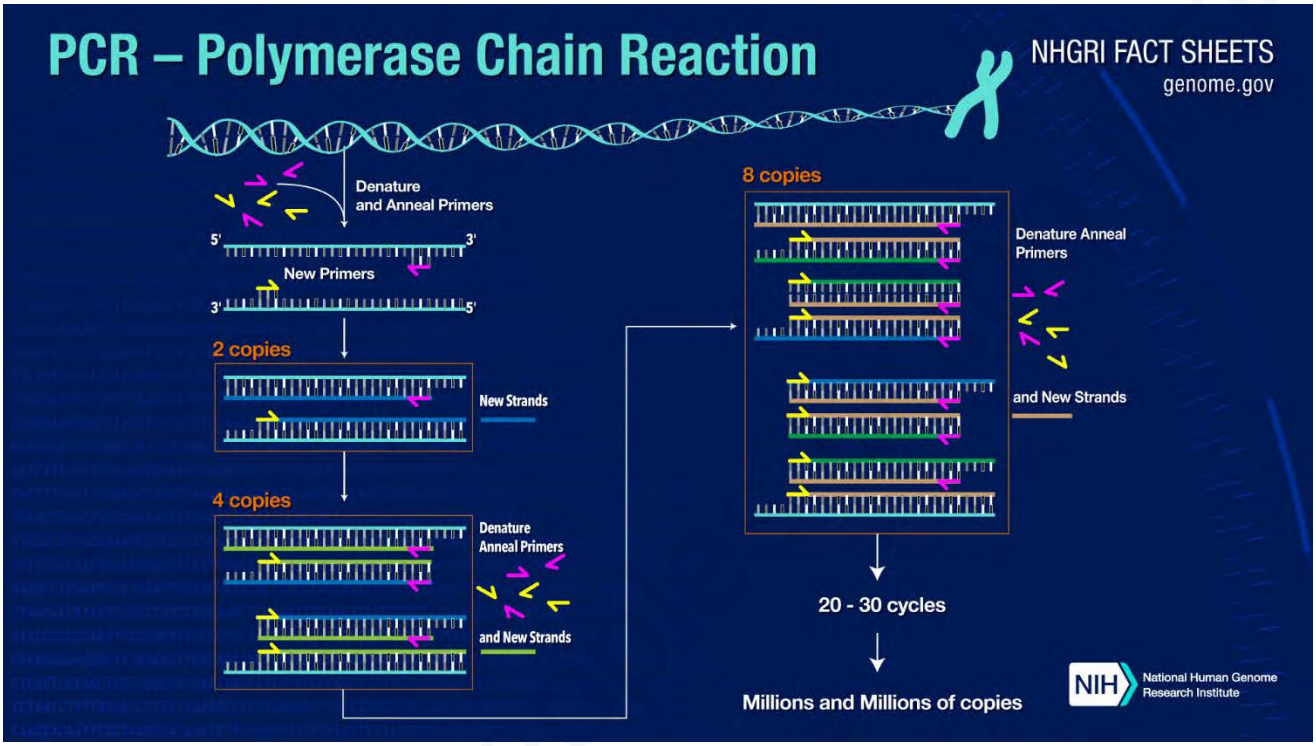
Often heralded as one of the most important scientific advances in molecular biology, PCR revolutionized the study of DNA to such an extent that its creator, Kary B. Mullis, was awarded the Nobel Prize for Chemistry in 1993.

What is PCR used for?

Once amplified, the DNA produced by PCR can be used in many different laboratory procedures. For example, most mapping techniques in the Human Genome Project (HGP) relied on PCR.

PCR is also valuable in a number of laboratory and clinical techniques, including DNA

fingerprinting, detection of bacteria or viruses (particularly AIDS), and diagnosis of genetic disorders.



How does PCR work?

To amplify a segment of DNA using PCR, the sample is first heated so the DNA denatures, or separates into two pieces of single-stranded DNA. Next, an enzyme called "Taq polymerase" synthesizes - builds - two new strands of DNA, using the original strands as templates. This process results in the duplication of the original DNA, with each of the new molecules containing one old and one new strand of DNA. Then each of these strands can be used to create two new copies, and so on, and so on. The cycle of denaturing and synthesizing new DNA is repeated as many as 30 or 40 times, leading to more than one billion exact copies of the original DNA segment.

The entire cycling process of PCR is automated and can be completed in just a few hours. It is

directed by a machine called a thermocycler, which is programmed to alter the temperature of the reaction every few minutes to allow DNA denaturing and synthesis.

Last updated: August 17, 2020

Polymerase Chain Reaction (PCR)

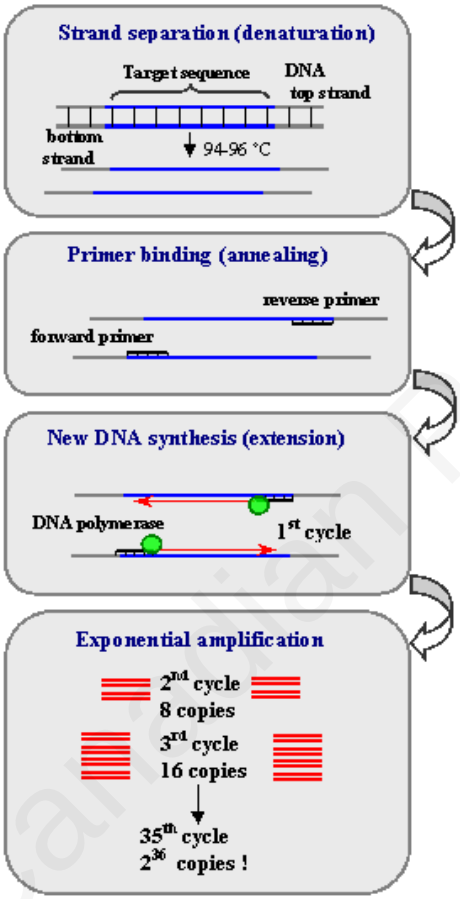
Last

Introduction

PCR (Polymerase Chain Reaction)

is a revolutionary method developed by Kary Mullis in the 1980s. PCR is based on using the ability of DNA polymerase to synthesize new strand of DNA complementary to the offered template strand. Because DNA polymerase can add a nucleotide only onto a preexisting 3'-OH group, it needs a primer to which it can add the first nucleotide. This requirement makes it possible to delineate a specific region of template sequence that the researcher wants to amplify. At the end of the PCR reaction, the specific sequence will be accumulated in billions of copies (amplicons).

How It Works



Components of PCR

DNA template - the sample DNA that contains the target sequence. At the beginning of the reaction, high temperature is applied to the original double-stranded DNA molecule to separate the strands from each other.- a type of **DNA polymerase** enzyme that synthesizes new strands of DNA complementary to the target sequence. The first and most commonly used of these enzymes is*Taq*DNA polymerase (from*Thermis aquaticus*), whereas*Pfu*DNA polymerase (from*Pyrococcus furiosus*) is used widely because of its higher fidelity when copying DNA. Although these enzymes are subtly different, they both have two capabilities that make them suitable for PCR: 1) they can generate new strands of DNA using a DNA template and **Primers** primers, and 2) they are heat resistant.- short pieces of single-stranded DNA that are complementary to the target sequence. The polymerase begins synthesizing new DNA from the end of the primer.- single units of the **Nucleotides (dNTPs or deoxynucleotide triphosphates)** bases A, T, G, and C, which are essentially **RT-PCR** "building blocks" for new DNA strands.(Reverse Transcription PCR) is PCR preceded with conversion of sample RNA into **reverse transcriptase** cDNA with enzyme.

Limitations of PCR and RT-PCR

The PCR reaction starts to generate copies of the target sequence exponentially. Only during the exponential phase of the PCR reaction is it possible to extrapolate back to determine the starting quantity of the target sequence contained in the sample. Because of inhibitors of the polymerase reaction found in the sample, reagent limitation, accumulation of pyrophosphate molecules, and self-annealing of the accumulating product, the PCR reaction eventually ceases to amplify target sequence at an exponential rate and a "plateau effect" occurs,

Help

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- Announcements
- Downloading
- Glossary

Applications

- Gene Expression
- Gene Silencing
- Variation Analysis
- Genome Mapping

Technologies

- Bead Arrays
- Microarrays
- Morpholinos
- Overgo probes
- Resequencing
- RNAi
- PCR
- STS
- Real Time qRT-PC
- SSO probes
- RAPD
- RFLP
- AFLP
- CAPS
- dCAPS
- MPSS
- MIP
- ISH

Projects

- GENSAT
- HapMap
- VariantSEQr
- TaqMan
- TRC
- RNAi Global

Distributors

- Open Biosystems
- Applied Biosysten

	making the end point quantification of PCR products unreliable. This is the attribute of PCR that makesReal-Time Quantitative RT-PCRso necessary.

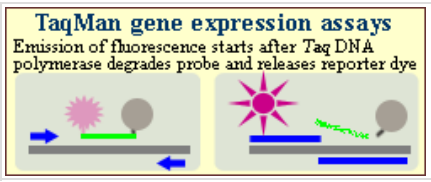
Sample Queries

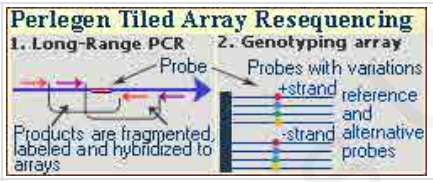
Search Text	Probes
"gene expression"[application]	0
"primer set"[probe type] AND "mus musculus"[organism]	0
TaqMan[probe type] AND "wet lab success"[validation]	0

Resources

» "Polymerase Chain Reaction"[MAJR]

Note: [MAJR] is a Medical Subject Heading (MeSH) tag for Major Heading. The tag is used to limit the search to articles for which major subjects are represented by terms included in the NLM MeSH database.





Canadian Human Rights Act (R.S.C. (Revised Statutes of Canada), 1985, c. H-6)
Act current to 2020-11-17 and last amended on 2019-07-12.

Canadian Human Rights Act

R.S.C. (Revised Statutes of Canada), 1985, c. H-6

An Act to extend the laws in Canada that proscribe discrimination

Short Title

Short title

1 This Act may be cited as the *Canadian Human Rights Act*.

1976-77, c. 33, s. 1.

Purpose of Act

Purpose

2 The purpose of this Act is to extend the laws in Canada to give effect, within the purview of matters coming within the legislative authority of Parliament, to the principle that all individuals should have an opportunity equal with other individuals to make for themselves the lives that they are able and wish to have and to have their needs accommodated, consistent with their duties and obligations as members of society, without being hindered in or prevented from doing so by discriminatory practices based on race, national or ethnic origin, colour, religion, age, sex, sexual orientation, gender identity or expression, marital status, family status, genetic characteristics, disability or conviction for an offence for which a pardon has been granted or in respect of which a record suspension has been ordered.

R.S., 1985, c. H-6, s. 2; 1996, c. 14, s. 1; 1998, c. 9, s. 9; 2012, c. 1, s. 137(E); 2017, c. 3, ss. 9, 11, c. 13, s. 1.

PART I

Proscribed Discrimination

General

Prohibited grounds of discrimination

3 (1) For all purposes of this Act, the prohibited grounds of discrimination are race, national or ethnic origin, colour, religion, age, sex, sexual orientation, gender identity or expression, marital status, family status, genetic characteristics, disability and conviction for an offence for which a pardon has been granted or in respect of which a record suspension has been ordered.

Idem

(2) Where the ground of discrimination is pregnancy or child-birth, the discrimination shall be deemed to be on the ground of sex.

Idem

(3) Where the ground of discrimination is refusal of a request to undergo a genetic test or to disclose, or authorize the disclosure of, the results of a genetic test, the discrimination shall be deemed to be on the ground of genetic characteristics.

R.S., 1985, c. H-6, s. 3; 1996, c. 14, s. 2; 2012, c. 1, s. 138(E); 2017, c. 3, ss. 10, 11, c. 13, s. 2.

Multiple grounds of discrimination

3.1 For greater certainty, a discriminatory practice includes a practice based on one or more prohibited grounds of discrimination or on the effect of a combination of prohibited grounds.

1998, c. 9, s. 11.

Orders regarding discriminatory practices

4 A discriminatory practice, as described in sections 5 to 14.1, may be the subject of a complaint under Part III and anyone found to be engaging or to have engaged in a discriminatory practice may be made subject to an order as provided in section 53.

R.S., 1985, c. H-6, s. 4; 1998, c. 9, s. 11; 2013, c. 37, s. 1.

Discriminatory Practices

Denial of good, service, facility or accommodation

5 It is a discriminatory practice in the provision of goods, services, facilities or accommodation customarily available to the general public

(a) to deny, or to deny access to, any such good, service, facility or accommodation to any individual, or

(b) to differentiate adversely in relation to any individual,

on a prohibited ground of discrimination.

1976-77, c. 33, s. 5.

Denial of commercial premises or residential accommodation

6 It is a discriminatory practice in the provision of commercial premises or residential accommodation

(a) to deny occupancy of such premises or accommodation to any individual, or

(b) to differentiate adversely in relation to any individual,

on a prohibited ground of discrimination.

1976-77, c. 33, s. 6.

Employment

7 It is a discriminatory practice, directly or indirectly,

(a) to refuse to employ or continue to employ any individual, or

(b) in the course of employment, to differentiate adversely in relation to an employee,

on a prohibited ground of discrimination.

1976-77, c. 33, s. 7; 1980-81-82-83, c. 143, s. 3(F).

Employment applications, advertisements

8 It is a discriminatory practice

(a) to use or circulate any form of application for employment, or

(b) in connection with employment or prospective employment, to publish any advertisement or to make any written or oral inquiry

that expresses or implies any limitation, specification or preference based on a prohibited ground of discrimination.

1976-77, c. 33, s. 8.

Employee organizations

9 (1) It is a discriminatory practice for an employee organization on a prohibited ground of discrimination

(a) to exclude an individual from full membership in the organization;

(b) to expel or suspend a member of the organization; or

(c) to limit, segregate, classify or otherwise act in relation to an individual in a way that would deprive the individual of employment opportunities, or limit employment opportunities or otherwise adversely affect the status of the individual, where the individual is a member of the organization or where any of the obligations of the organization pursuant to a collective agreement relate to the individual.

(2) [Repealed, 2011, c. 24, s. 165]

(3) [Repealed, 1998, c. 9, s. 12]

R.S., 1985, c. H-6, s. 9; 1998, c. 9, s. 12; 2011, c. 24, s. 165.

Discriminatory policy or practice

10 It is a discriminatory practice for an employer, employee organization or employer organization

(a) to establish or pursue a policy or practice, or

(b) to enter into an agreement affecting recruitment, referral, hiring, promotion, training, apprenticeship, transfer or any other matter relating to employment or prospective employment,

that deprives or tends to deprive an individual or class of individuals of any employment opportunities on a prohibited ground of discrimination.

R.S., 1985, c. H-6, s. 10; 1998, c. 9, s. 13(E).

Equal wages

11 (1) It is a discriminatory practice for an employer to establish or maintain differences in wages between male and female employees employed in the same establishment who are performing work of equal value.

Assessment of value of work

(2) In assessing the value of work performed by employees employed in the same establishment, the criterion to be applied is the composite of the skill, effort and responsibility required in the performance of the work and the conditions under which the work is performed.

Separate establishments

(3) Separate establishments established or maintained by an employer solely or principally for the purpose of establishing or maintaining differences in wages between male and female employees shall be deemed for the purposes of this section to be the same establishment.

Different wages based on prescribed reasonable factors

(4) Notwithstanding subsection (1), it is not a discriminatory practice to pay to male and female employees different wages if the difference is based on a factor prescribed by guidelines, issued by the Canadian Human Rights Commission pursuant to subsection 27(2), to be a reasonable factor that justifies the difference.

Idem

(5) For greater certainty, sex does not constitute a reasonable factor justifying a difference in wages.

No reduction of wages

(6) An employer shall not reduce wages in order to eliminate a discriminatory practice described in this section.

Definition of *wages*

(7) For the purposes of this section, ***wages*** means any form of remuneration payable for work performed by an individual and includes

(a) salaries, commissions, vacation pay, dismissal wages and bonuses;

(b) reasonable value for board, rent, housing and lodging;

(c) payments in kind;

(d) employer contributions to pension funds or plans, long-term disability plans and all forms of health insurance plans; and

(e) any other advantage received directly or indirectly from the individual's employer.

1976-77, c. 33, s. 11.

Date modified:

2020-11-27

Canadian Human Rights Act (R.S.C. (Revised Statutes of Canada), 1985, c. H-6)
Act current to 2020-11-17 and last amended on 2019-07-12.

PART III

Discriminatory Practices and General Provisions (continued)

Offences and Punishment

Offence

60 (1) Every person is guilty of an offence who

(a) [Repealed, 1998, c. 9, s. 31]

(b) obstructs a member or panel in carrying out its functions under this Part; or

(c) contravenes subsection 11(6) or 43(3) or section 59.

Punishment

(2) A person who is guilty of an offence under subsection (1) is liable on summary conviction to a fine not exceeding $50,000.

Prosecution of employer or employee organization

(3) A prosecution for an offence under this section may be brought against an employer organization or employee organization and in the name of the organization and, for the purpose of the prosecution, the organization is deemed to be a person and any act or thing done or omitted by an officer or agent of the organization within the scope of their authority to act on behalf of the organization is deemed to be an act or thing done or omitted by the organization.

Consent of Attorney General

(4) A prosecution for an offence under this section may not be instituted except by or with the consent of the Attorney General of Canada.

Limitation period

(5) A prosecution for an offence under this section may not be instituted more than one year after the subject-matter of the proceedings arose.

R.S., 1985, c. H-6, s. 60; 1998, c. 9, s. 31.

Reports

Annual report of Commission

61 (1) The Commission shall, within three months after December 31 in each year, prepare and submit to Parliament a report on the activities of the Commission under this Part and Part II for that year, including references to and comments on any matter referred to in paragraph 27(1)(e) or (g) that it considers appropriate.

Special reports

(2) The Commission may, at any time, prepare and submit to Parliament a special report referring to and commenting on any matter within the scope of its powers, duties and functions if, in its opinion, the matter is of such urgency or importance that a report on it should not be deferred until the time provided for submission of its next annual report under subsection (1).

Annual report of Tribunal

(3) The Tribunal shall, within three months after December 31 in each year, prepare and submit to Parliament a report on its activities under this Act for that year.

Transmission of report

(4) Every report under this section shall be submitted by being transmitted to the Speaker of the Senate and to the Speaker of the House of Commons for tabling in those Houses.

R.S., 1985, c. H-6, s. 61; 1998, c. 9, s. 32.

Minister Responsible

Minister of Justice

61.1 The Minister of Justice is responsible for this Act, and the powers of the Governor in Council to make regulations under this Act, with the exception of section 29, are exercisable on the recommendation of that Minister.

1998, c. 9, s. 32.

Application

Limitation

62 (1) This Part and Parts I and II do not apply to or in respect of any superannuation or pension fund or plan established by an Act of Parliament enacted before March 1, 1978.

Review of Acts referred to in subsection (1)

(2) The Commission shall keep under review those Acts of Parliament enacted before March 1, 1978 by which any superannuation or pension fund or plan is established and, where the Commission deems it to be appropriate, it may include in a report mentioned in section 61 reference to and comment on any provision of any of those Acts that in its opinion is inconsistent with the principle described in section 2.

1976-77, c. 33, s. 48.

Application in the territories

63 Where a complaint under this Part relates to an act or omission that occurred in Yukon, the Northwest Territories or Nunavut, it may not be dealt with under this Part unless the act or omission could be the subject of a complaint under this Part had it occurred in a province.

R.S., 1985, c. H-6, s. 63; 1993, c. 28, s. 78; 2002, c. 7, s. 127.

Canadian Forces and Royal Canadian Mounted Police

64 For the purposes of this Part and Parts I and II, members of the Canadian Forces and the Royal Canadian Mounted Police are deemed to be employed by the Crown.

1976-77, c. 33, s. 48.

Acts of employees, etc.

65 (1) Subject to subsection (2), any act or omission committed by an officer, a director, an employee or an agent of any person, association or organization in the course of the employment of the officer, director, employee or agent shall, for the purposes of this Act, be deemed to be an act or omission committed by that person, association or organization.

Exculpation

(2) An act or omission shall not, by virtue of subsection (1), be deemed to be an act or omission committed by a person, association or organization if it is established that the person, association or organization did not consent to the commission of the act or omission and exercised all due diligence to prevent the act or omission from being committed and, subsequently, to mitigate or avoid the effect thereof.

1980-81-82-83, c. 143, s. 23.

PART IV

Application

Binding on Her Majesty

66 (1) This Act is binding on Her Majesty in right of Canada, except in matters respecting the Yukon Government or the Government of the Northwest Territories or Nunavut.

(2) [Repealed, 2002, c. 7, s. 128]

(3) [Repealed, 2014, c. 2, s. 11]

Idem

(4) The exception referred to in subsection (1) shall come into operation in respect of the Government of Nunavut on a day to be fixed by order of the Governor in Council.

R.S., 1985, c. H-6, s. 66; 1993, c. 28, s. 78; 2002, c. 7, s. 128; 2014, c. 2, s. 11.

67 [Repealed, 2008, c. 30, s. 1]

Date modified:

2020-11-27

DIVISION XV.3

Genetic Testing

Definitions

247.98 (1) The following definitions apply in this Division.

disclose includes to authorize disclosure. (*communiquer*)

genetic test, in relation to an employee, means a test that analyzes the employee's DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (*test génétique*)

Genetic test

(2) Every employee is entitled not to undergo or be required to undergo a genetic test.

Disclosure of results

(3) Every employee is entitled not to disclose or be required to disclose the results of a genetic test.

Disciplinary action

(4) No employer shall dismiss, suspend, lay off or demote an employee, impose a financial or other penalty on an employee, or refuse to pay an employee remuneration in respect of any period that the employee would, but for the exercise of the employee's rights under this Division, have worked, or take any disciplinary action against or threaten to take any such action against an employee

(a) because the employee refused a request by the employer to undergo a genetic test;

(b) because the employee refused to disclose the results of a genetic test; or

(c) on the basis of the results of a genetic test undergone by the employee.

Disclosure by third party

(5) No person shall disclose to an employer that an employee has undergone a genetic test, or disclose to an employer the results of a genetic test, without the written consent of the employee.

Collection or use

(6) No employer shall collect or use the results of a genetic test without the written consent of the employee who has undergone the test.

2017, c. 3, s. 8

RESEARCH

Infectivity of severe acute respiratory syndrome coronavirus 2 in children compared with adults

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Cite as: *CMAJ* 2021 April 26;193:E601-6. doi: 10.1503/cmaj.210263; early-released April 9, 2021

ABSTRACT

BACKGROUND: The role of children in the transmission and community spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is unclear. We aimed to quantify the infectivity of SARS-CoV-2 in nasopharyngeal samples from children compared with adults.

METHODS: We obtained nasopharyngeal swabs from adult and pediatric cases of coronavirus disease 2019 (COVID-19) and from their contacts who tested positive for SARS-CoV-2 in Manitoba between March and December 2020. We compared viral growth in cell culture, cycle threshold values from the reverse transcription polymerase chain reaction (RT-PCR) of the SARS-CoV-2 envelope (E) gene and the 50% tissue culture infective dose ($TCID_{50}$/mL) between adults and children.

RESULTS: Among 305 samples positive for SARS-CoV-2 by RT-PCR, 97 samples were from children aged 10 years or younger, 78 were from children aged 11–17 years and 130 were from adults (≥ 18 yr). Viral growth in culture was present in 31% of samples, including 18 (19%) samples from children 10 years or younger, 18 (23%) from children aged 11–17 years and 57 (44%) from adults (children v. adults, odds ratio 0.45, 95% confidence interval [CI] 0.28–0.72). The cycle threshold was 25.1 (95% CI 17.7–31.3) in children 10 years or younger, 22.2 (95% CI 18.3–29.0) in children aged 11–17 years and 18.7 (95% CI 17.9–30.4) in adults ($p < 0.001$). The median $TCID_{50}$/mL was significantly lower in children aged 11–17 years (316, interquartile range [IQR] 178–2125) than adults (5620, IQR 1171 to 17 800, $p < 0.001$). Cycle threshold was an accurate predictor of positive culture in both children and adults (area under the receiver-operator curve, 0.87, 95% CI 0.81–0.93 v. 0.89, 95% CI 0.83–0.96, $p = 0.6$).

INTERPRETATION: Compared with adults, children with nasopharyngeal swabs that tested positive for SARS-CoV-2 were less likely to grow virus in culture, and had higher cycle thresholds and lower viral concentrations, suggesting that children are not the main drivers of SARS-CoV-2 transmission.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the nonpharmaceutical public health interventions (NPIs) to control it have had a considerable impact on society. Public health efforts directed to reduce the spread of coronavirus disease 2019 (COVID-19) have employed a number of NPIs, including suspension of in-person school attendance for school-aged children. These decisions were largely based on historical observations that children played a substantial role as drivers of transmission for epidemic respiratory viruses, such as influenza.[1] In the case of SARS-CoV-2, the role of children in transmission remains unclear, given few studies with conflicting data.[2–9] Most studies have been limited to epidemiological investigations from which the direction of transmission is challenging to discern.[3–7,9] As an alternative line of evidence, some studies have investigated the role of SARS-CoV-2 viral dynamics, also with heterogeneous results. Of these studies, some have shown higher viral loads in the nasopharynx of pediatric cohorts based on polymerase chain reaction testing, with others showing comparable levels of SARS-CoV-2 in children and adults.[2,8,10,11] Furthermore, evidence relating to other viruses has shown that detectable viral RNA can persist beyond infectivity.[3,4] An important proxy of in vivo infectiousness is recovery of live virus on cell culture. Assessment of this critical dimension has been lacking in virtually all pediatric

studies, limiting the ability to perform a more complete risk–benefit analysis when considering the role of children in SARS-CoV-2 transmission. Evidence shows that the infectivity of SARS-CoV-2 may be predicted using available data, such as the cycle threshold from the reverse transcription polymerase chain reaction (RT-PCR).[12,13] Cycle threshold is a relative measure of the quantity of genetic material, with lower values indicating the presence of more viral genetic material in the sample.

As an increasing number of jurisdictions consider whether in-school learning, daycares and extracurricular activities should continue or resume, a better understanding of the relative contributions of children and adolescents to SARS-CoV-2 transmission, when compared with adults, is essential. This is particularly important given the increased likelihood of asymptomatic infection in this group.[14,15] Our goal was to quantify rates of SARS-CoV-2 culture positivity from nasopharyngeal swabs positive for the virus after RT-PCR testing in children. We then characterized the viral load and titres in culture-positive specimens and compared this with an adult group.

Methods

Study population and design

Beginning in July 2020, the province of Manitoba, Canada (population 1.4 million) had large-scale outbreaks of COVID-19. In efforts to limit transmission, comprehensive testing of case contacts was performed. Definitions of COVID-19 cases and case contacts are provided in Appendix 1, available at www.cmaj.ca/lookup/doi/10.1503/cmaj.210263/tab-related-content.

We obtained nasopharyngeal swabs from patients with COVID-19 and their contacts. Sample RT-PCR testing was performed by the Cadham Provincial Laboratory, the reference laboratory for SARS-CoV-2 testing in Manitoba. Specimens were collected at COVID-19 testing sites and transported in viral transport medium to the laboratory, typically 1–4 days after collection. In the laboratory, the specimens were stored at 4°C for 24 hours until they were tested as previously described.[12] All samples were tested using laboratory-developed testing to minimize cycle threshold variation.

We submitted all specimens from children positive for SARS-CoV-2 after RT-PCR for cell culture from March to August 2020. As case numbers increased, a convenience sample of positive specimens was provided to the National Microbiology Laboratory for cell culture analysis. We selected specimens from the preceding week's samples to ensure freshness and thereby maximize yields from cell culture. In November, we purposely selected pediatric specimens with a cycle threshold of less than 25 to confirm our preliminary observation that culture positivity rates were lower than adult samples (all pediatric sampling from Mar. 27 to Nov. 8, 2020). Cycle threshold values less than 25 were previously determined to have higher culture yields.[12] Concurrently, we selected a convenience sample of adult specimens with cycle threshold values of 25 or less for comparison. Before the final cell culture analysis, we selected a convenience sample of specimens from adults (collected Mar. 12 to Dec. 14, 2020) for cell culture from the same health regions as pediatric samples.

Outcomes

Our main outcomes were culture positivity rates, RT-PCR cycle theshold values, the 50% tissue culture infectious dose ($TCID_{50}$/mL), viral load (log RNA copies/mL) and symptoms to test time. For all positive samples, we obtained the RT-PCR cycle threshold values of the SARS-CoV-2 envelope (E) gene. We also obtained the cycle threshold values of the human RNAse P gene, an endogenous internal amplification control used as a marker of quality of the nasopharyngeal sample.

The $TCID_{50}$/mL assay is one method for quantifying infectious virus titres. Specifically, it quantifies the amount of virus required to kill 50% of tissue culture cells, thereby producing a cytopathic effect. Most samples were stored at −80°C for 2 weeks before being processed for culture. Viral titres of samples were determined by the National Microbiology Laboratory (biocontainment level 4) using $TCID_{50}$/mL assays (full methodology described in Appendix 1). In brief, serially diluted samples were placed on Vero cells and incubated for 96–120 hours at 37°C and in 5% CO_2 before the $TCID_{50}$ was measured.

Viral load is commonly measured as the logarithmic number of RNA genome copies per millilitre (log RNA copies/mL), a more standardized quantitative value than cycle thresholds. For this study, and to quantify the amount of viral RNA present in each sample, we generated a standard curve using a known quantity of viral RNA or copied DNA that was serially diluted and run at the same time as the test samples to provide a relation between cycle threshold and genome copies/mL (Appendix 1).

We determined date of symptom onset through public health, epidemiology, surveillance and laboratory records. We also calculated the number of days from symptom onset to sample collection, known as symptoms to test time, based on laboratory records (see Appendix 1).

Statistical analysis

In our previous work,[12] we found that adults had a culture positivity rate of 28.9%. Therefore, we required 164 pediatric samples to detect a clinically significant difference (33% lower culture positivity rate at a power of 0.8 and α of 0.05) among children.

We present normally distributed data with means and standard deviations, and present nonnormally distributed data with medians and interquartile ranges (IQRs). We assessed normality using the Kolmorgorov–Smirnov test. We performed between-group comparisons using the Student *t* test or the Mann–Whitney test, and used the Fisher exact test for categorical data. We compared nonparametric group medians using Kruskal–Wallis analysis of variance. We performed multivariable logistic regression using robust standard errors to test predictors of positive cultures. We considered two-tailed *p* values less than 0.05 as significant. We performed statistical analysis with Stata version 16.1 and GraphPad Prism 9.

Ethics approval

The study was performed in accordance with protocol HS23906 (H2020:211) and approved by the University of Manitoba Research Ethics Board. The ethics board waived the need for informed consent as samples were obtained as part of routine clinical and public health management and were not taken specifically for inclusion in the current study.

Results

During the study period, about 360 000 nasopharyngeal swab tests were performed in Manitoba, of which about 20 000 were positive for SARS-CoV-2. Our final sample included 305 cultured specimens, representing 1.5% of positive samples in Manitoba and 7.2% (175 of 2440) of positive samples among children. Of 175 pediatric samples cultured, 97 samples were from children 10 years old or younger and 78 were from children 11–17 years old; these were compared with 130 adult specimens. Baseline demographics, cycle thresholds and viral RNA loads are shown in Table 1 and Table 2. We successfully cultured the virus in 93 of 305 samples (31%), including 57 of 130 adults (44%, 95% CI 35%–53%). In comparison, we cultured the virus in only 18 of 97 samples in children 10 years old or younger (19%, 95% CI 11%–28%, $p < 0.001$) and 18 of 78 samples in children aged 11–17 years old (23%, 95% CI 14%–34%, $p = 0.003$). The rate of positive cultures did not differ between younger and older children ($p = 0.5$). Compared with adults, children had a 55% reduced odds of growing live virus (odds ratio 0.45, 95% CI 0.28–0.72). Although children 10 years old or younger were more likely to have asymptomatic infections (47/97, 48%) than children 11–17 years old (19/78, 24%) or adults (9/130, 7%) ($p < 0.001$ for all comparisons), all children aged 17 years or younger were similarly likely to be asymptomatic regardless of whether they had culture-positive or culture-negative samples (42% v. 37%, $p = 0.9$).

The quality of nasopharyngeal samples, as shown by the cycle threshold values of the human RNAse P gene, did not differ among the 3 age groups ($p = 0.6$). The cycle threshold of the SARS-CoV-2 E gene was lower in adults (18.7, IQR 17.9–30.4) than children 10 years old or younger (25.1, IQR 17.7–31.3, $p < 0.001$) or children 11–17 years old (22.2, IQR 18.3–29.0, $p = 0.02$) (Table 1 and Figure 1).

Table 1: Measures of SARS-CoV-2 infectivity in children and adults

Variable	Children aged ≤ 10 yr *n* = 97	Children aged 11–17 yr *n* = 78	Adults *n* = 130	*p* value
Asymptomatic, no. (%)	47 (48)	19 (24)	9 (7)	< 0.001§
Positive culture, no. (%, 95% CI)	18 (19, 11–28)	18 (23, 14–34)	57 (44, 35–53)	< 0.001¶
Symptom to test time, median (IQR), d	1 (1–4)	2 (1–3.5)	2 (1–4)	0.6
Cycle threshold*, median (IQR)	25.1 (17.7–31.3)	22.2 (18.3–29.0)	18.7 (17.9–30.4)	< 0.001**
RNAseP†, mean ± SD	25.7 ± 2.8	26.1 ± 2.6	26.1 ± 2.0	0.6
$TCID_{50}$/mL‡, median (IQR)	1171 (316–5620)	316 (178–2125)	5620 (1171–17 800)	< 0.001††
Log RNA copies/mL, median (IQR)	5.4 (3.5–7.8)	6.4 (4.2–7.6)	7.5 (5.2–8.3)	< 0.001‡‡

Note: CI = confidence interval, IQR = interquartile range, RT-PCR = reverse transcription polymerase chain reaction, SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2, SD = standard deviation.
*Cycle threshold is a semiquantitative measure of how much genetic material is present in the initial sample. If more RT-PCR cycles are required to detect SARS-CoV-2, then less viral RNA was present in the sample.
†Cycle threshold values for human RNAse P gene, an endogenous internal amplification control, were used as a marker of quality of the nasopharyngeal sample.
‡Fifty percent tissue culture infective dose ($TCID_{50}$) is a measure of infectious virus titre and represents the amount of virus required to kill 50% of cells in inoculated tissue culture.
§*p* value is < 0.001 for all comparisons: children ≤ 10 years old compared with children aged 11–17 years, children aged 11–17 compared with adults and children ≤ 10 years old compared with adults.
¶$p = 0.5$ children ≤ 10 years v. children aged 11–17 years; $p = 0.003$ children aged 11–17 years v. adults; $p < 0.001$ children ≤ 10 years v. adults.
**$p = 0.99$ children ≤ 10 years v. children aged 11–17 years; $p = 0.02$ children aged 11–17 years v. adults; $p < 0.001$ children ≤ 10 years v. adults.
††$p = 0.6$ children ≤ 10 years v. children aged 11–17 years; $p < 0.001$ children aged 11–17 years v. adults; $p = 0.1$ children ≤ 10 years v. adults.
‡‡$p = 0.99$ children ≤ 10 years v. children aged 11–17 years; $p = 0.2$ children aged 11–17 years v. adults; $p < 0.001$ children ≤ 10 years v. adults.

Table 2: Measures of SARS-CoV-2 infectivity in pediatric culture-positive versus culture-negative samples

Variable	No. (%) of culture-positive samples* *n* = 36	No. (%) of culture-negative samples* *n* = 139	*p* value
Age, yr, median (IQR)	10 (5–15)	9 (5–14)	0.6
Asymptomatic	15 (42)	51 (37)	0.9
Male sex	22 (61)	80 (57)	0.7
Symptom to test time, median (IQR), d	1 (0–2)	2 (1–4)	0.3
Cycle threshold†, median (IQR)	16.8 (16.3–18.8)	25.8 (20.7–31.9)	< 0.001
Log RNA copies/mL, median (IQR)	8.1 (7.4–8.2)	5.2 (3.2–6.8)	< 0.001

Note: IQR = interquartile range, RT-PCR = reverse transcription polymerase chain reaction, SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
*Unless indicated otherwise.
†Cycle threshold is a semiquantitative measure of how much genetic material is present in the initial sample. If more RT-PCR cycles are required to detect SARS-CoV-2, then less viral RNA was present in the sample.

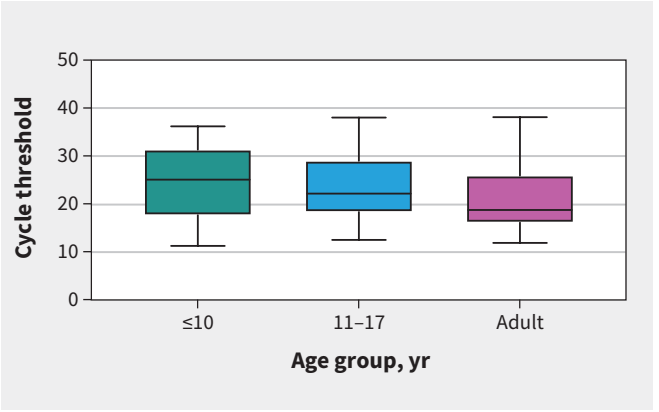

Figure 1: Reverse transcription polymerase chain reaction cycle threshold values of the severe acute respiratory syndrome coronavirus 2 envelope gene by age group. Adult samples had a significantly lower cycle threshold value (18.7, interquartile range [IQR] 17.9–30.4) than children aged ≤ 10 years (25.1, IQR 17.7–31.3, $p < 0.001$) and those aged 11–17 years (22.2, IQR 18.3–29.0, $p = 0.02$).

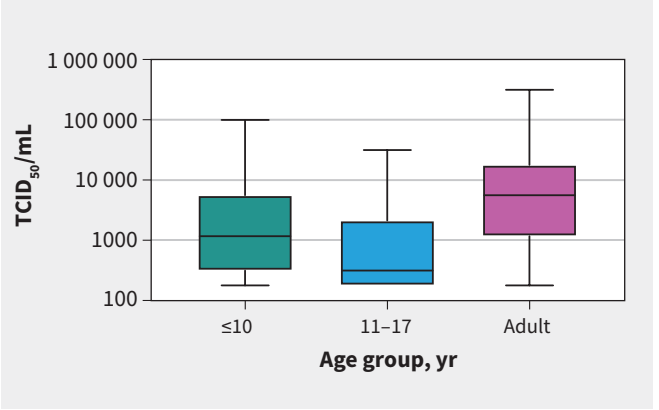

Figure 2: Tissue culture infective dose 50% ($TCID_{50}$/mL) by age group. Adult samples had significantly higher $TCID_{50}$/mL (5620, IQR 1171–17 800) than children aged 11–17 years (316, interquartile range [IQR] 178–2125, $p < 0.001$), but were not significantly higher than children aged ≤ 10 years (1171, IQR 316 to 5620, $p = 0.1$).

The median $TCID_{50}$/mL was significantly lower for children aged 11–17 years (316, IQR 178–2125) than adults (5620, IQR 1171–17 800, $p < 0.001$), but differences between adults and children 10 years old or younger (1171, IQR 316–5620, $p = 0.1$) did not reach statistical significance (Table 1 and Figure 2).

There was no difference between pediatric culture-positive and culture-negative samples, except for cycle threshold values and log RNA copies/mL (Table 2). The median cycle threshold was lower in culture-positive samples (16.8, IQR 16.3–18.8) than culture-negative samples (25.8, IQR 20.7–31.9, $p < 0.001$). The median log RNA copies/mL was higher in culture-positive samples 8.1, IQR 7.4–8.2) than culture-negative samples (5.2, IQR 3.2–6.8, $p < 0.001$). However, the median symptoms to test time was not different between the culture-positive (1 d, IQR 0–2 d) and culture-negative groups (2 d, IQR 1–4 d, $p = 0.3$). The probability of a positive culture varied by symptoms to test time, with likelihood of a positive culture being highest among specimens collected 4–6 days after symptom onset, whereas cycle threshold showed less variation across symptoms to test times (Figure 3).

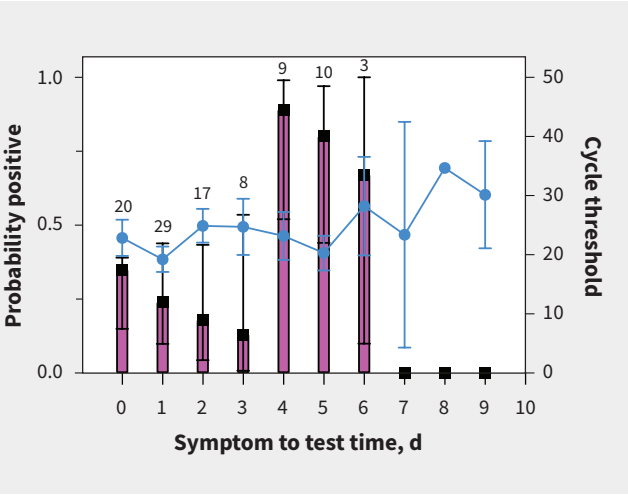

Figure 3: Symptom onset to test time (days), the mean revere transcription polymerase chain reaction cycle threshold value of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) envelope gene and the probability of successful viral culture in pediatric samples. The probability of SARS-CoV-2 culture is shown by the pink bars. Black lines represent 95% confidence intervals. Cycle threshold values are represented by the blue line, with circles representing medians and blue bars representing the 95% confidence intervals. Numbers above the pink bar indicate the number of samples per day.

Receiver operating characteristic (ROC) analysis of the cycle threshold to discriminate between children with and without positive viral culture showed an area under the receiver-operator curve (AUC) of 0.87 (95% CI 0.81–0.93) (Appendix 1, Supplementary Figure 1). The specificity of a cycle threshold of 23 was 97.2% (95% CI 85.8%–99.9%) (Appendix 1, Supplementary Table 1). Similar results were seen in adults (AUC 0.89, 95% CI 0.83–0.96, $p = 0.6$ v. children) (Appendix 1, Supplmentary Figure 1, Supplementary Table 2). Symptoms to test time was not as accurate as cycle threshold in discriminating between samples with and without positive viral culture (children, AUC 0.67, 95% CI 0.55 to 0.79 v. adults, AUC 0.78, 95% CI 0.68–0.88, $p = 0.2$) (Appendix 1, Supplementary Figure 2), with a specificity of 100% (95% CI 84.5%–100%) at a symptoms to test time of greater than 6 days. Of note, our sample had only 8 patients with symptoms to test time of 6 days or more, calling into question the accuracy of the results in determining a cut-off period of symptoms to test time for cell culture positivity and possible infectivity because of a lack of power.

Multivariable logistic regression showed that, for pediatric samples, cycle threshold was an independent predictor of positive culture (odds ratio 0.81, 95% CI 0.69–0.94), but symptoms to test time, age and sex were not (Table 3).

In a supplementary analysis, we found no difference in the culture-positive rates between children aged 0–4 years compared with children aged 5–10 years. The level of virus (based on $TCID_{50}$/mL) also did not differ among culture-positive samples from children in these 2 age groups.

Table 3: Multivariable logistic regression model of measures associated with a positive viral culture from pediatric samples

Variable	Adjusted odds ratio (95% CI)
Cycle threshold*	0.81 (0.69–0.94)
Symptoms to test time	0.90 (0.64–1.27)
Age	1.13 (0.97–1.31)
Sex	2.18 (0.48–9.87)
RNAseP†	0.69 (0.48–1.00)

Note: CI = confidence interval, RT-PCR = reverse transcription polymerase chain reaction, SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
*Cycle threshold is a semiquantitative measure of how much genetic material is present in the initial sample. If more RT-PCR cycles are required to detect SARS-CoV-2, then less viral RNA was present in the sample.
†Cycle threshold values for human RNAse P gene, an endogenous internal amplification control, were used as a marker of quality of the nasopharyngeal sample.

Interpretation

Our results show that samples from 175 children 17 years old or younger had about half the odds of containing culturable virus than samples from adults. When SARS-CoV-2 was successfully cultured, the median $TCID_{50}$/mL was significantly lower for pediatric samples than adults, meaning that less viable virus was present. Moreover, the culture positivity rate of samples from children 10 years or younger was significantly lower than for children aged 11–17 years or adults. These results illustrate that RT-PCR positivity does not necessarily equate to culture positivity, as RT-PCR positivity alone does not distinguish between live virus in an infectious patient and residual viral RNA in a patient who may no longer be infectious.

We found that the cycle threshold value was highly predictive of culture positivity. In contrast, symptoms to test time was not able to discriminate between children with positive and negative cultures. Thus, in children who have tested positive for SARS-CoV-2 by RT-PCR, knowing the cycle threshold value may be more informative for determining the potential infectiousness of a child, and may have implications for duration of isolation.

These results are contrary to what has been observed with other respiratory viruses for which efficient infection and transmission in children often herald widespread community transmission. However, these findings are consistent with epidemiological studies that show limited SARS-CoV-2 spread from children younger than 10 years old.[16,17] A recent seroprevalence study from Germany showed that children, particularly those aged 1–10 years, have a significantly lower seropositivity than their parents, making undetected asymptomatic infections in children less likely.[18] A meta-analysis showed that children have a lower susceptibility to SARS-CoV-2 and may not drive community transmission to the same degree as adults.[19] Severe acute respiratory syndrome coronavirus 2 also has an overly dispersed reproduction number (R_o), suggesting that its transmission dynamics are fundamentally different than epidemic seasonal respiratory viruses.[20–22] Overdispersion refers to high individual-level variation in the distribution of the number of secondary transmissions, which can lead to so-called "superspreading" events.[21]

Others have looked at the ability to grow live virus from pediatric samples, the gold standard for microbiological diagnosis. L'Huillier and colleagues grew live virus from a higher proportion of pediatric samples than our study (52%; 12/23, v. 31% in our combined samples).[11] Their findings of symptoms to test time were similar to what we observed, and the 95% CIs of our results almost overlap theirs, suggesting that their smaller sample size may be responsible for their higher proportion of culture-positive results. However, closer inspection of the L'Huillier data reveals that, consistent with our current study, culture positivity varied with age, such that virus was cultured from only 4 of 11 (36.4%) children 10 years old or younger, but 8 of 12 (66.6%) children 11 years old or older. Recognizing that cycle threshold is a limited surrogate of viral load, other studies have attempted to further quantify viral load in children by using log RNA copies/mL based on standardized curves. Although this approach does improve the ability to compare data across time and laboratories, it remains a surrogate measure of viable viral load, cannot predict recoverable live virus and is vulnerable to being confounded by shedding of noninfectious viral genetic material. As such, inferences from measures of viral load derived from cycle threshold data have substantial limitations. We quantified viral presence through the use of $TCID_{50}$/mL, which provides additional discriminatory power compared with methods that limit the analysis to simply the presence or absence of cytopathic effect.[11]

The observation of a cycle threshold value greater than 23 signalling a significant reduced risk of recovering live virus is worth examining in a larger study. This value is in keeping with our previous work that showed a decreased ability to grow live virus in adult samples where the cycle threshold was greater than 24.[12] Finally, defining a robust symptom-based cut-off period for cell culture positivity should be undertaken, although testing often occurs shortly after symptom onset. It may prove challenging to answer this question in the current COVID-19 testing environment.

Limitations

Other possible explanations for our findings should be considered. Viral genetic variation may play a role; however, genomic surveillance shows that samples represented the diverse global lineages present in the initial and subsequent waves of cases in Manitoba. Sample collection from children can be challenging, resulting in a suboptimal specimen. The lack of significant differences in cycle threshold values of RNAse P (an endogenous internal control), however, suggests similar sampling quality across age groups. Degradation of samples while in storage, affecting the chance of viral recovery, was also considered, but the time to cell culture was similar across age groups, making this possibility unlikely.

Although young children had similar symptoms to test time, children may be most infectious at a different time postexposure than adolescents or adults. Our local epidemiology (unpublished data, 2021) does not support this argument, as pediatric cases of COVID-19 are consistent with community transmission.[23,24] It is possible that children were at a different point in their viral trajectory relative to adolescents and adults when they were sampled. As only a single sample was taken, it would not be possible to determine the longitudinal trend in cycle threshold value relative to sampling time. Regression analysis (data not shown) from adults and children did not show any correlation between symptoms to test time and cycle threshold or $TCID_{50}$/mL value. Recall bias of symptom onset is possible and symptoms may be subtle in children, thus compounding

recall bias, but this is likely equally distributed among all patients. Finally, we cannot be certain that our findings apply to novel SARS-CoV-2 variants that have shown higher levels of infectivity, as such variants were not commonly circulating during the study period.

Conclusion

We found that SARS-CoV-2 grew from pediatric samples less often than adult samples, and when the virus was successfully cultured, significantly less viable virus was present. These data, along with our local epidemiology, suggest that children do not appear to be the main drivers of SARS-CoV-2 transmission. Our findings have important public health and clinical implications. If younger children are less capable of transmitting infectious virus, daycare, in-person school and cautious extracurricular activities may be safe to continue, with appropriate precautions in place, and with lower risk to child care staff, educators and support staff than initially anticipated. Given the difficulties in keeping children isolated within the home environment and the significant impact of prolonged isolation on both child development and parental function (such as loss of work or income), a robust tool to decrease the length of, or need for, quarantine would be an important public health development.

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Competing interests: Lauren Garnett, Kaylie Tran, Alex Bello and James Strong report A-base funding from the Government of Canada. No other competing interests were declared.

This article has been peer reviewed.

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Contributors: All of the authors contributed to the conception and design of the work, and the acquisition, analysis, and interpretation of data. All of the authors drafted the manuscript, revised it critically for important intellectual content, gave final approval of the version to be published and agreed to be accountable for all aspects of the work.

Data sharing: Data with potential personal health information cannot be shared by Manitoba Health and are regulated by the Health Information Privacy Committee (HIPC) under the Public Health Information Act of Manitoba. Upon request, data that have been appropriately anonymized and deidentified may be provided to researchers through consultation with the corresponding author.

Acknowledgments: This work was supported by the collaborative efforts in the public health response to the COVID-19 pandemic by Manitoba Health, Cadham Provincial Laboratory, the Public Health Agency of Canada and the National Microbiology Laboratory. The authors also thank the teachers and educators, who have maintained some normalcy for the children of Manitoba, and the children themselves.

Accepted: Mar. 30, 2021

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Clinical Infectious Diseases

MAJOR ARTICLE

Predicting Infectious Severe Acute Respiratory Syndrome Coronavirus 2 From Diagnostic Samples

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(See the Editorial Commentary by Binnicker on pages 2667–8.)

Background. Reverse-transcription polymerase chain reaction (RT-PCR) has become the primary method to diagnose viral diseases, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). RT-PCR detects RNA, not infectious virus; thus, its ability to determine duration of infectivity of patients is limited. Infectivity is a critical determinant in informing public health guidelines/interventions. Our goal was to determine the relationship between E gene SARS-CoV-2 RT-PCR cycle threshold (Ct) values from respiratory samples, symptom onset to test (STT), and infectivity in cell culture.

Methods. In this retrospective cross-sectional study, we took SARS-CoV-2 RT-PCR–confirmed positive samples and determined their ability to infect Vero cell lines.

Results. Ninety RT-PCR SARS-CoV-2–positive samples were incubated on Vero cells. Twenty-six samples (28.9%) demonstrated viral growth. Median tissue culture infectious dose/mL was 1780 (interquartile range, 282–8511). There was no growth in samples with a Ct > 24 or STT > 8 days. Multivariate logistic regression using positive viral culture as a binary predictor variable, STT, and Ct demonstrated an odds ratio (OR) for positive viral culture of 0.64 (95% confidence interval [CI], .49–.84; $P < .001$) for every 1-unit increase in Ct. Area under the receiver operating characteristic curve for Ct vs positive culture was OR, 0.91 (95% CI, .85–.97; $P < .001$), with 97% specificity obtained at a Ct of > 24.

Conclusions. SARS-CoV-2 Vero cell infectivity was only observed for RT-PCR Ct < 24 and STT < 8 days. Infectivity of patients with Ct > 24 and duration of symptoms > 8 days may be low. This information can inform public health policy and guide clinical, infection control, and occupational health decisions. Further studies of larger size are needed.

Keywords. SARS-CoV-2; COVID-19; RT-PCR; infectivity; public health.

The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19), represents a public health emergency of historic proportion. The global containment efforts have had broad societal and economic impacts. Policy decisions to relax public health measures will require a better understanding of duration of infectivity. This information will also impact infection control practices and occupational health.

To date, the diagnosis of COVID-19 has relied on the detection of SARS-CoV-2 through molecular detection. While this method is both rapid and highly sensitive, there are important limitations. Several studies describe the persistence of SARS-CoV-2 RNA within different body sites [1, 2]. It is known from other viruses that viral RNA can persist beyond infectivity [3, 4]. As a result, demonstration of in vitro infectiousness on cell lines is a more informative surrogate of viral transmission. The ability of viral culture to inform infectivity is an important aspect of diagnostics, but its use is hampered by its difficult and labor-intensive nature. This is further complicated by the need for Biosafety Level 3 facilities in the case of SARS-CoV-2. In a recent cohort study of 9 patients, no virus could be recovered beyond 7 days after symptom onset [1]. This important study is limited by the small number of patients examined and the fact that all 9 cases are linked; therefore, the data may represent a unique viral subpopulation. Here we add to the existing body of literature by presenting viral culture results on a larger cross-sectional group of patients, compared to polymerase chain reaction (PCR) data and time of symptom onset.

MATERIALS AND METHODS

SARS-CoV-2 Reverse-Transcription PCR Cycle Threshold Values and Symptom Onset to Test

All samples in this study were obtained to support routine care and surveillance of the public health response in the province of Manitoba, Canada. All suspected COVID-19 cases had

Received 7 May 2020; editorial decision 20 May 2020; accepted 21 May 2020; published online May 22, 2020.

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Clinical Infectious Diseases® 2020;71(10):2663–6

DOI: 10.1093/cid/ciaa638

SARS-CoV-2 reverse-transcription PCR (RT-PCR) performed on nasopharyngeal (NP) or endotracheal (ETT) samples at Cadham Provincial Laboratory (CPL), the public health laboratory.

The NP swabs and ETT specimens in viral transport media were stored at 4°C for 24–72 hours until they were tested for the presence of SARS-CoV-2 RNA using real-time RT-PCR targeting a 122-nt portion of the Sarbecovirus envelope gene (E gene) [5]. Fifty-five microliters of RNA was extracted from 200 µL of a respiratory specimen using the Ambion AM1836 RNA kit (Thermo Fisher) paired with the Kingfisher Flex instrument (Thermo Fisher). The 20 µL reactions, comprised of TaqMan Fast Virus One-step master mix and 5 µL of RNA, were cycled for 5 minutes at 50°C, 20 seconds at 95°C followed by 40 cycles of 5 seconds at 95°C and 30 seconds at 58°C on a Bio-Rad CFX96 thermal cycler. RT-PCR results were analyzed with the CFX manager software (version 3.1).

Through public health and epidemiology/surveillance and laboratory records, date of symptom onset was determined. Time from symptom onset to RT-PCR, or symptoms to test (STT), was calculated based on laboratory records. For all positive samples, the cycle threshold (Ct) was obtained. The study was performed in accordance with protocol HS23906 (H2020:211), approved by the University of Manitoba Research Ethics Board.

Median Tissue Culture Infectious Dose Assay

Samples were stored at −80°C for between 2 and 4 weeks before being processed for culture. Viral titers of patient samples were determined through median tissue culture infectious dose ($TCID_{50}$) assays inside a Biosafety Level 4 laboratory. In brief, Vero cells (ATCC: CCL-81), maintained in modified Eagle's medium (MEM) supplemented with 5% fetal bovine serum (FBS), 1% penicillin/streptomycin, 0.5 µg/mL amphotericin B, and 1% L-glutamine, were seeded into 96-well plates (Thermo Scientific, 167008) at 70% confluency. Using dilution blocks, patient samples were serially diluted 10-fold from 10^{-1} to 10^{-8} in MEM supplemented with 2% FBS, 1% penicillin/streptomycin, 0.5 µg/mL amphotericin B, and 1% L-glutamine. Dilutions were placed onto the Vero cells in triplicate and incubated at 37°C with 5% carbon dioxide for 96 hours. Following incubation of 4 days, cytopathic effect was evaluated under a microscope and recorded. $TCID_{50}$ and $TCID_{50}$/mL were calculated using the Reed and Muench method previously described [6]

Statistical Methods

Data are presented as mean ± standard deviation for normally distributed data and as median with interquartile range (IQR) for nonnormally distributed data. *P* values are reported as 2-tailed. All statistical analysis was performed with Stata version 14.2 (StataCorp, College Station, Texas). Between-group comparisons were performed using a Student *t* test or Mann-Whitney test. Normality was assessed using the Kolmogorov-Smirnov test, and logistic regression was performed with robust standard errors.

RESULTS

A total of 90 samples were analyzed. Median age of the patients sampled was 45 (IQR, 30–59) years. Almost half (49%) of our samples were from males. SARS-CoV-2 was successfully cultivated from 26 (28.9%) of the samples. The samples included in this study included those positive for SARS-CoV-2 by RT-PCR from day of symptom onset (day 0) up to 21 days after symptom onset. Within this range of samples, positive cultures were only observed up to day 8 after symptom onset (Figure 1). Median Ct count of all samples was 23 (IQR, 17–32). The median $TCID_{50}$/mL was 1780 (IQR, 282–8511). Positive culture samples had a significantly lower Ct compared with culture-negative samples (17 [IQR, 16–18] vs 27 [IQR, 22–33]; $P < .001$; Figure 2). Symptom to test time was also significantly lower in culture-positive vs culture-negative samples (3 [IQR, 2–4] days vs 7 [IQR, 4–11] days; $P < .001$; Figure 2).

Multivariate logistic regression using positive culture as a predictor variable (binary result) and STT, age, and sex as independent variables showed Ct as being significant (odds ratio [OR], 0.64 [95% confidence interval {CI}, .49–.84]; $P < .001$). This implies that for every 1-unit increase in Ct, the odds of a positive culture decreased by 32%. Increasing symptom to test time was also significantly associated with a negative culture (OR, 0.63 [95% CI, .42–.94]; $P = .025$). For every 1-day increase in STT, the odds ratio of being culture positive was decreased by 37%. Receiver operating characteristic curves constructed using Ct vs positive culture showed an area of 0.91 (95% CI, .85–.97; $P < .001$) with 97% specificity obtained at a Ct of > 24. Similarly, STT vs positive culture showed an area of 0.81 (95% CI .73–.90; $P < .001$), with 96% specificity at > 8 days. The probability of successfully cultivating SARS-CoV-2 on Vero cell culture compared to STT is demonstrated in Figure 3. The probability of

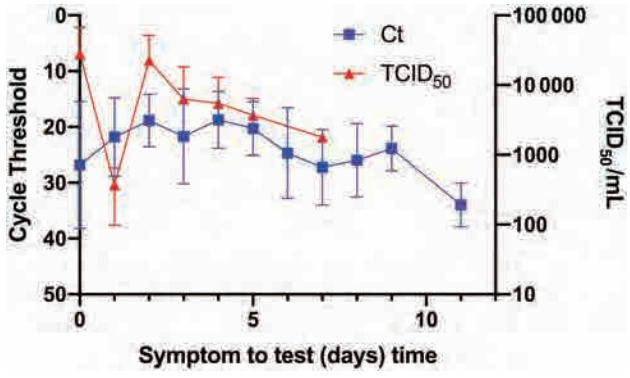

Figure 1. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral dynamics as expressed by E gene reverse-transcription polymerase chain reaction cycle threshold (Ct) value and cell culture median tissue culture infectious dose ($TCID_{50}$)/mL, over time (days).

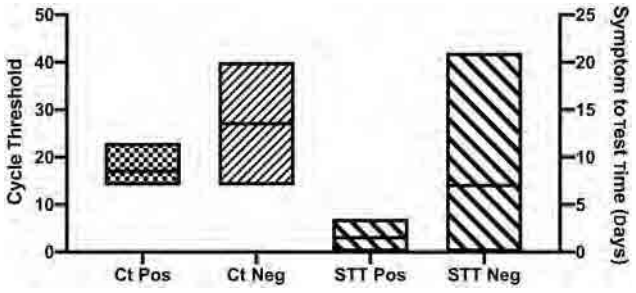

Figure 2. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) E gene reverse-transcription polymerase chain reaction cycle threshold (Ct) values and symptom to test time (STT) in samples that were culture positive or negative. Positive SARS-CoV-2 culture samples had a significantly lower Ct compared with culture-negative samples (17 [interquartile range {IQR}, 16–18] vs 27 [IQR, 22–33]; $P < .001$). STT was also significantly lower in culture-positive vs culture-negative samples (3 [IQR, 2–4] days vs 7 [IQR, 4–11] days; $P < .001$).

obtaining a positive viral culture peaked on day 3 and decreased from that point.

DISCUSSION

PCR and other nucleic amplification (NA) strategies have surpassed viral culture as the gold standard viral diagnostic, because of their wider application, higher sensitivity, rapid performance, and ability for field deployment. A major drawback to PCR and other diagnostic approaches (including other NA, serology, and antigen detection) is that they all fail to determine virus infectivity; PCR sensitivity is excellent but specificity for detecting replicative virus is poor [7]. Our study utilized a cross-sectional approach to correlate COVID-19 symptom onset to specimen collection with SARS-CoV-2 E gene RT-PCR and virus viability as determined by cell culture.

These results demonstrate that infectivity (as defined by growth in cell culture) is significantly reduced when RT-PCR Ct values are > 24. For every 1-unit increase in Ct, the odds ratio for infectivity decreased by 32%. The high specificity of Ct and STT suggests that Ct values > 24, along with duration of symptoms > 8 days, may be used in combination to determine duration of infectivity in patients. Positive cell culture results in our study were most likely between days 1 and 5. This finding is consistent with existing literature [1, 2].

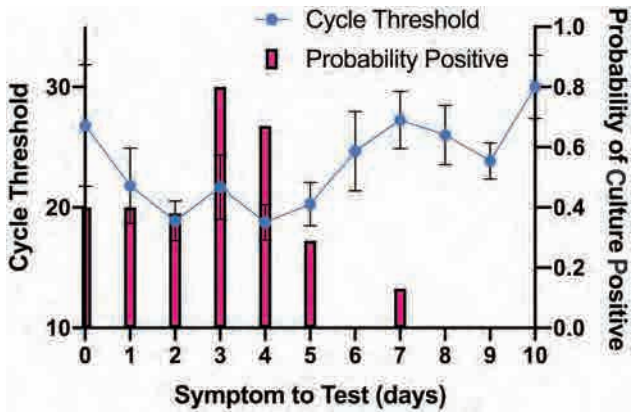

Figure 3. Comparison of symptom onset to test (days) to the probability of successful cultivation on Vero cells (Probability Positive) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) E gene reverse-transcription polymerase chain reaction cycle threshold (Ct) value.

This study is the first to report a large enough data set that demonstrates a link between in vitro viral growth, Ct value, and STT. These results have implications for clinical care, infection prevention and control, and public health. These data can be used to efficiently target case finding efforts by better defining the period of maximal transmission risk. This will be of particular importance in the maintenance phase of the response, where case finding efforts to rapidly interrupt chains of transmission will be essential. Isolation of COVID-19 cases in the community is typically recommended for at least 10 days after symptom onset. Our data supports this approach. Jurisdictions across Canada and the United States are recommending a variety of strategies to discontinue isolation of hospitalized COVID-19 cases [8–13]. Clinical criteria including 14 days from symptom onset or 72 hours symptom free (whichever is longer) are being used in some, while other jurisdictions are using 2 negative NP RT-PCR results 48 hours apart after 14 days of symptoms. Our data support the former approach since RT-PCR positivity persists significantly beyond infectivity; the alternative approach may lead to unnecessary isolation, and use of personal protective equipment and testing resources. The qualitative reporting of results of SARS-CoV-2 RT-PCR as positive or negative is sufficient for diagnosis but may be supplemented by Ct, a semiquantitative value, as well as time of symptom onset to guide infection control, public health, and occupational health decisions.

Our study has important limitations. First, our study utilized a single SARS-CoV-2 gene target (E gene). Though other gene targets may offer greater specificity, the SARS-CoV-2 E gene is more consistently used in both laboratory-developed tests and commercial assays. The testing criteria in Manitoba had sufficient pretest probability to make the likelihood of a false-positive remote. In addition, the first 71 of 90 samples were confirmed using the described protocol with the Centers for Disease Control and Prevention N1 gene target [14]. Second target confirmation was discontinued at that time based on being satisfied with testing criteria and assay sensitivity to accurately identify true COVID-19 cases. Reagent supply also played a role. Second, the recall bias of symptom onset is possible, but this likely would have been equally distributed between those who were culture positive and negative. Third, the infectivity of certain individual cases and the accuracy of our culture assay may have unique variations. Though some individuals in our cross-sectional study would be considered immunocompromised, patients with these conditions could have prolonged shedding of infective SARS-CoV-2 and may not be

fully represented here. Few children have been diagnosed with COVID-19 in our province (median age of positive PCR, 45 [IQR, 30–59] years). With other respiratory viruses, children may have prolonged shedding. Finally, our patient numbers remain small and larger studies are needed to establish Ct criteria that reliably correlate with loss of infectivity and that utilize additional SARS-CoV-2 gene targets.

In conclusion, the SARS-CoV-2/COVID-19 pandemic represents a dynamic situation where decisions and policy must be guided by evidence. Our study showed no positive viral cultures with a Ct > 24 or STT > 8 days. The odds of a positive culture were decreased by 32% for each unit increase in Ct. These data, if confirmed, may help guide isolation, contact tracing, and testing guidelines.

Notes

Acknowledgments. This work was supported by the collaborative efforts in the public health response to the current pandemic by Manitoba Health and Cadham Provincial Laboratory (CPL), and the Public Health Agency of Canada and the National Microbiology Laboratory. A special acknowledgment goes to the medical laboratory technologists in the Virus Detection Section of CPL. We would be blind without you.

Potential conflicts of interest. The authors: No reported conflicts of interest. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest.

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Manitoba Chief Microbiologist and Laboratory Specialist: 56% of positive "cases" are not infectious

POSTED ON: MAY 11, 2021

WINNIPEG: The Justice Centre represents churches and individuals who are challenging government lockdown restrictions in the Court of Queen's Bench as unjusti ed violations of the *Charter* freedoms to associate, worship, and assemble peacefully. The hearing commenced on May 3, 2021 and is continuing this week.

The onus is on the Manitoba Government to justify its restrictions on *Charter* rights and freedoms as being reasonable, necessary and bene cial.

One of the crucial issues in this trial is the operation and reliability of the Polymerase Chain Reaction (PCR) test that is used by governments across Canada, including the Manitoba Government, to diagnose Covid and measure its spread.

The *Westphalian Times* explains PCR tests as follows:

The current COVID testing is based on polymerase chain reaction (PCR) – "a fast and inexpensive technique used to 'amplify' – copy – small segments of DNA." Many internationally recognized experts on virology and PCR testing are questioning if the tests have been made overly sensitive and many positives are the result of long dead and no longer contagious virus or even contamination in labs. PCR testing was invented to nd genetic viral material in a sample and has not traditionally been used as the sole method for identifying people suffering from a viral or bacterial disease.

COVID testing is typically performed using a nasopharyngeal swab, a 6-inch long swab inserted deep into the nostril. The swab is rotated for a while and then it is sent to a lab where a PCR test will dramatically amplify the amount of genetic material captured and then compare it to the DNA or RNA of a particular segment of the COVID virus (reference RNA).

To get enough genetic material to test, the PCR process increases the genetic material present by copying it and then copying it again, over and over. Each of these increasing steps is called a "cycle" and the genetic material in the solution is reacted against the reference DNA to determine a positive. If the sample contains a large amount of COVID virus it will react positive after only a few cycles, while a sample with small amounts of genetic material will require more cycles to amplify enough genetic material to get a positive result.

Since the PCR test ampli es traces of COVID-19 through cycles, a lower number of cycles needed to get a positive suggests the presence of a higher viral load for the person being tested and therefore a higher contagion potential.

The number of cycling required to identify viral material in a given sample is called the cycle threshold (Ct).

The Justice Centre's expert medical witnesses, Dr. Jay Bhattacharya, world-famous epidemiologist and Professor of Medicine from Stanford University, and Dr. Thomas Warren, infectious disease specialist and medical microbiologist, both provided evidence that the PCR test is unreliable in determining whether a person is infectious with the actual Covid-19 disease.

Chief Microbiologist and Laboratory Specialist Dr. Jared Bullard is a witness for the Manitoba government in this hearing. Questioned under oath by Justice Centre lawyers on Monday May 10, Dr. Bullard acknowledged that the PCR test has signi cant limitations. The head of Cadham Provincial Laboratory in Winnipeg, Dr. Bullard admitted that PCR test results do not verify infectiousness, and were never intended to be used to diagnose respiratory illnesses.

Dr. Bullard testi ed that PCR tests can be positive for up to 100 days after an exposure to the virus, and that PCR tests do nothing more than con rm the presence of fragments of viral RNA of the target SARS CO-V2 virus in someone's nose. He testi ed that, while a person with Covid-19 is infectious for a one-

to-two week period, non-viable (harmless) viral SARS CO-V2 fragments remain in the nose, and can be detected by a PCR test for up to 100 days after exposure.

Dr. Bullard testi ed that the most accurate way to determine whether someone is actually infectious with Covid is to attempt to grow a cell culture in the lab from a patient sample. If a cell culture will not grow the virus in the lab, a patient is likely not infectious. **A study from Dr. Bullard and his colleagues found that only 44% of positive PCR test results would actually grow in the lab.**

Dr. Bullard's ndings call into question the practice used in Manitoba (and elsewhere in Canada) of the results of classifying positive PCR tests as "cases," which implies infectivity. Equating positive PCR tests to infectious cases, as so many provinces have done over the course of the past 13 months, is incorrect and inaccurate, according to this Manitoba Government witness.

Dr. Bullard acknowledged that he has been closely studying the correlation between Cycle threshold (Ct) value and infectiousness since at least May 7, 2020. Dr. Bullard acknowledged that Manitoba has known for some time that a given PCR test's Ct value is inversely correlated with infectiousness. This means that testing for Covid at higher threshold levels can result in false positives as explained in this article. Even the World Health Organization (WHO) notes that careful interpretation of weak positive results is needed.

Weak results are those run at higher thresholds (more cycles). For example, someone with a positive PCR test that is run at 18 cycles is more likely to be sick and infectious than someone who has a test run at a Ct value of 40.

Dr. Bullard con rmed this was one of the rst studies of its kind linking Ct value to infectiousness, and his study con rmed the ndings of other studies in France and elsewhere.

Dr. Bullard also testi ed that **Ct value** (how many ampli cation cycles were used in a given PCR test to reach a positive test result) **is signi cant** as a proxy or indicator for infectiousness.

However, despite Dr. Bullard's ndings and recommendations in his two peer-reviewed studies, Manitoba still does not consider Ct values as a proxy for infectiousness in its public health response to Covid-19. Both Dr. Bullard and Manitoba Chief Medical Of cer Dr. Brent Roussin con rmed under cross-examination that Ct values are not provided to public health of cials by laboratories. Dr. Roussin admitted that he could mandate that the Ct value be provided to him, but that he has not done so.

Some jurisdictions, for example Florida, do consider Ct value in their public health response to Covid.

Finally, it should be noted that some Canadian news agencies have quoted Dr. Bullard as testifying that a positive PCR tests indicates infectivity 99.9% of the time. This is incorrect. Rather, Dr. Bullard testi ed that a PCR test will detect any viral RNA that is present in a sample 99.9% of the time. However, Dr. Bullard testi ed that determining whether or not a sample is actually infectious (containing a viable virus, capable of replicating) needs to be con rmed by lab culture. As noted, only 44% of the "positive" samples using a Ct of 18 returned a viable lab culture. **Samples tested at a Ct of over 25, according to Dr. Bullard's report, produced no viable lab cultures.**

Manitoba has con rmed that it utilizes Ct's of up to 40, and even 45 in some cases. This indicates "cases" resulting from such tests (above a Ct of 25) are almost certainly not actually infectious.

The hearing into Manitoba's response to Covid and its violation of *Charter* rights and freedoms continues this week.

United Nations CCPR/C/128/2

International Covenant on Civil and Political Rights

Distr.: General
30 April 2020

Original: English

Human Rights Committee

Statement on derogations from the Covenant in connection with the COVID-19 pandemic*

1. A number of States parties to the International Covenant on Civil and Political Rights have in recent weeks notified the Secretary-General, pursuant to article 4 of the Covenant, of emergency measures that they have taken or are planning to take with a view to curb the spread of the coronavirus (COVID-19) pandemic, in derogation from their obligations under the Covenant. It has been brought to the attention of the Committee, however, that several other States parties have resorted to emergency measures in response to the COVID-19 pandemic in a manner seriously affecting the implementation of their obligations under the Covenant, without formally submitting any notification of derogation from the Covenant. The Committee calls upon all State parties that have taken emergency measures in connection with the COVID-19 pandemic that derogate from their obligations under the Covenant to comply without delay with their duty to notify the Secretary-General thereof immediately, if they have not already done so.

2. The Committee is of the view that, in the face of the COVID-19 pandemic, States parties must take effective measures to protect the right to life and health of all individuals within their territory and all those subject to their jurisdiction. It also recognizes that such measures may, in certain circumstances, result in restrictions on the enjoyment of individual rights guaranteed by the Covenant. Furthermore, the Committee acknowledges that States parties confronting the threat of widespread contagion may, on a temporary basis, resort to exceptional emergency powers and invoke their right of derogation from the Covenant under article 4 provided that it is required to protect the life of the nation. The Committee wishes nonetheless to remind States parties of the requirements and conditions laid down in article 4 of the Covenant and explained by the Committee in its general comments, particularly in general comment No. 29 (2001) on states of emergency, in which it provided guidance on the following aspects of derogations: the official proclamation of a state of emergency; formal notification to the Secretary-General; the strict necessity and proportionality of any derogating measure taken; the conformity of measures taken with other international obligations; non-discrimination; and the prohibition on derogating from certain non-derogable rights. In particular, States parties must observe the following requirements and conditions when exercising emergency powers in connection with the COVID-19 pandemic:

(a) Where measures derogating from the obligations of States parties under the Covenant are taken, the provisions derogated from and the reasons for the derogation must be communicated immediately to the other States parties through the Secretary-General. Notification by a State party must include full information about the derogating measures taken and a clear explanation of the reasons for taking them, with complete documentation of any laws adopted. Further notification is required if the State party subsequently takes additional measures under article 4, for instance by extending the duration of a state of emergency. The requirement of immediate notification applies equally to the termination of

* Adopted by the Committee on 24 April 2020.

the derogation. The Committee considers the implementation of the obligation of immediate notification essential for the discharge of its functions, as well as for the monitoring of the situation by other States parties and other stakeholders;

(b) Derogating measures may deviate from the obligations set out by the Covenant only to the extent strictly required by the exigencies of the public health situation. Their predominant objective must be the restoration of a state of normalcy, where full respect for the Covenant can again be secured. Derogations must, as far as possible, be limited in duration, geographical coverage and material scope, and any measures taken, including sanctions imposed in connection with them, must be proportional in nature. Where possible, and in view of the need to protect the life and health of others, States parties should replace COVID-19-related measures that prohibit activities relevant to the enjoyment of rights under the Covenant with less restrictive measures that allow such activities to be conducted, while subjecting them as necessary to public health requirements, such as physical distancing;

(c) States parties should not derogate from Covenant rights or rely on a derogation made when they are able to attain their public health or other public policy objectives by invoking the possibility to restrict certain rights, such as article 12 (freedom of movement), article 19 (freedom of expression) or article 21(right to peaceful assembly), in conformity with the provisions for such restrictions set out in the Covenant, or by invoking the possibility of introducing reasonable limitations on certain rights, such as article 9 (right to personal liberty) and article 17 (right to privacy), in accordance with their provisions;

(d) States parties may not resort to emergency powers or implement derogating measures in a manner that is discriminatory, or that violates other obligations that they have undertaken under international law, including under other international human rights treaties from which no derogation is allowed. Nor can States parties deviate from the non-derogable provisions of the Covenant – article 6 (right to life), article 7 (prohibition of torture or cruel, inhuman or degrading treatment or punishment, or of medical or scientific experimentation without consent), article 8, paragraphs 1 and 2 (prohibition of slavery, the slave trade and servitude), article 11 (prohibition of imprisonment because of inability to fulfil a contractual obligation), article 15 (principle of legality in the field of criminal law), article 16 (recognition of everyone as a person before the law) and article 18 (freedom of thought, conscience and religion) – or from other rights that are essential for upholding the non-derogable rights found in the aforementioned provisions and for ensuring respect for the rule of law and the principle of legality even in times of public emergency, including the right of access to court, due process guarantees and the right of victims to obtain an effective remedy;

(e) Furthermore, States parties may not derogate from their duty to treat all persons, including persons deprived of their liberty, with humanity and respect for their human dignity, and must pay special attention to the adequacy of health conditions and health services in places of incarceration, and also to the rights of individuals in situations of confinement, and to the aggravated threat of domestic violence arising in such situations. Nor can States parties tolerate, even in situations of emergency, the advocacy of national, racial or religious hatred that would constitute incitement to discrimination, hostility or violence, and they must take steps to ensure that public discourse in connection with the COVID-19 pandemic does not constitute advocacy or incitement against specific marginalized or vulnerable groups, including minorities and foreign nationals;

(f) Freedom of expression and access to information and a civic space where a public debate can be held constitute important safeguards for ensuring that States parties resorting to emergency powers in connection with the COVID-19 pandemic comply with their obligations under the Covenant.

Antiviral Res. 2020 Jun; 178: 104787. PMCID: PMC7129059
Published online 2020 Apr 3. doi: 10.1016/j.antiviral.2020.104787 PMID: 32251768

The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 *in vitro*

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Received 2020 Mar 18; Revised 2020 Mar 27; Accepted 2020 Mar 29.

Abstract

Although several clinical trials are now underway to test possible therapies, the worldwide response to the COVID-19 outbreak has been largely limited to monitoring/containment. We report here that Ivermectin, an FDA-approved anti-parasitic previously shown to have broad-spectrum anti-viral activity *in vitro*, is an inhibitor of the causative virus (SARS-CoV-2), with a single addition to Vero-hSLAM cells 2 h post infection with SARS-CoV-2 able to effect ~5000-fold reduction in viral RNA at 48 h. Ivermectin therefore warrants further investigation for possible benefits in humans.

1. Introduction

Ivermectin is an FDA-approved broad spectrum anti-parasitic agent (Gonzalez Canga et al., 2008) that in recent years we, along with other groups, have shown to have anti-viral activity against a broad range of viruses (Gotz et al., 2016; Lundberg et al., 2013; Tay et al., 2013; Wagstaff et al., 2012) *in vitro*. Originally identified as an inhibitor of interaction between the human immunodeficiency virus-1 (HIV-1) integrase protein (IN) and the importin (IMP) α/β1 heterodimer responsible for IN nuclear import (Wagstaff et al., 2011), Ivermectin has since been confirmed to inhibit IN nuclear import and HIV-1 replication (Wagstaff et al., 2012). Other actions of ivermectin have been reported (Mastrangelo et al., 2012), but ivermectin has been shown to inhibit nuclear import of host (eg. (Kosyna et al., 2015; van der Watt et al., 2016)) and viral proteins, including simian virus SV40 large tumour antigen (T-ag) and dengue virus

(DENV) non-structural protein 5 (Wagstaff et al., 2012, Wagstaff et al., 2011). Importantly, it has been demonstrated to limit infection by RNA viruses such as DENV 1-4 (Tay et al., 2013), West Nile Virus (Yang et al., 2020), Venezuelan equine encephalitis virus (VEEV) (Lundberg et al., 2013) and influenza (Gotz et al., 2016), with this broad spectrum activity believed to be due to the reliance by many different RNA viruses on IMPα/β1 during infection (Caly et al., 2012; Jans et al., 2019). Ivermectin has similarly been shown to be effective against the DNA virus pseudorabies virus (PRV) both *in vitro* and *in vivo*, with ivermectin treatment shown to increase survival in PRV-infected mice (Lv et al., 2018). Efficacy was not observed for ivermectin against Zika virus (ZIKV) in mice, but the authors acknowledged that study limitations justified re-evaluation of ivermectin's anti-ZIKV activity (Ketkar et al., 2019). Finally, ivermectin was the focus of a phase III clinical trial in Thailand in 2014–2017, against DENV infection, in which a single daily oral dose was observed to be safe and resulted in a significant reduction in serum levels of viral NS1 protein, but no change in viremia or clinical benefit was observed (see below) (Yamasmith et al., 2018).

The causative agent of the current COVID-19 pandemic, SARS-CoV-2, is a single stranded positive sense RNA virus that is closely related to severe acute respiratory syndrome coronavirus (SARS-CoV). Studies on SARS-CoV proteins have revealed a potential role for IMPα/β1 during infection in signal-dependent nucleocytoplasmic shutting of the SARS-CoV Nucleocapsid protein (Rowland et al., 2005; Timani et al., 2005; Wulan et al., 2015), that may impact host cell division (Hiscox et al., 2001; Wurm et al., 2001). In addition, the SARS-CoV accessory protein ORF6 has been shown to antagonize the antiviral activity of the STAT1 transcription factor by sequestering IMPα/β1 on the rough ER/Golgi membrane (Frieman et al., 2007). Taken together, these reports suggested that ivermectin's nuclear transport inhibitory activity may be effective against SARS-CoV-2.

To test the antiviral activity of ivermectin towards SARS-CoV-2, we infected Vero/hSLAM cells with SARS-CoV-2 isolate Australia/VIC01/2020 at an MOI of 0.1 for 2 h, followed by the addition of 5 μM ivermectin. Supernatant and cell pellets were harvested at days 0–3 and analysed by RT-PCR for the replication of SARS-CoV-2 RNA (Fig. 1 A/B). At 24 h, there was a 93% reduction in viral RNA present in the supernatant (indicative of released virions) of samples treated with ivermectin compared to the vehicle DMSO. Similarly a 99.8% reduction in cell-associated viral RNA (indicative of unreleased and unpackaged virions) was observed with ivermectin treatment. By 48 h this effect increased to an ~5000-fold reduction of viral RNA in ivermectin-treated compared to control samples, indicating that ivermectin treatment resulted in the effective loss of essentially all viral material by 48 h. Consistent with this idea, no further reduction in viral RNA was observed at 72 h. As we have observed previously (Lundberg et al., 2013; Tay et al., 2013; Wagstaff et al., 2012), no toxicity of ivermectin was observed at any of the timepoints tested, in either the sample wells or in parallel tested drug alone samples.

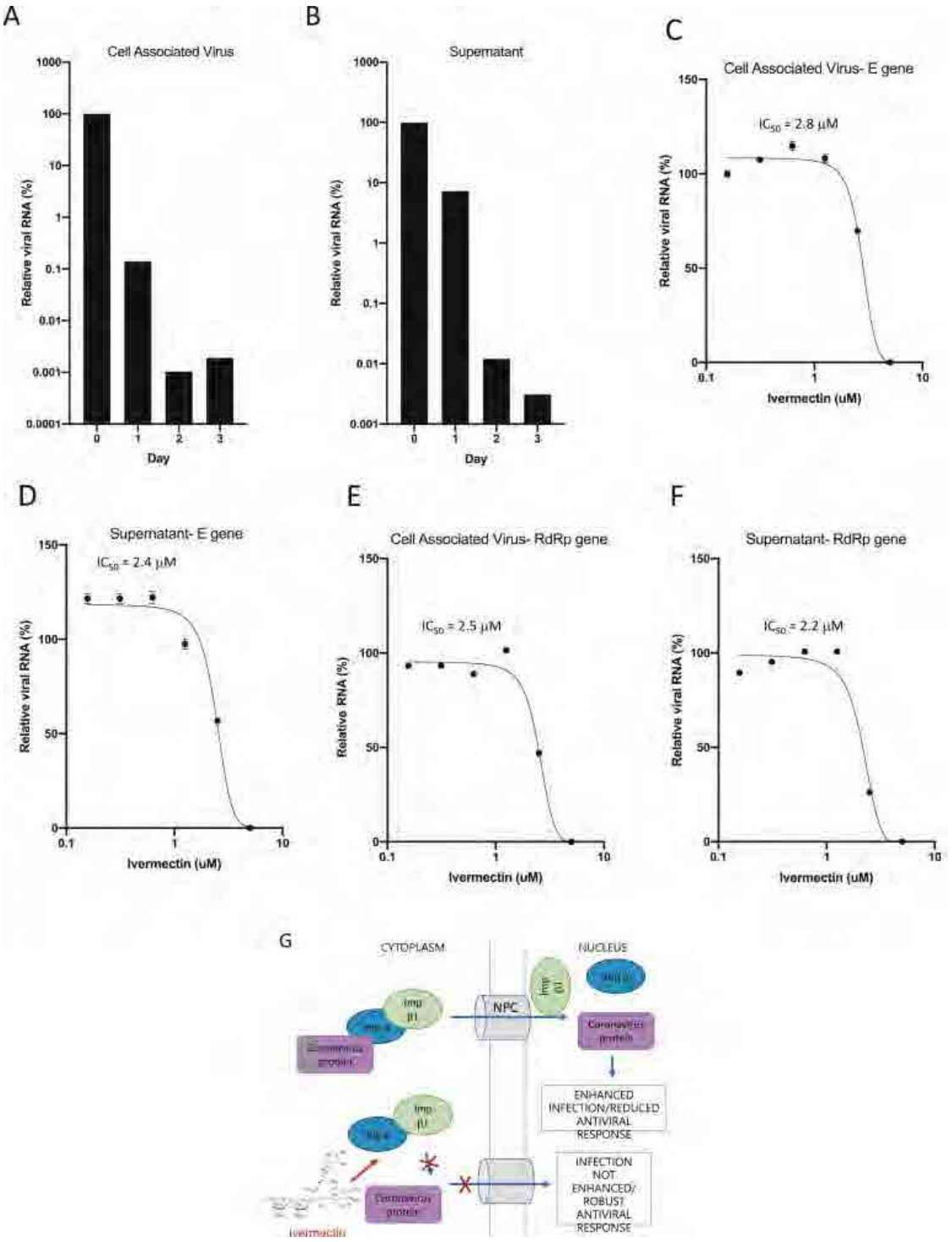

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Fig. 1

Ivermectin is a potent inhibitor of the SARS-CoV-2 clinical isolate Australia/VIC01/2020. Vero/hSLAM cells were in infected with SARS-CoV-2 clinical isolate Australia/VIC01/2020 (MOI = 0.1) for 2 h prior to addition of vehicle (DMSO) or Ivermectin at the indicated concentrations. Samples were taken at 0–3 days post infection for quantitation of viral load using real-time PCR of cell associated virus (**A**) or supernatant (**B**). IC_{50} values were determined in subsequent experiments at 48 h post infection using the indicated concentrations of Ivermectin (treated at 2 h post infection as per **A**/**B**). Triplicate real-time PCR analysis was performed on cell associated virus (**C**/**E**) or supernatant (**D**/**F**) using probes against

either the SARS-CoV-2 E (**C/D**) or RdRp (**E/F**) genes. Results represent mean ± SD (n = 3). 3 parameter dose response curves were fitted using GraphPad prism to determine IC_{50} values (indicated). **G.** Schematic of ivermectin's proposed antiviral action on coronavirus. IMPα/β1 binds to the coronavirus cargo protein in the cytoplasm (top) and translocates it through the nuclear pore complex (NPC) into the nucleus where the complex falls apart and the viral cargo can reduce the host cell's antiviral response, leading to enhanced infection. Ivermectin binds to and destabilises the Impα/β1 heterodimer thereby preventing Impα/β1 from binding to the viral protein (bottom) and preventing it from entering the nucleus. This likely results in reduced inhibition of the antiviral responses, leading to a normal, more efficient antiviral response.

To further determine the effectiveness of ivemectin, cells infected with SARS-CoV-2 were treated with serial dilutions of ivermectin 2 h post infection and supernatant and cell pellets collected for real-time RT-PCR at 48 h (Fig. 1C/D). As above, a >5000 reduction in viral RNA was observed in both supernatant and cell pellets from samples treated with 5 μM ivermectin at 48 h, equating to a 99.98% reduction in viral RNA in these samples. Again, no toxicity was observed with ivermectin at any of the concentrations tested. The IC50 of ivermectin treatment was determined to be ~2 μM under these conditions. Underlining the fact that the assay indeed specifically detected SARS-CoV-2, RT-PCR experiments were repeated using primers specific for the viral RdRp gene (Fig. 1E/F) rather than the E gene (above), with nearly identical results observed for both released (supernatant) and cell-associated virus.

Taken together these results demonstrate that ivermectin has antiviral action against the SARS-CoV-2 clinical isolate *in vitro*, with a single dose able to control viral replication within 24–48 h in our system. We hypothesise that this is likely through inhibiting IMPα/β1-mediated nuclear import of viral proteins (Fig. 1G), as shown for other RNA viruses (Tay et al., 2013; Wagstaff et al., 2012; Yang et al., 2020); confirmation of this mechanism in the case of SARS-CoV-2, and identification of the specific SARS-CoV-2 and/or host component(s) impacted (see (Yang et al., 2020)) is an important focus future work in this laboratory. Ultimately, development of an effective anti-viral for SARS-CoV-2, if given to patients early in infection, could help to limit the viral load, prevent severe disease progression and limit person-person transmission. Benchmarking testing of ivermectin against other potential antivirals for SARS-CoV-2 with alternative mechanisms of action (Dong et al., 2020; Elfiky, 2020; Gordon et al., 2020; Li and De Clercq, 2020; Wang et al., 2020) would thus be important as soon as practicable. This Brief Report raises the possibility that ivermectin could be a useful antiviral to limit SARS-CoV-2, in similar fashion to those already reported (Dong et al., 2020; Elfiky, 2020; Gordon et al., 2020; Li and De Clercq, 2020; Wang et al., 2020); until one of these is proven to be beneficial in a clinical setting, all should be pursued as rapidly as possible.

Ivermectin has an established safety profile for human use (Gonzalez Canga et al., 2008; Jans et al., 2019; Buonfrate et al., 2019), and is FDA-approved for a number of parasitic infections (Gonzalez Canga et al., 2008; Buonfrate et al., 2019). Importantly, recent reviews and meta-analysis indicate that high dose ivermectin has comparable safety as the standard low-dose treatment, although there is not enough evidence to make conclusions about the safety profile in pregnancy (Navarro et al., 2020; Nicolas et al., 2020). The critical next step in further evaluation for possible benefit in COVID-19 patients will be to examine a multiple addition dosing regimen that mimics the current approved usage of ivermectin in humans. As noted, ivermectin was the focus of a recent phase III clinical trial in dengue patients in Thailand, in which a single daily dose was found to be safe but did not produce any clinical benefit. However, the investigators noted that an improved dosing regimen might be developed, based on pharmacokinetic data (Yamasmith et al., 2018). Although DENV is clearly very different to SARS-CoV-2,

this trial design should inform future work going forward. Altogether the current report, combined with a known-safety profile, demonstrates that ivermectin is worthy of further consideration as a possible SARS-CoV-2 antiviral.

2. Methods

2.1. Cell culture, viral infection and drug treatment

Vero/hSLAM cells (Ono et al., 2001) were maintained in Earle's Minimum Essential Medium (EMEM) containing 7% Fetal Bovine Serum (FBS) (Bovogen Biologicals, Keilor East, AUS) 2 mM L-Glutamine, 1 mM Sodium pyruvate, 1500 mg/L sodium bicarbonate, 15 mM HEPES and 0.4 mg/ml geneticin at 37 °C, 5% CO_2. Cells were seeded into 12-well tissue culture plates 24 h prior to infection with SARS-CoV-2 (Australia/VIC01/2020 isolate) at an MOI of 0.1 in infection media (as per maintenance media but containing only 2% FBS) for 2 h. Media containing inoculum was removed and replaced with 1 mL fresh media (2% FBS) containing Ivermectin at the indicated concentrations or DMSO alone and incubated as indicated for 0–3 days. At the appropriate timepoint, cell supernatant was collected and spun for 10 min at 6,000 g to remove debris and the supernatant transferred to fresh collection tubes. The cell monolayers were collected by scraping and resuspension into 1 mL fresh media (2% FBS). Toxicity controls were set up in parallel in every experiment on uninfected cells.

2.2. Generation of SARS-CoV-2 cDNA

RNA was extracted from 200 µL aliquots of sample supernatant or cell suspension using the QIAamp 96 Virus QIAcube HT Kit (Qiagen, Hilden, Germany) and eluted in 60 µl. Reverse transcription was performed using the BioLine SensiFAST cDNA kit (Bioline, London, United Kingdom), total reaction mixture (20 µl), containing 10 µL of RNA extract, 4 µl of 5x TransAmp buffer, 1 µl of Reverse Transcriptase and 5 µl of Nuclease free water. The reactions were incubated at 25 °C for 10 min, 42 °C for 15 min and 85 °C for 5 min.

2.3. Detection of SARS-CoV-2 using a TaqMan Real-time RT-PCR assay

TaqMan RT-PCR assay were performed using 2.5 µl cDNA, 10 µl Primer Design PrecisonPLUS qPCR Master Mix 1 µM Forward (5′- AAA TTC TAT GGT GGT TGG CAC AAC ATG TT-3′), 1 µM Reverse (5′- TAG GCA TAG CTC TRT CAC AYT T-3′) primers and 0.2 µM probe (5′-FAM- TGG GTT GGG ATT ATC-MGBNFQ-3′) targeting the BetaCoV RdRp (RNA-dependent RNA polymerase) gene or Forward (5′-ACA GGT ACG TTA ATA GTT AAT AGC GT -3′), 1 µM Reverse (5′-ATA TTG CAG CAG TAC GCA CAC A-3′) primers and 0.2 µM probe (5′-FAM-ACA CTA GCC ATC CTT ACT GCG CTT CG-286 NFQ-3′) targeting the BetaCoV E-gene (Corman et al., 2020). Real-time RT-PCR assays were performed on an Applied Biosystems ABI 7500 Fast real-time PCR machine (Applied Biosystems, Foster City, CA, USA) using cycling conditions of 95 °C for 2 min, 95 °C for 5 s, 60 °C for 24 s. SARS-CoV-2 cDNA (Ct~28) was used as a positive control. Calculated Ct values were converted to fold-reduction of treated samples compared to control using the ΔCt method (fold changed in viral RNA = 2^ΔCt) and expressed as % of DMSO alone sample. IC50 values were fitted using 3 parameter dose response curves in GraphPad prism.

Funding

This work was supported by a National Breast Cancer Foundation Fellowship, Australia (ECF-17-007) for KMW and an National Health and Medical Research Council (NHMRC), Australia Senior Prinicple Research Fellow (SPRF) (APP1103050) for DAJ.

Footnotes

The authors would like readers to be aware of the following letter issued by the FDA titled: “Do Not Use Ivermectin Intended for Animals as Treatment for COVID-19 in Humans” at https://www.fda.gov/animal-veterinary/product-safety-information/fda-letter-stakeholders-do-not-use-ivermectin-intended-animals-treatment-covid-19-humans.

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R (on the application of Miller) v Prime Minister

Cherry and others v Advocate General for Scotland

[2019] CSOH 70
[2019] EWHC 2381 (QB)
[2019] CSIH 49
[2019] UKSC 41

COURT OF SESSION (OUTER HOUSE)

LORD ORDINARY (DOHERTY)

3, 4 SEPTEMBER 2019

QUEEN'S BENCH DIVISION (DIVISIONAL COURT)

LORD BURNETT CJ, SIR TERENCE ETHERTON MR AND DAME VICTORIA SHARP P

5, 6, 11 SEPTEMBER 2019

COURT OF SESSION (INNER HOUSE)

LORD PRESIDENT (CARLOWAY), LORD BRODIE AND LORD DRUMMOND YOUNG

11, 13 SEPTEMBER 2019

SUPREME COURT

LADY HALE P, LORD REED DP, LORD KERR, LORD WILSON, LORD CARNWATH, LORD HODGE, LADY BLACK, LORD LLOYD-JONES, LADY ARDEN, LORD KITCHIN AND LORD SALES JJSC

17–19, 24 SEPTEMBER 2019

Crown – Prerogative – Review of exercise of prerogative power by court – Prorogation of Parliament – Prime Minister advising Crown to prorogue Parliament for extended period ahead of United Kingdom withdrawal from European Union ('Brexit') – Whether justiciable – Whether lawful – Appropriate remedy – Bill of Rights (1688), art 9.

On 27 or 28 August 2019 the Prime Minister advised Her Majesty the Queen that Parliament should be prorogued from a date between 9 and 12 September until 14 October 2019 and, on 28 August, following a meeting of the Privy Council, an Order in Council that Parliament be prorogued between those dates was made. Prorogation was a prerogative power exercised by the Crown on the advice of the Privy Council. It brought the current session of

Parliament to an end, the next session beginning, usually a short time later, with the Queen's Speech. The United Kingdom was due to leave the European Union ('Brexit') on 31 October 2019 ('exit day') and, under the European Union (Withdrawal) Act 2018, Parliamentary approval was required of any withdrawal agreement reached by the government. While Parliament was prorogued, however, neither House could meet, debate or pass legislation. The Prime Minister's decision to prorogue Parliament was challenged in two sets of proceedings, one in Scotland ('the *Cherry* case') and one in England ('the *Miller* case'). On 4 September 2019, the Lord Ordinary refused the petition in the *Cherry* case, on the ground that the issue was not justiciable in a court of law. The Divisional Court also dismissed the claim in the *Miller* case on the ground that the issue was not justiciable. It accepted the government's submission that the courts should not enter the political arena but should respect the separation of powers. It held that the Prime Minister's decision that Parliament should be prorogued at the time and for the duration chosen, and his advice to Her Majesty to that effect, were inherently political in nature, and there were no legal standards against which to judge their legitimacy. The Divisional Court's judgment was delivered on 11 September 2019. On the same day, the Inner House of the Court of Session delivered their decision that the petitioners' appeal in the *Cherry* case would be allowed. It held that the advice given to Her Majesty was justiciable, that it was motivated by the improper purpose of 'stymying' Parliamentary scrutiny of the executive, and that it and the prorogation which followed it were unlawful and thus null and of no effect. The Advocate General in the *Cherry* case and the claimant in the *Miller* case appealed to the Supreme Court. Both cases raised the same issues: (i) whether the Prime Minister's advice to the Queen was justiciable in a court of law and, if it was, by what standard its lawfulness was to be judged; (ii) whether, by that standard, it was lawful; and (iii) if it was not, what remedy the court should grant. With respect to remedy, the government contended that to declare the prorogation null and of no effect would be contrary to art 9[a] of the Bill of Rights of 1688 or the wider privileges of Parliament relating to matters within its 'exclusive cognisance'.

Held – The appeal in the *Miller* case would be allowed and the appeal in the *Cherry* case would be dismissed for the following reasons—

(1) The decision of the Prime Minister was justiciable. In the case of prerogative powers, it was necessary to distinguish between two different issues: first, whether a prerogative power existed, and if it did, its extent; and second, whether, granted that a prerogative power existed, and that it had been exercised within its limits, the exercise of the power was open to legal challenge on some other basis. The first issue lay within the jurisdiction of the courts and was justiciable. No question of justiciability, whether by reason of subject matter or otherwise, could arise in relation to whether the law recognised the existence of a prerogative power, or in relation to its legal limits. Those were by definition questions of law and under the separation of powers, it was the function of the courts to determine them. The second issue, on the other hand, might raise questions of justiciability. The question then was not whether the power existed, or whether a purported exercise of the power was beyond its legal limits, but whether its exercise within its legal limits was challengeable in the courts on the basis of one or more of the recognised

a Article 9 is set out at [64] of the Supreme Court judgment, below.

grounds of judicial review. A prerogative power was limited by statute and the common law, including, in the present context, the constitutional principles with which it would otherwise conflict. Two fundamental principles of constitutional law were relevant to the present case: Parliamentary sovereignty and Parliamentary accountability. For the purposes of the present case, therefore, the relevant limit on the power to prorogue was that a decision to prorogue Parliament (or to advise the monarch to prorogue Parliament) would be unlawful if the prorogation had the effect of frustrating or preventing, without reasonable justification, the ability of Parliament to carry out its constitutional functions as a legislature and as the body responsible for the supervision of the executive. That standard was not concerned with the mode of exercise of the prerogative power within its lawful limits. On the contrary, it was a standard which determined the limits of the power, marking the boundary between the prerogative on the one hand and the operation of the constitutional principles of the sovereignty of Parliament and responsible government on the other hand. The court would have to consider any justification advanced with sensitivity to the responsibilities and experience of the Prime Minister, and with a corresponding degree of caution. Nevertheless, it was the court's responsibility to determine whether the Prime Minster had remained within the legal limits of the power. An issue which could be resolved by the application of that standard was by definition one which concerned the extent of the power to prorogue, and was therefore justiciable (see [35]–[37], [41], [42], [46]–[52], below); *Council of Civil Service Unions v Minister for the Civil Service* [1984] 3 All ER 935, *R v Secretary of State for the Home Dept, ex p Fire Brigades Union* [1995] 2 All ER 244 and *R (on the application of UNISON) v Lord Chancellor* [2017] 4 All ER 903 applied.

(2) The Prime Minister's decision was unlawful. His action had had the effect of frustrating or preventing the constitutional role of Parliament in holding the government to account and there had been no reasonable justification for taking action which had such an extreme effect upon the fundamentals of democracy. It was not a normal prorogation in the run-up to a Queen's Speech. It had prevented Parliament from carrying out its constitutional role for five out of a possible eight weeks between the end of the summer recess and exit day. The circumstances were exceptional. A fundamental change in the constitution was due to take place on 31 October and Parliament had a right to have a voice in how that change came about. It was impossible for the court to conclude, on the evidence which had been put before it, that there had been any reason to advise Her Majesty to prorogue Parliament for five weeks until 14 October (see [56], [57], [61], below).

(3) The court was not precluded by art 9 of the Bill of Rights 1688 or by any wider Parliamentary privilege from considering the validity of the prorogation itself. Prorogation was neither a 'proceeding in Parliament' nor the core or essential business of Parliament. It followed that the Prime Minister's advice, the Order in Council and the actual prorogation to which it had led were unlawful, null and of no effect. Parliament had not been prorogued and declarations would be granted accordingly (see [66]–[70], below); *R v Chaytor* [2011] 1 All ER 805 applied.

Decision of the Divisional Court [2019] EWHC 2381 (QB) (set out below) reversed.

Decision of the Inner House, Court of Session [2019] CSIH 49 (set out below) affirmed.

Notes

For a justiciable issue and judicial review of the Crown prerogative, see 61A *Halsbury's Laws* (5th edn) (2018) paras 8, 9.

For the Bill of Rights (1688), art 9, see 10(1) *Halsbury's Statutes* (4th edn) (2016 reissue) 104.

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R (on the application of Jackson) v A-G [2005] UKHL 56, [2005] 4 All ER 1253, [2006] 1 AC 262, [2006] 2 LRC 499, [2005] 3 WLR 733.

R (on the application of McClean) v First Secretary of State [2017] EWHC 3174 (Admin), [2018] 1 Costs LO 37, DC.

R (on the application of Miller) v Secretary of State for Exiting the European Union, Re Agnew's application for judicial review (reference by the A-G for Northern Ireland), Re McCord's application for judicial review (reference by the Court of Appeal (Northern Ireland)) [2017] UKSC 5, [2017] 1 All ER 593, [2018] AC 61, [2017] NI 141, [2017] 2 WLR 583; *affg* [2016] EWHC 2768 (Admin), [2017] 1 All ER 158, [2018] AC 61, [2017] 2 WLR 583.

R (on the application of Morgan Grenfell & Co Ltd) v Special Comr of Income Tax [2002] UKHL 21, [2002] 3 All ER 1, [2003] 1 AC 563, [2002] STC 786, [2002] 2 WLR 1299.

R (on the application of Quark Fishing Ltd) v Secretary of State for Foreign and Commonwealth Affairs [2002] EWCA Civ 1409, [2002] All ER (D) 450 (Oct).
R (on the application of Sandiford) v Secretary of State for Foreign and Commonwealth Affairs [2014] UKSC 44, [2014] 4 All ER 843, [2014] 1 WLR 2697, [2015] 3 LRC 23.
R (on the application of UNISON) v Lord Chancellor [2017] UKSC 51, [2017] 4 All ER 903, [2017] 3 WLR 409, [2017] IRLR, [2017] ICR 1037.
R (on the application of Wheeler) v Office of the Prime Minister [2008] EWHC 1409 (Admin), [2008] All ER (D) 333 (Jun).
R (on the application of Youssef) v Secretary of State for Foreign and Commonwealth Affairs [2016] UKSC 3, [2016] 3 All ER 261, [2016] AC 1457, [2016] 5 LRC 85, [2016] 2 WLR 509.
R v Chaytor [2010] UKSC 52, [2011] 1 All ER 805, [2011] 1 AC 684, [2011] 3 LRC 1, [2010] 3 WLR 1707.
R v Ministry of Defence, ex p Smith [1996] 1 All ER 257, [1996] QB 517, [1996] IRLR 100, [1996] 2 WLR 305, CA.
R v Secretary of State for Foreign and Commonwealth Affairs, ex p Everett [1989] 1 All ER 655, [1989] QB 811, [1989] LRC (Const) 966, [1989] 2 WLR 224, CA.
R v Secretary of State for the Home Dept, ex p Bentley [1993] 4 All ER 442, [1994] QB 349, [1993] 4 LRC 15, [1994] 2 WLR 101, DC.
R v Secretary of State for the Home Dept, ex p Fire Brigades Union [1995] 2 All ER 244, [1995] 2 AC 513, [1995] 2 WLR 464, HL.
R v Wilde (1670) 1 Lev 296, (1670) 83 ER 415, Ct of KB.
Robinson v Secretary of State for Northern Ireland [2002] UKHL 32, [2002] NI 390, [2002] All ER (D) 364 (Jul).
Scotch Whisky Association v Lord Advocate [2016] CSIH 77, 2017 SC 465, 2017 SCLR 410, 2016 Scot (D) 7/11, 2016 SLT 1141.
Scott v Scott [1913] AC 417, [1911–13] All ER Rep 1, HL.
Scottish Lion Insurance Co Ltd v Goodrich Corp [2011] CSIH 18, 2011 SC 534, Scot (D) 16/3.
Shergill v Khaira [2014] UKSC 33, [2014] 3 All ER 243, [2015] AC 359, (2014) 17 ITELR 700, [2014] 3 WLR 1.
Somerville v Scottish Ministers (HM Advocate General for Scotland intervening) [2007] UKHL 44, 2008 SC (HL) 45, [2007] 1 WLR 2734, 2007 SCLR 830.
Teh Cheng Poh v Public Prosecutor, Malaysia [1980] AC 458, [1979] 2 WLR 623, PC.
Wightman v Secretary of State for Exiting the European Union [2018] CSIH 62, 2019 SC 111, [2019] 1 CMLR 795, 2018 Scot (D) 26/9, 2018 SLT 959; *on reference* (Case C-621/18) EU: C: 2018:999, [2019] QB 199, [2019] 1 CMLR 973, [2018] 3 WLR 1965, ECJ.

Judicial review

The petitioners, (1) Joanna Cherry QC MP, (2) Jolyon Maugham QC, (3) Joanne Swinson MP, (4) Ian Murray MP, (5) Geraint Davies MP, (6) Hywel Williams MP, (7) Heidi Allen MP, (8) Angela Smith MP, (9) the Rt Hon Peter Hain, the Lord Hain of Neath, (10) Jennifer Jones, the Baroness Jones of Moulescoomb, (11) the Rt Hon Janet Royall, the Baroness Royall of Blaisdon, (12) Robert Winston, the Lord Winston of Hammersmith, (13) Stewart Wood, the Lord Wood of Anfield, (14) Debbie Abrahams MP, (15) Rushanara Ali MP, (16) Tonia Antoniazzi MP, (17) Hannah Bardell MP, (18) Dr Roberta Blackman-Woods MP, (19) Ben Bradshaw MP, (20) the Rt Hon Tom Brake MP, (21) Karen Buck MP, (22) Ruth Cadbury MP, (23) Marsha de Cordova MP,

(24) Ronnie Cowan MP, (25) Neil Coyle MP, (26) Stella Creasy MP, (27) Wayne David MP, (28) Emma Dent Coad MP, (29) Stephen Doughty MP, (30) Rosie Duffield MP, (31) Jonathan Edwards MP, (32) Paul Farrelly MP, (33) James Frith MP, (34) Ruth George MP, (35) Stephen Gethins MP, (36) Preet Kaur Gill MP, (37) Patrick Grady MP, (38) Kate Green MP, (39) Lilian Greenwood MP, (40) John Grogan MP, (41) Helen Hayes MP, (42) Wera Hobhouse MP, (43) the Rt Hon Dame Margaret Hodge MP, (44) Dr Rupa Huq MP, (45) Ruth Jones MP, (46) Ged Killen MP, (47) Peter Kyle MP, (48) Ben Lake MP, (49) the Rt Hon David Lammy MP, (50) Clive Lewis MP, (51) Kerry McCarthy MP, (52) Stuart C McDonald MP, (53) Anna McMorrin MP, (54) Carol Monaghan MP, (55) Madeleine Moon MP, (56) Layla Moran MP, (57) Jess Phillips MP, (58) Lloyd Russell-Moyle MP, (59) the Rt Hon Liz Saville Roberts MP, (60) Tommy Sheppard MP, (61) Andy Slaughter MP, (62) Owen Smith MP, (63) Chris Stephens MP, (64) Jo Stevens MP, (65) Wes Streeting MP, (66) Paul Sweeney MP, (67) Gareth Thomas MP, (68) Alison Thewliss MP, (69) the Rt Hon Stephen Timms MP, (70) Anna Turley MP, (71) Catherine West MP, (72) Matt Western MP, (73) Martin Whitfield MP, (74) Dr Philippa Whitford MP, (75) Dr Paul Williams MP, (76) Daniel Zeichner MP, (77) Caroline Lucas MP, (78) Rosena Allin-Khan and (79) Luciana Berger, sought judicial review of the decision of the United Kingdom Prime Minister, the Rt Hon Boris Johnson MP, to advise the Queen to prorogue Parliament from a date between 9 and 12 September until 14 October 2019. The respondent to the petition was Her Majesty's Advocate General for Scotland. The Lord Advocate intervened. The facts are set out in the opinion.

Aidan O'Neill QC and *David Welsh* (instructed by *Balfour and Manson LLP*) for the petitioners.

David Johnston QC, Andrew Webster QC and *Neil Taylor* (instructed by and of the *Office of the Advocate General for Scotland*) for the Advocate General.

James Mure QC (instructed by the *Scottish Government Legal Directorate*) for the intervener (written submissions only).

4 September 2019. The following opinion was delivered.

LORD ORDINARY (**DOHERTY**)**.**

INTRODUCTION

[**1**] By an Order in Council made on 28 August 2019 at the Court at Balmoral Her Majesty the Queen ordered that Parliament be prorogued on a day no earlier than Monday 9 September 2019 and no later than 12 September 2019, until Monday 14 October 2019. This petition for judicial review challenges (i) the lawfulness of the Order; and (ii) the lawfulness of the advice to prorogue which was given to Her Majesty by the Prime Minister. It is common ground that in making the Order Her Majesty accepted that advice.

[**2**] I shall not rehearse the earlier history of the proceedings. For that, reference can be made to my Opinion of 30 August 2019 (*Petition of Cherry and others for Judicial Review* [2019] CSOH 68).

[**3**] On 2 September 2019 two applications for leave to intervene were lodged, the first by the Lord Advocate and the second by Mr Graham Senior-Milne. At the outset of the substantive hearing on 3 September 2019 I invited observations from the parties on each of the applications. Mr O'Neill

supported the proposed intervention by the Lord Advocate, but he resisted the application by Mr Senior-Milne. Mr Johnston adopted a neutral position in relation to both applications. Having considered the terms of both applications I was satisfied that the Lord Advocate's application was relevant and was likely to assist the court, and that the other requirements of RCS 58.19(4) were met. I granted the application. However, I was not satisfied that the propositions to be advanced in Mr Senior-Milne's application were relevant to the proceedings or that they were likely to assist the court. I refused that application.

THE ARGUMENTS

[**4**] Given the desirability of the court reaching a speedy decision, I do not propose to rehearse the arguments at length, nor do I propose to mention all of the authorities which were referred to. I shall confine myself to setting out the gist of the parties' positions.

The Lord Advocate's written submissions

[**5**] The executive is accountable to Parliament. The effect of the prorogation is to insulate it entirely from accountability during the period of prorogation. The relevant context is (i) that the United Kingdom's membership of the European Union will end (unless the period is extended by agreement between the Government and the EU) some eight weeks after the date on which prorogation takes effect and less than three weeks after the prorogation ends; (ii) the Government continues to negotiate with the European Union in connection with a proposed withdrawal agreement to take effect immediately after exit day; (iii) the Prime Minister has declared himself content to see the United Kingdom leave the European Union without having concluded such a withdrawal agreement; (iv) the Prime Minister's policy approach to withdrawal from the EU without a withdrawal agreement being in place is markedly different from that of his predecessor; (v) a majority of members of the House of Commons has expressed its opposition to that course; (vi) preparations are being made and will continue to require to be made in anticipation of the withdrawal of the UK from the EU on 31 October 2019; (vii) those preparations include both administrative arrangements in anticipation of withdrawal without a withdrawal agreement being in place, and legislative measures to prepare the statute book for the UK's withdrawal from the EU; (viii) Parliament has been engaged in ongoing scrutiny of the arrangements being made by the Government in anticipation of withdrawal from the EU; (ix) elected representatives in both the Scottish and UK Parliaments require to participate in the preparation of the statute book for exit day; and (x) the present administration is a minority Government whose ability to command the confidence of the House of Commons has not yet been tested. In the particular context, for the Prime Minister to advise and procure the prorogation of Parliament for five weeks may properly be characterised as an unlawful abuse of executive power which calls for the intervention of the Court. The abuse of power lies in the timing and duration of the prorogation; its effect on accountable government; and the marked absence of any compelling justification offered in that regard by the Prime Minister for that timing and length. It may be inferred that a purpose of the decision under review is to insulate the executive from Parliamentary scrutiny, for what (in the context of the anticipated withdrawal of the UK from the EU on 31 October 2019) is a significant period of time. In any event, the decision under review has

a a disproportionate impact on the principle of responsible government, where there is no compelling justification for that impact. A prorogation of five weeks is disproportionate to a purpose of bringing the current session of Parliament to an end and paving the way for a Queen's speech at the opening of the new session. There is a significant distinction between such a recess (which is voted upon by each House and is no more than a periodic adjournment) and
b prorogation. During such a recess: (a) either House may be recalled; (b) ongoing Parliamentary business does not fall; (c) Parliamentary committees may continue to sit and to scrutinise the executive; and (d) Members of Parliament may continue to table questions to the executive. None of these is possible during prorogation. In all the circumstances, and in the absence of any
c other explanation for the duration of the prorogation, the court may infer that a purpose of the decision under review is to curtail significantly the opportunity for Parliament to scrutinise the policies and actions of the executive at this time, and to insulate it entirely from Parliamentary scrutiny throughout the period of the prorogation. That would not be a proper purpose of prorogation. The effect which prorogation will have on the principle of
d responsible government for five weeks at this time calls for close scrutiny of the justification which is advanced. Given the particular context, there is a burden on the executive to provide a clear and compelling justification for a decision to deprive the sovereign UK Parliament of the ability to sit for a period of five weeks. No such compelling justification has been advanced. The impact on the principle of representative government is wholly disproportionate to
e such justification as has been advanced by the executive. In all these circumstances the intervener considers that the Court should reduce the Order in Council dated 28 August 2019.

The petitioners' submissions

f [**6**] Mr O'Neill moved the court:

> (1) to pronounce a declarator that it is *ultra vires et separatim* unconstitutional for any Minister of the Crown, including the Prime Minister, with the intention and aim of denying before exit day sufficient time for proper parliamentary consideration of the withdrawal of the United Kingdom from the European Union, to purport to advise the
g Queen to prorogue the Union Parliament;
>
> (2) to order reduction of the Order in Council of 28 August 2019;
>
> (3) to interdict Ministers of the Crown in right of the United Kingdom from acting upon the Order in Council of 28 August 2019 proroguing the Union Parliament.

h He submitted that Parliamentary sovereignty is a fundamental principle of the UK constitution. The executive must act within the powers permitted it by Parliament, and must exercise those powers for the purposes for which they were left with it by Parliament. The prerogative is a source of power which is only available for a case not covered by statute. The executive's prerogative power cannot be used to defeat or frustrate domestic rights which have been
j created by Parliament. This includes rights under EU law (*R (on the application of Miller) v Secretary of State for Exiting the European Union, Re Agnew's application for judicial review (reference by the A-G for Northern Ireland), Re McCord's application for judicial review (reference by the Court of Appeal (Northern Ireland))* [2017] UKSC 5, [2017] 1 All ER 593, [2018] AC 61 (at paras [44]–[45])). The executive is politically accountable to Parliament for its exercise of its powers. If and

insofar as the executive would use the power of prorogation of Parliament to avoid its political accountability to Parliament, or to impede Parliament from exercising its control over the executive, the executive is acting unlawfully. Reference was made to *Moohan v Lord Advocate* [2014] UKSC 67, [2015] 2 All ER 361, [2015] AC 901 per Lord Hodge at para [35]. The executive's political accountability to Parliament and its legal accountability to the courts are not mutually exclusive, but complementary constitutional checks on the power of the executive. They may overlap (*R (on the application of Barclay) v Secretary of State for Justice and Lord Chancellor* [2014] UKSC 54, [2014] 1 All ER 429, [2015] AC 276 per Baroness Hale at para [57]). It is for the court to ensure the rule of law by providing an effective remedy against any constitutional violations (*Teh Cheng Poh v Public Prosecutor, Malaysia* [1980] AC 458 at 473, [1979] 2 WLR 623 at 633–634 per Lord Diplock).

[7] The Claim of Right Act 1689 regulates and constrains the executive's power to prorogue Parliament. It outlaws any abusive use by the executive of the power of prorogation to avoid, impede or restrain Parliament from carrying out its constitutional function of addressing and redressing grievances and amending, strengthening and preserving the law. Therefore the exercise of the executive's power to prorogue Parliament is a matter which is justiciable before the courts and is reviewable on the grounds of irrationality or breach of other judicial review principles (cf *R (on the application of Sandiford) v Secretary of State for Foreign and Commonwealth Affairs* [2014] UKSC 44, [2014] 4 All ER 843, [2014] 1 WLR 2697 per the joint judgment of Lord Carnwath and Lord Mance JJSC at paras [50], [52], [65]).

[8] The executive's exercise of the power of prorogation of Parliament can only be exercised for a proper purpose. The exercise of the power, even for a proper purpose, is subject to review on ordinary principles of legality, rationality and procedural impropriety in the same way as any other executive action (*R (on the application of Bancoult) v Secretary of State for Foreign and Commonwealth Affairs* [2008] UKHL 61, [2008] 4 All ER 1055, [2009] AC 453, per Lord Hoffmann at para [35], Lord Rodger at para [105]).

[9] The executive is subject in the present case to the obligation owed to the court by a public authority facing a challenge to its decision 'to co-operate and to make candid disclosure, by way of affidavit, of the relevant facts and (so far as they are not apparent from contemporaneous documents which have been disclosed) the reasoning behind the decision challenged in the judicial review proceedings' (*Belize Alliance of Conservation Non-Governmental Organisations v Dept of the Environment (No 2)* [2004] UKPC 6, (2004) 64 WIR 68, [2004] Env LR 38, per Lord Walker of Gestingthorpe at para [86]). The Prime Minister has declined to lodge an affidavit. Accordingly, the court should subject the reasons given to anxious scrutiny. The executive ought to be required to demonstrate that the most compelling of justifications exist for the exercise of the prorogation power in this way and at this time because the manner in which the power is being exercised affects individuals' fundamental rights and has profoundly intrusive and distortive effects on the constitution (*R v Ministry of Defence, ex p Smith* [1996] 1 All ER 257 at 263, [1996] QB 517 at 554 per Sir Thomas Bingham MR).

[10] It is clear that the executive's exercise of the power of prorogation in the present case involves the improper exercise of this power 'for an alien purpose or in a wholly unreasonable manner', namely: to prevent or impede Parliament from holding the executive politically to account in the run up to Exit Day; to prevent or impede Parliament from legislating on the United Kingdom's exit

from the European Union; to allow the executive, notwithstanding that it has no Parliamentary mandate to do so, to pursue a policy of a no deal Brexit without further Parliamentary interference. The executive has purported to use the power of prorogation as a pre-emptive strike intending to silence and disempower Parliament for the crucial period in the immediate run up to Exit Day.

[**11**] Further, the executive's exercise of the power of prorogation in the present case is unlawful because it runs contrary to the intention of Parliament by rendering futile, inter alia, the provisions of ss 9 and 13 of the European Union (Withdrawal) Act 2018 which clearly provide that Parliament should have proper time and opportunity to give full consideration to and, if approved, legislate to give full effect to the terms of any withdrawal of the United Kingdom from the European Union, with or without a deal. When and if Parliament passes the necessary statute, then and only then does the executive have authority to effect the withdrawal of the United Kingdom from the EU in accordance with whatever terms Parliament has stipulated in primary legislation.

[**12**] The executive's exercise of the power of prorogation in the present case is vitiated by error in law, because it is wrongly predicated on the idea that it has the authority to cause or allow the United Kingdom to leave the EU on the basis of no deal. Primary legislation is required from Parliament to conclude the art 50 Treaty on European Union ('TEU') process by authorising the executive to end the United Kingdom's membership of the EU, whether on the basis of the terms of a concluded deal or on the basis that no agreement on the terms of withdrawal could ultimately be reached. The executive has not been given the necessary express statutory authority by Parliament to allow it to pursue a policy of no deal Brexit. Given that the exercise of the power of prorogation at issue is aimed, at least in part, to facilitate the achievement, if so advised, of an executive policy ('no deal Brexit') which is unlawful in the absence of express statutory authorisation, the exercise of prorogation in this way is itself unlawful.

The respondent's submissions

[**13**] Mr Johnston submitted that there are important differences between statutory and prerogative powers. The exercise of some prerogative powers is justiciable, but the exercise of others is not. The court's role in relation to prerogative powers is dependent on the nature and the subject matter of the power or its exercise, particularly on whether the subject matter is justiciable (*R (on the application of Sandiford) v Secretary of State for Foreign and Commonwealth Affairs* [2014] 4 All ER 843, [2014] 1 WLR 2697, per the joint judgement of Lord Carnwath and Lord Mance at paras [52], [60] and [61]). Whether the exercise of a prerogative power is reviewable depends on the subject-matter and the context of the power and of the challenge. Some functions exercised or decisions taken are non-justiciable. Among them are matters of high policy. The courts will not seek to impose legal controls on such matters. Here the claim is non-justiciable. There is no statute or source of law that regulates prorogation or the advice given to the Queen in relation to prorogation. The advice involved high policy and political judgement, not law. The court does not have the tools or standards to assess the legality of political advice. This is political territory and decision-making which cannot be measured against legal standards, but rather only by political judgments. The

law does not superimpose on political considerations additional legal standards. That would make the political process unworkable. Reference was made to *Shergill v Khaira* [2014] UKSC 33, [2014] 3 All ER 243, [2015] AC 359, per the joint judgment of Lords Neuberger, Sumption and Hodge at para [40]; *Council of Civil Service Unions v Minister for the Civil Service* [1984] 3 All ER 935 at 951, [1985] AC 374 at 411 per Lord Roskill; *A v Secretary of State for the Home Dept, X v Secretary of State for the Home Dept* [2004] UKHL 56, [2005] 3 All ER 169, [2005] 2 AC 68, per Lord Bingham at para [29]; *R (on the application of Wheeler) v Office of the Prime Minister* [2008] EWHC 1409 (Admin), [2008] All ER (D) 333 (Jun) (at para [34]); *R (on the application of McClean) v First Secretary of State* [2017] EWHC 3174 (Admin), [2018] 1 Costs LO 37 (DC), per Sales LJ at paras [21]–[22]; and *Robinson v Secretary of State for Northern Ireland* [2002] UKHL 32, [2002] NI 390, per Lord Bingham at para [12] and Lord Hoffmann at para [33]. The petitioners seek to rely on a denial of 'sufficient' time for 'proper' consideration of the withdrawal of the UK from the EU. There are no judicial or manageable standards by reference to which the court could determine that claim. The courts are not the right place for matters of high policy and political judgement to be sorted out. Accountability for such matters is to Parliament and the electorate. The very fact that the court is faced with trying to weigh political judgments and the reasons for which they were reached suggests that the claim here is outside the territory where legal standards can helpfully be deployed.

[**14**] A more specific point which follows on from that is that Parliament has recently, in the Northern Ireland (Executive Formation etc) Act 2019, s 3, made its own clear and express provision about when it wishes to sit. It provides in the period covered by that Act (which goes to the end of this calendar year) that Parliament may be prorogued at some point; and it makes provision for it to be recalled if that is necessary for a report to be laid about progress in formation of the Northern Ireland Executive. Where Parliament wishes to lay down the law about when it should be in session and not prorogued, it has a means of doing that, and it has recently used that means. Parliament has occupied this area for itself.

[**15**] Wider constitutional considerations also confirm that decisions about prorogation or advice about prorogation are not matters for the courts.

[**16**] Parliament is the master of its own proceedings, rules and privileges and has exclusive control over its own affairs. The separation of powers entails that the courts will not interfere. It is for Parliament to decide when it will sit and it routinely does so. It is not for the courts to devise further restraints on prorogation which go beyond the limits which Parliament has chosen to provide.

[**17**] The exercise by the Sovereign of the power to prorogue upon receipt of advice from the Prime Minister is governed by constitutional convention alone. The courts cannot enforce a political convention. The sanction for non-observance of a convention is political, not legal.

[**18**] There is no material difference between Scots law and English law as regards any of the issues in the case. The petitioners do not actually identify anything that points to a difference in result or approach between Scots law and English law.

[**19**] Second, the claim is academic. The complaint is that Parliament is going to be denied the opportunity to sit and to call the executive to account. However, provision has already been made to enable Parliament to sit for

certain periods up to the end of October – in the Northern Ireland (Executive Formation etc) Act 2019, s 3 and in the Order in Council. That being so, Parliament will be sitting. That renders the claim an academic one.

[**20**] Third, the claim that the Claim of Right Act 1689 is breached by the Order in Council is non-justiciable. The words 'Parliaments … be frequently called and allowed to sit' provides no legal limit or standard by which the court can judge the legality of any prorogation. Even if there were some legal standard, there is nothing to support any breach of this provision, because the words 'Parliaments … be frequently called and allowed to sit' contemplate Parliament being adjourned, prorogued, dissolved – certainly not sitting in permanent session. Any prorogation before the end of October must comply with s 3 of the Northern Ireland (Executive Formation etc) Act 2019. Any prorogation that cut across the dates set out there would need to be interrupted.

[**21**] Prorogation does not frustrate the will of Parliament as expressed in the primary legislation relied upon by the petitioners. It is not the purpose of prorogation to frustrate s 13 of the European Union (Withdrawal) Act 2018. In any case, s 13 doesn't apply to exit without a deal. Neither does prorogation cut across s 20, or the provisions of s 3 of the Northern Ireland (Executive Formation etc) Act 2019.

[**22**] The application is not concerned with the legal requirements of exiting the EU under art 50 of the Treaty on European Union. It is concerned with prorogation of Parliament. The fact Parliament may not be sitting for five weeks does not of itself have any direct effect on individuals' EU law rights. It is not correct to say that it is unlawful for the United Kingdom to leave the EU with no deal unless there is further legislation. Section 1(1) of the European Union (Notification of Withdrawal) Act 2017 provided the requisite legislative authority for the Prime Minister to notify the intention of the UK to withdraw from the EU under art 50(2). On 29 March 2017 the Prime Minister formally notified the EU of the UK's intention to withdraw under art 50(2), and the European Council accepted that notification. Withdrawal from the EU has therefore been approved by Parliament in the unconditional form of the 2017 Act, enacted in the knowledge and understanding of the meaning and effect of art 50 TEU, that with or without an agreement the UK would exit the EU upon the expiry of the art 50 period. Withdrawal from the EU without an agreement would not, in those circumstances, be contrary to *Miller* and would not, as the petitioners maintain, require further primary legislation.

[**23**] While in accordance with the duty of candour the respondent had disclosed the documents showing reasons for the advice, the respondent's position is that the advice is non-justiciable and the courts should not enquire into the reasons or scrutinise their adequacy. However, the reasons are lawful, relevant and legitimate.

DECISION AND REASONS

Introduction

[**24**] This part of my opinion is shorter than it would have been had I had the advantage of greater time to prepare it. Nevertheless, I have endeavored to outline briefly my views on the material issues. I have sought to explain why it is that the parties have won or lost. Once again, I am grateful to counsel and those instructing them for all that they have done to facilitate the presentation of arguments at the hearing yesterday. That has been of considerable assistance to me.

Is the issue raised justiciable?

[**25**] In my opinion the authorities discussed during the submissions vouch the following propositions. The exercise of some prerogative powers in some circumstances is justiciable, in other cases it is not. The court's role in relation to prerogative powers is dependent on the nature and the subject matter of the power or its exercise, particularly on whether the subject matter is justiciable. Whether the exercise of a prerogative power is reviewable depends on the subject-matter and the context of the power and of the challenge. Some functions exercised or decisions taken are non-justiciable. Among them are matters of high policy and political judgement. The court does not have the tools or standards to assess the legality of such matters. That is political territory and decision-making which cannot be measured against legal standards, but rather only by political judgments. The courts will not seek to superimpose legal controls on such matters. Rather, the accountability for them is to Parliament and the electorate.

[**26**] I am not persuaded that any of the matters relied upon by the petitioners or the Lord Advocate result in the claim being justiciable. In my view the advice given in relation to the prorogation decision is a matter involving high policy and political judgement. This is political territory and decision-making which cannot be measured against legal standards, but only by political judgements. Accountability for the advice is to Parliament and, ultimately, the electorate, and not to the courts.

[**27**] I do not accept the submission that the prorogation contravenes the rule of law, and that the claim is justiciable because of that. In my opinion there has been no contravention of the rule of law. The power to prorogue is a prerogative power and the Prime Minister had the *vires* to advise the sovereign as to its exercise. The executive is accountable to Parliament and the electorate for the advice to prorogue.

[**28**] Parliament is the master of its own proceedings, rules and privileges and has exclusive control over its own affairs. The separation of powers entails that the courts will not interfere. It is for Parliament to decide when it will sit and it routinely does so. It is not for the courts to devise further restraints on prorogation which go beyond the limits which Parliament has chosen to provide. Parliament can sit before and after the prorogation. It has recently, in the Northern Ireland (Executive Formation etc) Act 2019, s 3, exercised its legislative power to make provision about periods when it should sit.

[**29**] That is sufficient to dispose of the petition. However, since the matter may go further I shall also provide my views on other issues which were raised.

Breach of the Claim of Right Act 1689?

[**30**] I see some force in Mr Johnston's submission that the claim that the Claim of Right Act 1689 is breached by the Order in Council is non-justiciable. However, I prefer to decide this issue on the more straightforward ground that there is nothing to support any breach of the provisions of the Act. I accept Mr Johnston's submissions on that point.

Does prorogation frustrate the will of Parliament by rendering existing legislation futile?

[**31**] In my opinion Mr Johnston's legal analysis of the legislative provisions upon which Mr O'Neill relied is also correct. Prorogation does not render those provisions futile.

The other matters discussed

[**32**] Given that the two bulwarks of the petitioners' argument that prorogation is unlawful are not made out (i e because it was said to be in breach of the Claim of Right Act 1689 and that it rendered some existing legislation futile), I do not think it necessary to say much about any of the other matters which were discussed. None of the matters founded upon by the petitioners or the Lord Advocate cause me to conclude that prorogation is unlawful if, contrary to my view, the claim is justiciable.

[**33**] I am not much attracted to Mr Johnston's submission that the petitioners' claim is academic. However, I am inclined to agree with him that the application is concerned with prorogation, not with the legal requirements of exiting the EU under art 50 of the Treaty on European Union; and that the fact Parliament may not be sitting for five weeks does not of itself have any direct effect on individuals' EU law rights. I am also inclined to agree with his analysis of *Miller* and the consequences of the subsequent legislation.

[**34**] Finally, I should say something about the reasons for the prorogation given by the respondent. Even if, contrary to my view, the claim is justiciable, in my opinion the context in which those reasons would fall to be assessed would be that political judgements may be relevant and legitimate considerations. On the basis of the material which I have seen I am not persuaded that the reasons for the advice were unlawful.

DISPOSAL

[**35**] I shall refuse the petition.

Petition refused.

Judicial review

The claimant, Gina Miller, sought judicial review of the decision of the Prime Minster, the Rt Hon Boris Johnson MP, to advise Her Majesty the Queen to prorogue Parliament from a date between 9 and 12 September until 14 October 2019. The following parties were granted permission to intervene: (1) the Rt Hon the Baroness Chakrabarti; (2) the Counsel General for Wales; (3) the Rt Hon Sir John Major KG CH; and (4) the Lord Advocate. The facts are set out in the judgment of the court.

Lord Pannick QC, *Tom Hickman QC* and *Warren Fitt* (instructed by *Mishcon de Reya LLP*) for the claimant.

Sir James Eadie QC, *David Blundell*, *Christopher Knight* and *Richard Howell* (instructed by the *Government Legal Department*) for the Prime Minister.

Deok Joo Rhee QC (instructed by *Howe & Co Solicitors*) for the first intervener.

Michael Fordham QC, *Hollie Higgins* and *Celia Rooney* (instructed by *Legal Services Department, Welsh Government*) for the second intervener.

Lord Garnier QC, *Tom Cleaver* and *Anna Hoffmann* (instructed by *Herbert Smith Freehills LLP*) for the third intervener.

James Wolffe QC (Lord Advocate), *James Mure QC*, *Alan Maclean QC* and *Christine O'Neill* (instructed by *Baker & McKenzie LLP*) for the fourth intervener.

6 September 2019. The court announced that the claim would be dismissed for reasons to be given later.

11 September 2019. The following judgment of the court was delivered.

BURNETT LCJ, ETHERTON MR, SHARP P.

[**1**] On Wednesday 28 August 2019 at a Privy Council held at the Court at Balmoral Her Majesty ordered that Parliament should be prorogued from a date between 9 and 12 September until 14 October 2019. The order was made on the advice of the Prime Minister. These proceedings were started later the same day. The main issue we have to decide is whether the decision of the Prime Minister to seek the prorogation of Parliament is justiciable (is capable of challenge) in Her Majesty's courts or whether it is an exclusively political matter. We heard argument on Thursday 5 September and the following morning gave our decision. We concluded that the decision of the Prime Minister was not justiciable. It is not a matter for the courts. In formal terms we granted permission to apply for judicial review but dismissed the claim. We acceded to an application that any appeal from our order could leap-frog to the Supreme Court pursuant to s 12(3A)(c) of the Administration of Justice Act 1969 should leave to appeal be granted.

[**2**] Parallel proceedings were progressing in Scotland. They had been issued long before the order to prorogue Parliament had been made in the context of a growing concern that the Prime Minister might secure prorogation either side of the date appointed by statute for the departure of the United Kingdom from the European Union, currently 31 October 2019. Their focus changed following the prorogation order. On Wednesday 4 September Lord Doherty sitting in the Outer House of the Court of Session dismissed the claim. He too concluded that this was not a matter for the courts. An appeal is proceeding in the Inner House of the Court of Session. We have had the advantage of reading Lord Doherty's judgment.

[**3**] We heard oral argument from Lord Pannick QC for the claimant and Sir James Eadie QC for the Prime Minister. In the week between the commencement of these proceedings and the hearing we received a large number of applications from individuals and bodies to intervene or be joined as claimants. Many came too late to enable the parties to deal with any submissions within the very tight timetable to which we were operating. We took steps to ensure that the Lord Speaker and Speaker were notified of the proceedings but, entirely understandably, neither chose to place submissions before the court. We acceded to four applications to intervene in writing: from the Shadow Attorney General on behalf of the Official Opposition; from the Rt Hon Sir John Major KG CH, who was Prime Minister between 1990 and 1997; from the Counsel General for Wales on behalf of the Welsh Government; and from the Lord Advocate on behalf of the Scottish Government. All supported the claimant. We have been assisted by the written materials provided. We record our thanks to all those representing both the parties and the interveners for the assistance we have been given and acknowledge the pressure under which they have worked over the last few days.

PROROGATION

[**4**] A decision to prorogue Parliament is made by the Sovereign formally on the advice of the Privy Council but in reality on the advice of the Prime Minister. It is a prerogative power. By constitutional convention the Sovereign invariably acts on the advice of the Prime Minister. Parliament is prorogued

between sessions. The new session begins with a Queen's Speech which sets out the Government's legislative agenda. There is no fixed duration for a session of Parliament although as a matter of recent practice each session usually lasts about a year. As it happens, the current session of Parliament has lasted since 21 June 2017, over two years. Prorogation brings to an end all proceedings in both Houses for the current session. Practical arrangements exist for some pending legislation to be carried over into the next session so that it does not have to start again and before prorogation there is usually a 'wash-up' period to enable the passage of bills approaching completion of parliamentary stages. All business of both Houses is immediately suspended upon prorogation and does not recommence until the new session starts with a State Opening of Parliament. Amongst the consequences of prorogation are that no legislation may be discussed or passed, no questions asked of ministers and select committees do not continue to function. For practical purposes, Parliament ceases to operate whilst it stands prorogued.

[**5**] Prorogation is different from dissolution. Parliament is dissolved pending a general election. Until recently, dissolution was a matter for the Prime Minister of the day who would ask the Sovereign to dissolve Parliament. Constitutional experts, for example the late Professor RV Heuston, consider that the Queen retains a personal discretion both to refuse a Prime Minister's request for a dissolution and to dissolve Parliament without a request. But in modern times the reality invariably has been that when asked to dissolve Parliament the Sovereign has agreed. This too was an example of the exercise of the Royal Prerogative, but Parliament legislated in the Fixed-term Parliaments Act 2011 to prescribe exhaustively the circumstances in which a general election may be called. Section 6 of that Act preserved unaltered the prerogative power to prorogue Parliament.

[**6**] Prorogation should also be contrasted with the adjournment of either or both Houses during a session, including for a recess. That is commonplace. Either House can, if it chooses, sit without interruption. But both Houses adjourn from day to day whilst they are sitting and from one week to another. They also may, and customarily do, adjourn for much longer periods. Those include, for example, over Christmas and the New Year, Easter and Whitsun and over the summer. Parliament adjourned on 25 July 2019 for its summer recess and reassembled on Tuesday 3 September. It has been customary for Parliament to go into recess for a period to coincide with party conferences, usually about three weeks. The House of Commons briefing paper on the Brexit Timeline (No 7960 13 August 2019) includes in its future timetable a period from mid-September to early October for party conferences, but that would be a matter for decision by both Houses. Whilst standing adjourned or in recess the business of Parliament continues to some extent. In particular, select committees continue with their investigations and may direct inquiries to ministers and written questions may be asked of ministers.

STATUTORY REFERENCES TO PROROGATION

[**7**] There are statutory references to prorogation other than in the Fixed-term Parliaments Act 2011. The Succession to the Crown Act 1707 was concerned with ensuring that Queen Anne would be succeeded on the throne by a Protestant. It expressly preserved the power of the Queen and her heirs and successors to prorogue Parliament. The Meeting of Parliament Act 1797 empowered the Monarch to foreshorten a period of prorogation by giving notice that Parliament should reassemble. The Prorogation Act 1867 was

designed to simplify the way in which Parliament could be prorogued whilst Parliament was in recess, but did not apply to prorogation at the end of a session. All of these statutes recognise the power to prorogue. The Civil Contingencies Act 2004 by s 28 and the Reserve Forces Act 1996 by s 52(8) both make provision for prorogation to be curtailed in given circumstances.

[**8**] The Northern Ireland (Executive Formation etc) Act 2019 received Royal Assent on 24 July 2019. It is concerned with extending the period allowed for forming an Executive in Northern Ireland from 25 August 2019. Section 3 requires the Secretary of State, on or before 4 September 2019, to report to both Houses on progress towards the formation of an Executive; and make arrangements for motions in both Houses to be moved by ministers within five days of the report being laid. Those obligations continue to arise periodically thereafter. Section 3(4) provides that if it is impossible for ministers to move the motions because Parliament stands prorogued or adjourned, then Parliament should be summoned using the powers contained in the Meeting of Parliament Act 1797. This illustrates the undoubted power of the Crown in Parliament to legislate to ensure that Parliament sits notwithstanding prorogation. Sir James also submits that, by a side wind it could be said, it is at least possible that Parliament will be called back into session during the period of prorogation. We were not told the date on which the Secretary of State published his report nor whether motions were moved in accordance with s 3. For the moment, the position remains unclear.

THE DECISION TO PROROGUE

[**9**] The Rt Hon Theresa May MP resigned as leader of the Conservative Party on 7 June 2019. The Rt Hon Boris Johnson MP won the subsequent leadership competition on 23 July and following the resignation from office of Mrs May became Prime Minister on 24 July 2019. During the leadership campaign the issue of whether Parliament might be prorogued either side of 31 October was raised and not ruled out by a number of the candidates, including the Prime Minister. Earlier in the year there had been a lively debate between constitutional experts and lawyers about both the constitutional propriety and legality of proroguing Parliament in advance of exit day. It was sparked by writings of Professor John Finnis in advance of the exit date then fixed by statute, namely 29 March 2019.

[**10**] On 15 August 2019 a submission entitled 'Ending the Session' was made to the Prime Minister. Its author was Nikki da Costa, the Director of Legislative Affairs at 10 Downing Street. It noted that the current session was the longest since records began and that all the bills announced in the last Queen's Speech had received Royal Assent or were paused awaiting the next session. Filling parliamentary time had become difficult and there was an expectation that the Prime Minister would 'set out a refreshed domestic agenda'. The first week's business (ie following Parliament's return on 3 September) had already been announced. The submission recommended dedicating the second week to 'wash-up bills' (as noted those close to completing the passage through Parliament), expected to take no more than three or four days. Ms da Costa recommended that Parliament should be prorogued on a date between 9 and 12 September and return for a Queen's Speech on 14 October. The period of the recommended prorogation was explained as including 'the long-standing conference recess'.

[**11**] In a description of the background to the decision Ms da Costa explained that Parliament had been considering small, low priority bills and

that business managers of both Houses were asking for new bills to ensure that Parliament was using its time gainfully. She identified a problem in introducing new bills now, namely that unless the session was to continue for at least four to six months more, they might fall when the session otherwise ended. The last Prime Minister had been aware of these tensions. Dates had been placed in the diary for a Queen's Speech in April/May 2019 and in October 2019 but at the time, October was considered a very late end to the session. Ms da Costa suggested that the decision was now pressing. She explained that the Prime Minister had to make two decisions. First, when to end the session; and secondly, but subject to the availability of Her Majesty, when to hold the State Opening of the new session. She added, 'the decision will be influenced by practical, legal and political considerations'.

[**12**] The passage in the submission dealing with legal issues has properly been redacted because it contains privileged legal advice. The practical considerations identified the need to leave enough time for Parliament to complete the passage of some bills thus pointing to between 9 and 12 September rather than the previous week. The proposed date for the Queen's Speech allowed sufficient time to prepare the new legislative agenda. An earlier date would be 'extremely pressured'. Furthermore, returning on 7 October would interrupt the conference of the Scottish National Party which does not traditionally benefit from the conference recess. The political considerations were summarised in these terms:

> '14. Finally, politically it is essential that Parliament is sitting before and after the EU Council [17/18 October] – MPs and Peers must be in a position to consider what is negotiated, and hopefully pass the Withdrawal Agreement Bill. If there is no deal, they need to have an opportunity to hear what you have to say, and respond accordingly.
>
> 15. From the Government's perspective, it is equally important that key votes associated with the Queen's speech – traditionally seen as matters of confidence – fall at a time when parliamentarians are best placed to judge your programme, and whether to endorse it. If the Queen's Speech is on 14th October, the usual six day debate would mean votes fall on 21st 22nd October. Parliament would have the opportunity to debate your Government's overall approach to Brexit in the run up to the EU Council and then vote on this once we know the outcome of the council. The debate on the Loyal Address can be truncated, but ideally it would be coming to a close anyway immediately after the EU Council.
>
> 16. This does mean there will be a vote risk in mid to late October, but that might also have political benefits: those MPs most anxious about no-deal may welcome the Government facilitating key votes on a known date close to the EU Council, and the chance to table amendments, rather than having to find some peculiar mechanism which tears up convention and parliamentary procedure.
>
> 17. By contrast a Queen's Speech on 8/9th October would put the key votes at the same time as the EU Council – forcing MPs to make critical decisions on the future of the UK government before they've seen the result of the negotiations.
>
> 18. Finally it must be recognised that the situation has become more complicated because prorogation, on its own and separate from a Queen's Speech has been portrayed as a potential tool to prevent MPs intervening prior to the UK's departure from the EU on 31st October. Despite usually

being an annual affair, there will be nervousness about prorogation even to start a new session. The dates proposed seek to provide reassurance by ensuring that parliament will sit for three weeks prior to exit, and that a maximum of seven sitting days are lost separate of the period usually set aside for conference recess.'

[**13**] Ms da Costa continued by noting that there was no statutory provision governing the length of prorogation but that it is usually under ten days. In the first half of the 20th century it had usually been much longer. There had been five occasions since 1980 when Parliament stood prorogued for more than ten days, the longest being 21 days. The proposal was for prorogation for up to 34 calendar days but 'given the expected conference recess period of typically three weeks, the number of sitting days lost by such prorogation would be far less than that: 1–3 sitting days during the week commencing 9th September, and 4 sitting days during the week commencing 7th October'. She added that it would be undesirable to leave 'wash-up' until after the conference recess or to interrupt it. She concluded by noting that there was no record of the House of Commons sitting in late September or early October since the start of the 20th century.

[**14**] The Prime Minister placed a tick against the recommendation and added a short covering note:

'1. The whole September session is a rigmarole introduced … to show the public that MPs were earning their crust

2. So I don't see anything especially shocking about this prorogation

3. As Nikki notes, it is OVER THE CONFERENCE SEASON so that the sitting days lost are actually very few.'

STATUTORY CONTROL OF THE BREXIT PROCESS

[**15**] The European Union Referendum Act 2015 required a referendum to be held on continued membership of the European Union. It was held on 23 June 2016. The result was a majority for leaving the European Union. A Member State must initiate the process prescribed under art 50 of the Treaty on European Union to achieve exit. The period specified between giving notice and departure is two years, unless extended by mutual agreement. The question arose whether primary legislation was required to authorise the giving of notice or whether the Government could use prerogative powers to do so. The Supreme Court decided that statutory authority was required: *R (on the application of Miller) v Secretary of State for Exiting the European Union, Re Agnew's application for judicial review (reference by the A-G for Northern Ireland), Re McCord's application for judicial review (reference by the Court of Appeal (Northern Ireland))* [2017] UKSC 5, [2017] 1 All ER 593, [2018] AC 61 ('*Miller No 1*').

[**16**] Parliament thereafter enacted the European Union (Notification of Withdrawal) Act 2017 which provided the Prime Minister with the necessary legislative authority. On 29 March 2017 the Prime Minister gave notification of the intention of the United Kingdom to leave the European Union pursuant to art 50(2). Its effect was that unless time was extended the United Kingdom would leave on 29 March 2019.

[**17**] The next legislative step was the European Union (Withdrawal) Act 2018. It makes provision for the repeal of the European Communities Act 1972 and (in broad terms) for the retention in domestic law of much

European Union law on exit day. Exit day was defined in s 20(1) as 29 March 2019, but that date could be extended by regulation made by statutory instrument. Section 13 requires parliamentary approval of the outcome of negotiations between the United Kingdom Government and the European Union. It was in those circumstances that the House of Commons eventually came three times to reject the withdrawal agreement concluded between the Government and the European Union.

[**18**] On 20 March 2019, following a failure to secure parliamentary approval of the deal, Mrs May sought an extension of the art 50 period. The European Council approved an extension until 22 May if the deal were to be approved by Parliament but only to 12 April if it were again rejected. The necessary regulations were made to redefine 'exit day'. Given Parliament's continued rejection of the deal, the extension was the shorter of the two. It was in those circumstances that Parliament enacted the European Union (Withdrawal) Act 2019 which empowered the House of Commons to require the Prime Minister to seek a further extension of the art 50 period to a specified date. In accordance with the statutory provisions, the Government sought an extension to 31 October which was agreed by the European Council on 10 April 2019. The necessary regulations to redefine 'exit day' for the purposes of the European Union (Withdrawal) Act 2018 were made the following day.

RECENT DEVELOPMENTS

[**19**] The central contention of the claimant set out in her witness statement is that 'the purpose of the prorogation is to prevent or frustrate Parliament from holding the Government to account and, in particular, from passing legislation that would require the Prime Minister to take steps to avoid the UK leaving the EU without an agreement … under Article 50(3) of [the] Treaty of the European Union'.

[**20**] Lord Pannick draws our attention to an interview given by the Prime Minister to Sky News on 30 August 2019 in which he said that 'the more our friends and partners think at the back of their minds that Brexit could be stopped, that the UK could be kept in by Parliament, the less likely they are to give us the deal that we need and so that is why I really hope that MPs will allow the UK to do a deal …'. That is said to illustrate the true reason, or at least part of the reason for prorogation: to stop Parliament undermining the negotiations.

[**21**] Political and parliamentary events are capable of moving quickly with the result that legal proceedings, however much expedited, may be outpaced. As we prepare these reasons those events are continuing to develop. Parliament returned on Tuesday 3 September. The Rt Hon Sir Oliver Letwin MP proposed a motion that Members of Parliament should 'take control of the Order Paper'. That motion passed. On Wednesday 4 September the European Union (Withdrawal) (No 6) Bill was introduced into the House of Commons and passed all its stages. The Prime Minister opposed it inside and outside Parliament with the argument he had deployed on Sky News. The Bill was sent to the House of Lords. On Thursday 5 September (the day on which we were hearing argument) a motion was passed in the House of Lords that the normal rules on how Lords business runs should be suspended, to allow the remaining stages of the Bill to be brought to a conclusion at 17.00 on Friday 6 September. That is what happened. The Bill received Royal Assent on Monday 9 September as the European Union (Withdrawal) (No 2) Act 2019. The Act makes 'provision in connection with the period for negotiations for withdrawing from

the European Union' including steps that would follow the failure of the European Union and the Government to agree a revised deal in mid-October.

[**22**] On 4 September the Prime Minister failed to secure the agreement of the House of Commons in accordance with the Fixed-term Parliaments Act to hold a general election; and again on Monday 9 September. The Act requires a two thirds majority of Members of Parliament to support a motion to trigger a general election. The other mechanism found in the Act requires the Government to lose a motion of no confidence followed by a failure of the House to pass a motion of confidence. The opposition has decided thus far not to table a motion of no confidence in the Government.

THE ARGUMENT FOR THE CLAIMANT

[**23**] Lord Pannick made submissions which he says are informed by and take account of those made by the Interveners. He submits that the Prime Minister's advice to Her Majesty to prorogue Parliament is an unlawful abuse of power, substantially influenced by extraneous and improper considerations, and the court has a duty to intervene on ordinary public law principles, albeit recognising the wide discretion accorded to the Prime Minister. The decision breaches the legal principle of Parliamentary Sovereignty because the effect of prorogation is to remove the ability of Parliament to enact legislation as it sees fit on issues relating to the arrangements for this country to leave the European Union, when time is of the essence, because of the existing deadline of 31 October 2019. Prorogation also prevents Parliament from performing its other 'scrutiny' functions which inform its decisions on this vital issue of public policy.

[**24**] The argument focuses on three issues: Parliamentary Sovereignty; the factual circumstances which Lord Pannick says demonstrate that the claimant's case is well-founded on the merits; and justiciability.

[**25**] The starting point taken by Lord Pannick is his characterisation of the principle of Parliamentary Sovereignty. He submits this is not confined to the principle that the Crown in Parliament is sovereign, and that primary legislation enacted by the Crown with the consent of both Houses of Parliament is supreme. It is a much broader legal principle than that. It entails the right of Parliament to make any law it sees fit and is therefore 'engaged' by a decision of the Executive to advise the Queen to exercise a prerogative power in order to 'prevent or impede' Parliament from sitting and making law as it thinks appropriate.

[**26**] Lord Pannick accepts that in normal circumstances, the exercise of the prerogative does not undermine Parliamentary Sovereignty and there would have to be a manifest abuse of the prerogative power for that to occur. He accepts the Prime Minister has a broad discretion in deciding when to advise the Queen that Parliament should be prorogued. He submits, however, that on the extraordinary facts of this case, there has been such a manifest abuse:

(1) because of the exceptional length of the prorogation, during a critical period, when time is of the essence;

(2) because the Prime Minister provides no reasonable justification on the facts for requiring a prorogation of such exceptional length; and

(3) because the evidence demonstrates that the decision of the Prime Minister is infected by 'rank bad reasons' for the prorogation, namely that Parliament does nothing of value in September and the risk that

Parliament will impede the achievement of his policies, both of which demonstrate a fundamental failure on the Prime Minister's part to understand the principle of Parliamentary Sovereignty.

[**27**] On justiciability, Lord Pannick submits the case law demonstrates that the mere fact that the source of a power is the prerogative, or that the fact that the power is exercised in the form of an Order in Council made by the Queen, on the advice of the Privy Council, does not exclude judicial review. All depends on the context. Further, rather than categorising certain prerogative powers as justiciable, and others as not, the correct approach for the court is to proceed with caution (and sometimes extreme caution) when considering whether there is any legal basis for a complaint, and the 'higher the policy context' the less likely that is to be. Whilst therefore there may be areas where it is inconceivable that the courts would intervene, the preferable analysis is not to identify or categorise such cases as non-justiciable *per se*, but to identify such cases as ones where there are no appropriate or judicial or legal standards for the court to apply and upon which it could properly be invited to intervene. In other words, Lord Pannick develops a submission that there are no areas of prerogative power into which the courts may not inquire. Nothing is non-justiciable in that sense.

[**28**] He submits, however, that he does not need to go that far in the present case. It suffices to say that only in the most exceptional circumstances should the court conclude that a claim that is otherwise well-founded on the merits, fails for lack of justiciability, and, Lord Pannick submits, this is not such a case. The court might conclude (contrary to the claimant's submissions) that the legal principle of Parliamentary Sovereignty, as identified by the claimant, does not assist her case; or applying that principle, there is no abuse of power and no basis for intervention on conventional public law grounds on the facts. If, however, the claimant's case in these respects is established, as he submits it is, then it cannot be right for the court to say it has no jurisdiction to review the decision under challenge. This would be to deny the claimant a remedy, despite the identification of a relevant legal principle, and the breach of it.

THE INTERVENERS

[**29**] As Lord Pannick says, his arguments reflect and encompass what is said on behalf of the Interveners, who support the claimant's grounds for judicial review. We therefore refer more briefly to their submissions.

[**30**] Ms Deok Joo Rhee QC on behalf of the Shadow Attorney General submits that the principle of Parliamentary Sovereignty should protect the freedom of Parliament to scrutinise and introduce new legislation. This requires that the prerogative power to prorogue Parliament be constrained within constitutional limits so as not to frustrate the discharge of Parliament's constitutional role. On the facts of this case prorogation would frustrate the ability of Parliament to carry out its legitimate role to vote on a motion of no confidence under the Fixed-term Parliaments Act 2011. There is also a cogent case that the Prime Minister's decision is vitiated by an improper purpose and/or by improper or irrelevant considerations, that is, to strengthen the Government's negotiating position with the European Union by frustrating Parliamentary activity to 'block' a 'no-deal' exit from the European Union.

[**31**] The Counsel General of Wales is the Law Officer of the Welsh Government, appointed by Her Majesty pursuant to s 49 of the Government of Wales Act 2006. Mr Michael Fordham QC's submissions on the Counsel

General's behalf reflect the position of the Welsh Government. Mr Fordham emphasises it is a matter of serious concern that the supervisory and legislative autonomy of Parliament should be suspended at this critical time when it is vital that the National Assembly of Wales is able to continue its dialogue with Westminster on the United Kingdom's exit from the European Union and for Parliament to continue its scrutiny of executive action. This is a case concerning judicially competent supervision of justiciable executive action to secure executive accountability and legislative autonomy through and in the forum of Parliament under the separation of powers. He submits the Prime Minister's actions in advising Her Majesty enjoy no immunity from the court's supervisory jurisdiction. Where foundational constitutional principles are invoked in judicial review, the courts apply principles of constitutionality little different from those which exist in countries with a written constitution. This means the court is the ultimate arbiter of the constitution. The reason why primary legislation enacted thus far about withdrawal from the European Union has not included provisions to regulate the position as exit day draws closer is because Parliament intended and understood that its ability to act and supervise would remain intact.

[**32**] Sir John Major, through written submissions of his counsel, Lord Garnier QC, supported by a witness statement in which Sir John gives evidence based on his experience as a long-serving Parliamentarian and a former Prime Minister, addresses the question of legitimate and illegitimate purposes in the context of a review of the exercise of prerogative powers of this kind. It is said on his behalf that it is a basic part of the constitutional framework of the United Kingdom that Parliament has the right to make or unmake any law whatever, and it follows from the existence of that right, that Parliament must be permitted to convene and exercise its law-making powers if it wishes to do so. It is unlawful to exercise the power of prorogation if the purpose of doing so is to obstruct Parliament from enacting legislation with which the Prime Minister disagrees or to frustrate it from convening to debate and legislate on an issue at all. The justification for prorogation, that the Prime Minister wishes to advance an ambitious programme of domestic legislation, cannot be a true and complete explanation. There is no reason why Parliament must be prorogued in order for the Government to pursue a legislative programme. Even if that were wrong, it would only be necessary to terminate the existing session and commence a new one, and the new session could commence a few days after the old; certainly there is no practical reason why a five-week period might be needed to meet the stated purpose of prorogation. The inference is inescapable that there is a link between the unexplained length of prorogation and the obvious political interest that the Prime Minister has in there being no activity in Parliament during that time.

[**33**] The Lord Advocate is the Senior Scottish Law Officer. He is, by virtue of his office, a member of the Scottish Government and represents the Scottish Government in litigation before the courts. He has applied to intervene in these proceedings because of the implications of the decision under review for the interests of the Scottish Parliament and the Scottish Government in the context of the withdrawal of the United Kingdom from the European Union. The Lord Advocate submits that in the factual circumstances of this case, the abuse of power lies in the timing and duration of prorogation, its effect on a fundamental principle – namely accountable government – and the marked absence of any compelling justification offered for its timing and length. In the circumstances, it may be inferred that the purpose of the decision under review

is to insulate the Government from Parliamentary scrutiny for what is, in the context of the date of anticipated withdrawal, a significant period of time. In any event, the decision has a disproportionate impact on a fundamental constitutional principle, namely the principle of responsible government, where there is no compelling justification for that impact.

DISCUSSION

[**34**] It is now well established, and was common ground before us, that decisions and actions of the Executive are not immune from judicial review merely because they were carried out pursuant to an exercise of the Royal Prerogative. That was settled by the House of Lords in *Council of Civil Service Unions v Minister for the Civil Service* [1984] 3 All ER 935, [1985] AC 374 (*'CCSU'*), in which it was held that the controlling factor in determining whether the exercise of prerogative is subject to review by the courts is not its source but its subject matter.

[**35**] In that case Lord Roskill ([1984] 3 All ER 935 at 956, [1985] AC 374 at 418) gave the following description of a number of prerogative powers which he thought could not be subject to review by the courts:

> 'Many examples were given during the argument of prerogative powers which as at present advised I do not think could properly be made the subject of judicial review. Prerogative powers such as those relating to the making of treaties, the defence of the realm, the prerogative of mercy, the grant of honours, the dissolution of Parliament and the appointment of ministers as well as others are not, I think, susceptible to judicial review because their nature and subject matter is such as not to be amenable to the judicial process.'

[**36**] As Lord Pannick observes, matters have moved on since those comments were made by Lord Roskill. In some of the cases mentioned by Lord Roskill the exercise of the prerogative has been regulated by statute. For example, the provisions of the Constitutional Reform and Governance Act 2010 relating to the ratification of treaties, and the provisions of the Fixed-term Parliaments Act 2011 regulating the holding of general elections. In other cases, the courts have now accepted the justiciability of decisions of the Executive relating to the grant of pardons, foreign affairs and national security: see *R v Secretary of State for the Home Dept, ex p Bentley* [1993] 4 All ER 442, [1994] QB 349 (grant of pardons); *Lewis v A-G of Jamaica* (2000) 57 WIR 275, [2001] 2 AC 50 (prerogative of mercy); *R v Secretary of State for Foreign and Commonwealth Affairs, ex p Everett* [1989] 1 All ER 655, [1989] QB 811 (refusal of passports); *R (on the application of Abbasi) v Secretary of State for Foreign and Commonwealth Affairs* [2002] EWCA Civ 1598, [2003] 3 LRC 297, [2003] UKHRR 76 (foreign relations/diplomatic representations); approved by the Supreme Court in *R (on the application of Sandiford) v Secretary of State for Foreign and Commonwealth Affairs* [2014] UKSC 44, [2014] 4 All ER 843, [2014] 1 WLR 2697 (at [50]ff); *R (on the application of Youssef) v Secretary of State for Foreign and Commonwealth Affairs* [2016] UKSC 3, [2016] 3 All ER 261, [2016] AC 1457 (the conduct of foreign relations in the UN Security Council).

[**37**] We do not, however, accept the proposition of Lord Pannick, advanced in the course of oral submissions, that the jurisprudential stage has now been reached where there is no longer any exercise of common law prerogative powers which is immune from judicial review, that is to say non-justiciable, but

that there are merely areas in which the courts must proceed with caution. Lord Pannick derives that formulation from the following statement of Lord Carnwath in *Youssef* (at [24]) in connection with the decision of the Secretary of State to agree to the proposal of the Sanctions Committee of the United Nations Security Council to place the claimant on a list of persons to be treated as associated with an Islamic terrorist group:

> 'The source of [the Secretary of State's] powers under domestic law lay not in any statute but in the exercise of prerogative powers for the conduct of foreign relations. That did not make it immune from judicial review, but it is an area in which the courts proceed with caution …'

[**38**] It is clear, reading that statement in its context, that Lord Carnwath was not there laying down a general proposition applicable to all exercises of common law prerogative powers but was making it by reference to the particular facts and issue in that case. That is apparent from his citation with approval (at [25]) of the following passage in the judgment of Taylor LJ in *Everett* summarising the effect of *CCSU*:

> 'The majority of their Lordships indicated that whether judicial review of the exercise of prerogative power is open depends upon the subject matter and in particular upon whether it is justiciable. At the top of the scale of executive functions under the prerogative are matters of high policy, of which examples were given by their Lordships; making treaties, making war, dissolving Parliament, mobilising the Armed Forces. Clearly those matters, and no doubt a number of others, are not justiciable. But the grant or refusal of a passport is in a quite different category. It is a matter of administrative decision, affecting the rights of individuals and their freedom of travel. It raises issues which are just as justiciable as, for example, the issues arising in immigration cases.' ([1989] 1 All ER 655 at 660, [1989] QB 811 at 820.)

[**39**] Lord Carnwath said (at [26]) that the facts in *Youssef* fell somewhere between the two ends of the spectrum indicated by Taylor LJ. He expressly confirmed that the conduct of foreign policy through the United Nations 'is clearly not amenable to review in the domestic courts so far as it concerns relations between sovereign states'. He went on to say, however, that the distinguishing factor in *Youssef* was that 'the Security Council's action, through the 1267 committee, is directed at the rights of specific individuals, and in this case of an individual living in the United Kingdom'. It is indeed notable, as observed by Sir James Eadie, that all the cases relied upon by Lord Pannick as extending the power of the courts to review exercises of prerogative powers to areas which Lord Roskill in *CCSU* thought were non-justiciable concern the impact of the exercise of the power on particular individuals.

[**40**] There are many other statements, in cases binding on this court, that the first question when considering the court's power to review the exercise of prerogative powers is whether the subject matter of the power is non-justiciable. They include *Abassi* at [106](iii), *R (on the application of Bancoult) v Secretary of State for Foreign and Commonwealth Affairs* [2008] UKHL 61, [2008] 4 All ER 1055, [2009] AC 453 (at [105]), *Mohammed v Ministry of Defence, Rahmatullah v Ministry of Defence, Iraqi Civilians v Ministry of Defence* [2017] UKSC 1, [2017] 3 All ER 179, [2017] AC 649 (at [8], [33] and [56]) and the cases cited and quoted below.

[**41**] It is central to Lord Pannick's submissions that we should explore the facts first, for the purpose of deciding whether there has been a public law error, and then turn to justiciability; and then in the limited sense of deciding whether 'caution' should forestall intervention. We are unable to accept that submission. The question of justiciability comes first, both as a matter of logic and of law.

[**42**] The criteria adopted by the courts for identifying non-justiciable exercises of prerogative power are whether they involve matters of 'high policy' or are 'political'. In this way the courts, whose function it is, have marked out the separation of powers between the judicial and the executive branches of government, a fundamental feature of our unwritten constitution. In the present case the Prime Minister contends that the advice to Her Majesty to prorogue Parliament, which was given effect in the Order in Council of 28 August 2019, was political.

[**43**] The refusal of the courts to review political questions is well established. In *A v Secretary of State for the Home Dept, X v Secretary of State for the Home Dept* [2004] UKHL 56, [2005] 3 All ER 169, [2005] 2 AC 68, Lord Bingham said (at [29]) in relation to the application of art 15 of the European Convention on Human Rights ('ECHR') and whether there was a public emergency threatening the life of the nation:

> 'The more purely political (in a broad or narrow sense) a question is, the more appropriate it will be for political resolution and the less likely it is to be an appropriate matter for judicial decision. The smaller, therefore, will be the potential role of the court. It is the function of political and not judicial bodies to resolve political questions.'

[**44**] The issue whether there was a public emergency threatening the life of the nation was justiciable because it arose for consideration under the Human Rights Act 1998; but the principle Lord Bingham articulated reflects the approach of the courts in deciding the question of justiciability of prerogative powers where questions do not arise in a statutory context or which affect individual rights.

[**45**] In *Gibson v Lord Advocate* 1975 SC 136 at 144 Lord Keith said:

> 'The making of decisions upon what must essentially be a political matter is no part of the function of the Court, and it is highly undesirable that it should be. The function of the Court is to adjudicate upon the particular rights and obligations of individual persons, natural or corporate, in relation to other persons or, in certain instances, to the State.'

[**46**] *Robinson v Secretary of State for Northern Ireland* [2002] UKHL 32, [2002] NI 390 concerned the question whether the election by the Northern Ireland Assembly of a First Minister and Deputy First Minister was legally valid and raised issues linked to the dissolution of the Assembly under the provisions of the Northern Ireland Act 1998. Lord Bingham said (at [12]):

> 'It would no doubt be possible, in theory at least, to devise a constitution in which all political contingencies would be the subject of predetermined mechanistic rules to be applied as and when the particular contingency arose. But such an approach would not be consistent with ordinary constitutional practice in Britain. There are of course certain fixed rules, such as those governing the maximum duration of parliaments or the period for which the House of Lords may delay the passage of legislation.

> But matters of potentially great importance are left to the judgment either of political leaders (whether and when to seek a dissolution, for instance) or, even if to a diminished extent, of the Crown (whether to grant a dissolution). Where constitutional arrangements retain scope for the exercise of political judgment they permit a flexible response to differing and unpredictable events in a way which the application of strict rules would preclude.'

[**47**] Almost all important decisions made by the Executive have a political hue to them. In the present context of non-justiciability, the essential characteristic of a 'political' issue is the absence of judicial or legal standards by which to assess the legality of the Executive's decision or action. That is reflected in the last sentence of the passage from Lord Bingham's speech in *A v Secretary of State* just quoted. It was stated more directly in the joint judgment of Lord Neuberger P, Lord Sumption and Lord Hodge in *Shergill v Khaira* [2014] UKSC 33, [2014] 3 All ER 243, [2015] AC 359 (at [40]):

> 'The issue was non-justiciable because it was political. It was political for two reasons. One was that it trespassed on the proper province of the executive, as the organ of the state charged with the conduct of foreign relations. The lack of judicial or manageable standards was the other reason why it was political.'

[**48**] The point was also made elegantly in two decisions of the Divisional Court.

[**49**] *R (on the application of Wheeler) v Office of the Prime Minister* [2008] EWHC 1409 (Admin), [2008] All ER (D) 333 (Jun) (DC) concerned the claimant's case that the Government's promise to hold a referendum in relation to the European Union Constitutional Treaty gave rise to a legitimate expectation that a referendum would be held in relation to the Lisbon Treaty. The Divisional Court said at [34]:

> 'We have expressed ourselves cautiously on the materiality of those various differences between the Constitutional Treaty and the Lisbon Treaty. We have done so because there is a further and deeper difficulty facing the claimant in relation to this issue. The court is in a position to determine the extent of factual differences between the two treaties, but how is it to assess the materiality of the differences that it finds? Whether the differences are sufficiently significant to treat the Lisbon Treaty as falling outside the scope of an implied representation to hold a referendum in respect of a treaty "with equivalent effect" must depend primarily, as it seems to us, on a political rather than a legal judgment. There are, as Mr Sumption submitted, no judicial standards by which the court can answer the question. The wide spectrum of opinion, both within and outside the United Kingdom, to which the parties have drawn the court's attention with regard to the extent of similarity or difference between the two treaties serves to underline the point.'

[**50**] In *R (on the application of McClean) v First Secretary of State* [2017] EWHC 3174 (Admin), [2018] 1 Costs LO 37 (DC) the claimant sought permission to review a confidence and supply agreement entered into between the Conservative Party and the Democratic Unionist Party of Northern Ireland. Sales LJ said at [21]:

> 'The claimant says that the government had an illegitimate conflict of interest when it made the relevant decisions to enter into the confidence and supply agreement and to announce spending commitments in accordance with it. In my view this is not remotely arguable as a contention of law. In this political context there is no relevant standard of impartiality or disinterestedness which has been breached. The confidence and supply agreement is a political agreement made in a context where some form of political agreement was inevitable and indeed required if a stable government was to be formed. All political parties seek to promote particular interests and particular interested points of view. That is the nature of the political process, and the disciplines to which they are subject are the usual political ones of needing to be able to command majorities in the House of Commons on important votes and of seeking re-election at the appropriate time. The law does not super-impose additional standards which would make the political process unworkable.'

[**51**] The Prime Minister's decision that Parliament should be prorogued at the time and for the duration chosen and the advice given to Her Majesty to do so in the present case were political. They were inherently political in nature and there are no legal standards against which to judge their legitimacy. The evidence shows that a number of considerations were taken into account. We have summarised them extensively already. They included the need to prepare the Government's legislative programme for the Queen's Speech, that Parliament would still have sufficient time before 31 October 2019 to debate Brexit and to scrutinise the Government's conduct of the European Union withdrawal negotiations, that a number of days falling within the period of prorogation would ordinarily be recess for party conferences, and that the current parliamentary session had been longer than for the previous 40 years. The Prime Minister had also been briefed in Ms da Costa's submission that it was increasingly difficult to fill parliamentary time with appropriate work and, if new bills were introduced, either the existing session would have to continue for another four to six months at a minimum or they would be introduced knowing that they would fall at the end of the session. All of those matters involved intensely political considerations.

[**52**] The principal focus of the claimant's criticism of the prorogation in her witness statement is its duration and what she says is its purpose and impact in preventing or frustrating Parliament from holding the Government to account, including passing legislation that would require the Prime Minister to take steps to avoid the United Kingdom leaving the European Union without an agreement. The interveners express similar criticism and concern. They assert that a period of five weeks between sessions is far more than the few days required and usual. They suggest that the reasonable inference is that it has been motivated, or at least influenced by, the effect that it would have in preventing or frustrating Parliament from passing legislation to prevent the United Kingdom leaving the European Union without an agreement.

[**53**] Sir John Major observed in his witness statement that Members of Parliament vote to approve recess dates. Although they do not meet during recess, other Parliamentary business can continue, and it is possible for Parliament to be recalled. This underscores Lord Pannick's submission that prorogation and recess are very different creatures; and supports his contention that, in public law terms, having regard to the possibility of the recess was irrational.

[**54**] All of these arguments face the insuperable difficulty that it is impossible for the court to make a legal assessment of whether the duration of the prorogation was excessive by reference to any measure. There is no legal measure of the length of time between Parliamentary sessions. There is not even a constitutional convention which governs the matter, albeit that constitutional conventions are not justiciable: see *Miller No 1* at [136] and following. The skeleton argument for the Prime Minister notes that there have been a number of occasions in modern times during which Parliament was prorogued for a lengthy period. It was, for example, prorogued on 1 August 1930 until 28 October 1930; on 18 September 1914 until 27 October 1914 and then further prorogued until 11 November 1914; and on 17 August 1901 until 5 November 1901.

[**55**] Those facts also highlight that Parliament may be prorogued for various reasons. There is no statute, other law or any convention which requires Parliament to sit in constant session. The purpose of prorogation is not limited to preparing for the Queen's Speech. We have noted that under the Meeting of Parliament Act 1797 and the Prorogation Act 1867 there can be a proclamation shortening or extending the period of prorogation. Prorogation has been used by the Government to gain a legislative and so political advantage. One of the most notable examples of that was its use to facilitate the speedy passage of what became the Parliament Act 1949. Under s 2 of the Parliament Act 1911 a non-money Bill could only be enacted without the consent of the House of Lords if it was passed in three successive sessions by the House of Commons. In order to procure the speedy enactment of the 1949 Act the Government arranged for a session of minimal length in 1948. Parliament was prorogued on 13 September 1948 to the following day. Following the passage of the Parliament Bill by the House of Commons, it was then prorogued again on 25 October 1948. Accordingly, even if the prorogation under consideration in the present case was, as the claimant and the interveners contend, designed to advance the Government's political agenda regarding withdrawal from the European Union rather than preparations for the Queen's Speech, that is not territory in which a court can enter with judicial review.

[**56**] In his reply to Sir James' submissions, Lord Pannick said 'this case is concerned with the question of how long the prorogation should be'. If the purpose or primary purpose of prorogation is to undertake preparations for the Queen's Speech, it would still be impossible for the court to state whether the period of prorogation is excessive. That would require the court to examine and assess how much time it was legitimate for the Government to spend on its preparations in relation to each aspect of its proposed legislative programme, the detail of which has not been made public. There is no legal measure by which the court could form a proper judgment on that matter. That too is purely political.

[**57**] Moreover, it is impossible for the court to assess by any measurable standard how much time is required 'to hold the Government to account', including passing legislation that would require the Prime Minister to take steps to avoid the United Kingdom leaving the European Union without an agreement. That has been graphically highlighted by the speed with which the European Union (Withdrawal) (No 6) Bill was enacted. As we have already mentioned, it completed all its parliamentary stages between Wednesday 4 and Friday 6 September 2019 and received Royal Assent on Monday 9 September 2019. The ability of Parliament to move with speed when it chooses to do so was illustrated with clarity and at the same time undermined the underlying

premise of the cases advanced by both the claimant and the interveners, namely that the prorogation would deny Parliament the opportunity to do precisely what it has just done.

[**58**] Lord Pannick sought to circumvent those difficulties in the claimant's case, and to cut through what is a consistent approach found in many cases by advancing a novel and sophisticated argument resting on Parliamentary Sovereignty. The argument has a number of strands, as broadly described earlier:

(1) One of the fundamental principles of our constitution is Parliamentary Sovereignty, which can be traced back to the *Case of Proclamations* (1610) 12 Co Rep 74, (1610) 77 ER 1352; *Miller No 1* at [43] and the other cases mentioned in *Miller No 1* at [45], [48] and [51], *British Railways Board v Pickin* [1974] 1 All ER 609 at 627–628, [1974] AC 765 at 798–799, the Bill of Rights 1688 and the Scottish Claim of Right Act 1689.

(2) Parliamentary Sovereignty entails the right of Parliament to make any law it sees fit (*Miller No 1* at [43]), and both the Government and the Prime Minister are subordinate to Parliament (The Cabinet Manual at paras 1–2 and *Miller No 1* at [45]). Parliament has a constitutional responsibility to hold the government to account.

(3) There is an inextricable link between Parliamentary Sovereignty and the Rule of Law. That is because Parliament makes laws, courts exist in order to ensure (among other things) that the laws made by Parliament are applied and enforced, including ensuring that the Executive carries out its functions in accordance with the law. The people have a right to unimpeded access to the courts, without which the work done by Parliament may be rendered nugatory and the democratic election of Members of Parliament may become a meaningless charade (*R (on the application of UNISON) v Lord Chancellor* [2017] UKSC 51, [2017] 4 All ER 903, [2017] 3 WLR 409 (at [68])).

(4) Irrespective of any political accountability of the Prime Minister and of the Government to Parliament, the courts have a constitutional duty fundamental to the Rule of Law to enforce rules of constitutional law (see the judgment of the Divisional Court in *Miller No 1* at [2016] EWHC 2768 (Admin), [2017] 1 All ER 158, [2018] AC 61 (at [18]) and *R v Secretary of State for the Home Dept, ex p Fire Brigades Union* [1995] 2 All ER 244 at 272, [1995] 2 AC 513 at 572).

(5) Prorogation may, depending on the facts and circumstances of the case, amount to a breach of Parliamentary Sovereignty insofar as it prevents Parliament from deciding what the law of the land should be and is not reasonably necessary to fulfil the proper objective of prorogation (adopting the test in the *UNISON* case at [80]).

(6) This provides a proper legal measure which the courts can apply to determine on the facts of the present case the legality of the advice on prorogation. It is different from dissolution to enable a general election to take place, which was a personal prerogative of the Crown at common law prior to the Fixed-term Parliaments Act 2011.

(7) Applying that measure, the advice was unlawful and an abuse of power because Parliament will be silenced for far longer than is necessary to prepare for the Queen's Speech. That is the purpose, or at least the stated purpose, for the prorogation. No explanation has been given by the Prime Minister in these proceedings which justifies the length of the

prorogation. It is a reasonable inference from the evidence, including the fact that different justifications have been given publicly by the Prime Minister for the prorogation and its length, that the advice to Her Majesty was motivated or at least influenced by improper considerations. They showed a misunderstanding of Parliamentary Sovereignty and Parliament's role, namely its function of considering, debating and enacting such laws as it sees fit. Such improper considerations included the Prime Minister's dislike of the views of Members of Parliament, his concern that Parliament might undermine the Government's strategy in negotiating an exit deal and his impression of Parliament as a potential threat to his policy of exiting the European Union whether or not a deal can be done – 'do or die, come what may'.

(8) It is not, therefore, necessary in the present case to say how long the prorogation should be to be lawful and it is irrelevant that there may be some limited opportunity for Parliament to conduct its affairs prior to 31 October 2019.

(9) The fact that the decision to prorogue was incorporated in an Order in Council does not make it non-justiciable (*Bancoult* at [35], [71], [105] and [141]). The order could be quashed or revoked and Parliament recalled, but in any event the Prime Minister accepts that, if the advice to Her Majesty was unlawful, he will take the necessary steps to comply with the terms of any declaration made by the court making a quashing order unnecessary.

[**59**] We shall return to Sir James' submission that Lord Pannick's expansive description of Parliamentary Sovereignty is incorrect in going well beyond the principle that the Queen in Parliament is sovereign in the sense that it may enact whatever it wishes by way of primary legislation, subject to its own self-imposed restraints such as the European Communities Act 1972 and the Human Rights Act 1998. We consider that the analysis advanced on behalf of the claimant (and interveners) founders for other reasons.

[**60**] In the first place, alongside the principle of Parliamentary Sovereignty, the separation of powers, reflecting the different constitutional areas of responsibility of the courts, the Executive and Parliament, is also a fundamental principle of our unwritten constitution. As we have said earlier, the line of separation is set by the courts in the present context by reference to whether the issue is one of 'high policy' or 'political' or both. In the circumstances and on the facts of the present case the decision was political for the reasons we have given. Secondly, the purpose of the power of prorogation is not confined to preparations for the Queen's Speech. It may be used for a number of different reasons, as, on the evidence, it has been in the present case. Such reasons may, depending upon the precise facts and circumstances, extend to obtaining a political advantage. Thirdly, again as we have already said, even if the prorogation in the present case must be justified as being to enable preparations for the Queen's Speech, the decision how much time to spend and what decisions to take for such preparations is not something the court can judge by any measurable standard.

[**61**] The concept of Parliamentary Sovereignty recognises that the Queen in Parliament is able to make law by primary legislation without legal restraint, save such restraint as it has imposed on itself for the time being. Parliament cannot bind its successors, but the prime example of self-imposed restraint is found in the European Communities Act 1972 which cedes primacy over statute to European Union law. This concept of Parliamentary Sovereignty was

discussed in *R* (*on the application of Jackson*) *v A-G* [2005] UKHL 56, [2005] 4 All ER 1253, [2006] 1 AC 262 by Lord Bingham at [9] and Lady Hale at [159]. The interpretation of legislation is for the courts which seek to give effect to the intention of Parliament divined from the statutory language, examined in accordance with established principles of statutory interpretation.

[**62**] Lord Pannick relies upon the passage at [68] in Lord Reed's judgment in the *UNISON* case to support the novel and wider legally enforceable concept of Parliamentary Sovereignty. Lord Reed summarised the functions of Parliament and the courts, noted that amongst the functions of the courts is to ensure that the Executive carries out its functions in accordance with law and that in principle people must have unimpeded access to the courts. The *UNISON* case was concerned with the introduction by statutory instrument of substantial fees for those commencing proceedings in the Employment Tribunal, the effect of which was to deny access to many potential litigants. That went beyond what was reasonably necessary to fulfil the objective of the legislation which empowered fees to be set. We are unable to extract from the passages relied upon (or the extensive discussion of the Rule of Law and access to justice found in Lord Reed's judgment) the principle contended for by the claimant.

[**63**] Lord Pannick's formulation of a wider legally enforceable concept of Parliamentary Sovereignty, distilled to its essence as an ability to conduct its business unimpeded, runs into similar difficulties in identifying measures against which allegedly offending action may be judged. Moreover, there is another fundamental objection to expanding the legal concept of Parliamentary Sovereignty in the manner contended for. The expanded concept has been fashioned to invite the judicial arm of the state to exercise hitherto unidentified power over the Executive branch of the state in its dealings with Parliament.

[**64**] The constitutional arrangements of the United Kingdom have evolved to achieve a balance between the three branches of the state; and the relationship between the Executive and Parliament is governed in part by statute and in part by convention. Standing Orders of both Houses elaborate the procedural relationship between the Executive and Parliament. This is territory into which the courts should be slow indeed to intrude by recognising an expanded concept of Parliamentary Sovereignty.

[**65**] The spectre was raised in argument of a Government seeking to rule without Parliament or, at the least, dispense with its sitting for very lengthy periods. A series of technical arguments was raised by Sir James to point to the practical impossibility of such a course, including the need for the vote of funds to govern and the need annually to extend the Armed Forces Act 2006.

[**66**] We do not believe that it is helpful to consider the arguments by reference to extreme hypothetical examples, not least because it is impossible to predict how the flexible constitutional arrangements of the United Kingdom, and Parliament itself, would react in such circumstances.

[**67**] For completeness, we note that there is nothing in *Miller No 1*, which concerned very different issues and ultimately rested on statutory interpretation, that is inconsistent with what we have said. The same is true of the *Fire Brigades Union* case. We also agree with Sir James that *Bobb v Manning* [2006] UKPC 22, [2006] 4 LRC 735, which is relied upon by the Counsel General for Wales, and concerned, among other things, whether the decision of the respondent Prime Minister of the Republic of Trinidad and Tobago not to call for a dissolution was unlawful and contrary to the constitution, is

against the claimant rather than in her favour. The Judicial Committee of the Privy Council rejected that challenge on the ground that the respondent 'was entitled to exercise his informed and political judgment'.

CONCLUSION

[**68**] For all these reasons we concluded that the claim must fail. In our view, the decision of the Prime Minister to advise Her Majesty the Queen to prorogue Parliament is not justiciable in Her Majesty's courts.

Permission to apply for judicial review granted. Claim dismissed.

Reclaiming motion

The petitioners, Joanna Cherry QC MP and 78 others, appealed by reclaiming motion against the decision of the Lord Ordinary (Lord Doherty) in the Outer House, Court of Session of 4 September 2019 ([2019] CSOH 70 (set out above)) refusing their petition for judicial review against the decision of the United Kingdom Prime Minster, the Rt Hon Boris Johnson MP, to advise Her Majesty the Queen to prorogue Parliament from a date between 9 and 12 September until 14 October 2019. HM Advocate General for Scotland was the respondent to the reclaiming motion. The Lord Advocate intervened. The BBC, the Times and the Sun ('the applicants') made an application for the production of certain documents. The facts are set out in the opinion of the court.

Aidan O'Neill QC and *David Welsh* (instructed by *Balfour and Manson LLP*) for the petitioners.

David Johnston QC and *Andrew Webster QC* (instructed by the *Office of the Advocate General for Scotland*) for the Advocate General.

James Mure QC and *Christine O'Neill* (instructed by and of the *Scottish Government Legal Directorate*) for the intervener.

Kenny McBrearty QC (instructed by *Burness Paull LLP*) for the applicants.

11 September 2019. The court announced that the appeal would be allowed with a summary of their reasons.

13 September 2019. The following opinions were delivered.

LORD PRESIDENT (**CARLOWAY**)**.**

INTRODUCTION

[**1**] This reclaiming motion (appeal) raises an issue of when the prorogation of the United Kingdom Parliament by an Order in Council, at the instance of Her Majesty the Queen on the advice of the UK Government, can be the subject of a judicial review. There are two central questions. The first, as a matter of law, is whether the prorogation can be judicially reviewed in circumstances in which it is alleged that it has been requested for what is said to be an improper motive *viz* the stymying of Parliamentary debate on the issue of the UK leaving the European Union. The second, as a matter of fact, is whether that improper motive has been demonstrated. The Government contends that the purpose is legitimate and is simply to prepare for a new

legislative programme, to be contained in HM the Queen's speech on 14 October, and to cover the period of the party conferences, during which time Parliament tends to be in recess.

[**2**] There are subsidiary questions. The first concerns access by the press to documents in the court process, including certain UK Government papers which have been produced by the respondent in obedience of the duty of candour in such matters. The second is whether the court should call for unredacted copies of these documents.

BACKGROUND

[**3**] Prorogation of Parliament is the means by which the Government, by the exercise of a prerogative power, can bring a Parliamentary session to an end. While Parliament is prorogued, members cannot 'debate government policy and legislation, submit parliamentary questions for response by government departments, scrutinise government activity through parliamentary committees or introduce legislation of their own' (House of Commons Library Briefing Paper No 8589: *Prorogation of Parliament*, 11 June 2019 p 3). The typical duration of a prorogation in recent times has been 'very short'. Since the 1980s, it has rarely lasted longer than two weeks and, between sessions, it has been less than a week (*ibid* pp 3–4).

[**4**] On 29 March 2017, following upon the authorisation which was provided by s 1 of the European Union (Notification of Withdrawal) Act 2017, the former Prime Minister (the Rt Hon Theresa May MP) wrote to the President of the European Council notifying the EU that, in terms of art 50 of the Treaty on European Union, the UK intended to withdraw from the EU. In terms of the article, this would take effect on 29 March 2019. The European Union (Withdrawal) Act 2018 provides (s 1) that, on 'exit day', the European Communities Act 1972 ceases to have effect, but (s 2) EU law is to be preserved within the domestic regime.

[**5**] On 21 March 2019, following two rejections by the House of Commons of a withdrawal agreement in terms of art 50, the Government and the European Council agreed to extend the UK's membership until 22 May, if the withdrawal agreement was approved by Parliament. Otherwise, the UK would cease to be a member on 12 April 2019. On 29 March, the withdrawal agreement was again rejected. On 10 April, a further extension to 31 October was agreed. On 24 May, the then PM resigned. On 24 July, the Rt Hon Boris Johnson MP was appointed in her place.

[**6**] On the same day, the Northern Ireland (Executive Formation etc) Act 2019 received Royal Assent. This provides (s 3) for reports on progress towards forming an Executive to be published before 4 September 2019 and thereafter laid before Parliament. Specific provision is made for the situation in which Parliament would stand prorogued or adjourned at the relevant time. In that event, a proclamation under the Meeting of Parliament Act 1797 would require Parliament to meet for several days after the date on which the report was laid.

[**7**] The prospect of prorogation in the context of the Parliamentary procedures involving the UK's withdrawal from the EU (commonly called 'Brexit') was first ventilated in the House of Commons as early as March 2019 as a method of circumventing the rule that the withdrawal agreement could not be the subject of a third vote during the same Parliamentary session. Prorogation, with the intention of preventing Parliament from blocking a

'no deal Brexit', was suggested in a paper by Policy Exchange on 25 March 2019. The idea is that, because the default position under art 50 is that the UK will leave the EU with 'no deal', if none is reached by 31 October, Parliament will be unable to prevent a no deal Brexit if the time elapses with no further parliamentary action. This was covered in an article in the Daily Telegraph and was thereafter the subject of academic discussion. During the Conservative Party leadership contest, following upon the former PM's resignation, there was occasional reference to this possibility.

[**8**] The petition was lodged on 30 July 2019 although the first orders were only made on 31 July 2019. The first plea-in-law is for declarator that it is *ultra vires* and unconstitutional for the Government to advise the Queen to prorogue Parliament with the intention of preventing sufficient time for proper consideration of Brexit. The second plea-in-law is for interdict on the basis that the petitioners are reasonably apprehensive that the Government intend to proceed in that manner. The respondent's fifth plea-in-law is that there is no basis for such an apprehension.

The Respondent's Documents

[**9**] On the eve of the hearing before the Lord Ordinary, the respondent produced a number of documents relative to what happened within the Government. The first is a Memorandum dated 15 August 2019 from Nikki da Costa, the Director of Legislative Affairs within the PM's Office, to the PM. This reads as follows:

> 'ENDING THE SESSION
>
> SUMMARY
>
> 1. The current session is the longest since records began, and all bills announced as part of the last Queen's Speech have now received Royal Assent, or are paused awaiting carry over into the next session: this makes it increasingly difficult to fill parliamentary time with anything other than general debates. As a new Prime Minister, there is an expectation that you will set out a refreshed domestic programme and it would be natural to do so when the House returns in the autumn.
>
> 2. As the first week's business in September has already been announced, I recommend dedicating the second to wash-up on bills such as R&R [Restoration and Renewals]. We would then prorogue sometime between the end of Monday 9th September and Thursday 12th September, allowing for the long-standing conference recess, and return on Monday 14th October with the State Opening of Parliament.
>
> 3. [REDACTED]
>
> RECOMMENDATION
>
> 2. [*sic*]. Are you content for your PPS to approach the Palace with a request for prorogation to begin with the period Monday 9th September and Thursday 12th September, and for a Queen's Speech on Monday 14th October?'

[**10**] The memorandum outlines certain practical considerations. Choosing when to end the Parliamentary session was a balance between having enough time for the completion of Bills which were close to Royal Assent and not wasting time that could be used for new measures in the fresh session. The recommendation was to close the session in early September. The memorandum continues:

> 'POLITICAL CONSIDERATIONS

14. Finally, politically it is essential that parliament is sitting before and after EU Council – MPs and Peers must be in a position to consider what is negotiated, and hopefully pass the Withdrawal Agreement Bill. If there is no deal, they need to have an opportunity to hear what you have to say, and respond accordingly.'

[**11**] The memorandum noted that, in modern times, prorogation was usually less than 10 days, although there were longer periods for up to 21 days since 1980. Although the planned prorogation would be 34 days, the expected conference recess of three weeks would mean that only one to three days would be lost in the week commencing 9 September and four in the week commencing 7 October. There was no record of the House of Commons sitting in late September or early October since the start of the 20th Century.

[**12**] The recommendation to prorogue was endorsed (presumably by the PM) with the word 'yes' and a tick. The second document is a redacted (although later leaked to the press in unredacted form) hand-written response from the PM, dated 16 August. It reads:

'1. The whole September session is a rigmarole introduced [REDACTED] to show the public that MPs were earning their crust

2. So I don't see anything especially shocking about this [prorogation]

3. As Nikki notes, it is OVER THE CONFERENCE SEASON so that the sitting days lost are actually very few.'

[**13**] The third document is a further memorandum, dated 23 August 2019, from Ms da Costa to the PM. This is headed 'ANNOUNCING THE QUEEN'S SPEECH'. It briefs the PM on a proposed 'handling plan'. It refers to the PM's agreement to approach HM the Queen with a request to prorogue Parliament within the period Monday, 9 to Thursday, 12 September and for a Queen's Speech on Monday, 14 October. A telephone call between the PM and the Queen was fixed for the evening of 27 August. The Order in Council was to be signed on 28 August. On that day, the Chief Whip and the Leaders of the Houses of Commons and Lords were to go to Balmoral to form the necessary meeting of the Privy Council. After the signing, the members of the Cabinet would be informed, followed by the Parliamentary Party and the press. The planned announcement to the Cabinet was to focus on the extraordinary length of the current parliamentary session. A statement would be made that this could not continue and that the PM would bring forward a new legislative agenda which would take matters 'through our exit from the EU and the months that follow'. At the heart of the agenda would be the Government's 'number one legislative priority' (Brexit). If a deal was forthcoming, a Withdrawal Agreement Bill could be introduced to 'move at pace to secure its passage before 31 October'. The PM would confirm that he was committed to facilitating Parliament's ongoing scrutiny of Brexit. He would deliver a statement and take questions on the 'first sitting back' (presumably 14 October). A draft letter to Conservative MPs was provided. This re-iterated the message to Cabinet Members. It stated that the Northern Ireland (Executive Formation etc) Act 2019 ('NIEFA 2019') would be debated on Monday, 9 September and that thereafter the Government would 'begin preparation to end the Parliamentary session ahead of a Queen's Speech'.

[**14**] On Wednesday, 28 August 2019, the three Privy Counsellors attended at Balmoral. HM the Queen promulgated an Order in Council in the following terms:

'It is this day ordered by Her Majesty in Council that the Parliament be prorogued on a day no earlier than Monday the 9th day of September and no later than Thursday the 12th day of September 2019 to Monday the 14th day of October 2019, to be then holden for the despatch of divers urgent and important affairs, and that the Right Honourable the Lord High Chancellor of Great Britain do cause a Commission to be prepared and issued in the usual manner for proroguing the Parliament accordingly.'

[**15**] The fourth document is a redacted Cabinet minute dated 28 August 2019. This records that the PM provided the Cabinet with the proposed dates for prorogation and the Queen's Speech. He said:

'This timetable gave Parliament ample time to debate Brexit in the period before the October European Council on 17–18 October, and again in the run up to the UK's departure date on 31 October. It was important to emphasise that this decision to prorogue Parliament for a Queen's Speech was not driven by Brexit considerations: it was about pursuing an exciting and dynamic legislative programme to take forward the Government's agenda.'

The minute records that the following points were made in discussion:

'b) any messaging should emphasise that the plan for a Queen's Speech was not intended to reduce parliamentary scrutiny or minimise Parliament's opportunity to make clear its views on Brexit. Parliament had already had a significant opportunity to debate Brexit and would still have remaining parliamentary time to do so before 31 October. Likewise, it was crucial that parliamentary colleagues understood that the Government was still seeking a deal and that this plan would allow time for the Withdrawal Agreement to be approved by Parliament if a deal was agreed at the European Council on 17/18 October. Therefore, any suggestion that Government was using this as a tactic to frustrate Parliament should be rebutted;

c) the number of sitting days had not been substantially reduced, because for the majority of the time that Parliament would be prorogued it would ordinarily be Recess for party conferences. Until relatively recently Parliament did not sit in September at all. Parliamentary colleagues should be made aware of this …;

d) the terrain between now and October would be rocky. Although there had been longer periods of prorogation in the past, they were exceptional. Parliament would not normally be prorogued for a longer period than one to two weeks. It should be explained why in this case the period was significantly longer. The Government would be attacked for this decision, but it would be manageable; …'

[**16**] The PM responded:

'… it was vital to persuade and enthuse parliamentary colleagues to get behind the Government's plan. The EU were likely to hold out for Parliament to block Brexit while they thought that was possible. The UK would only be able to negotiate a better deal by showing the EU: a united front, including in Parliament. Two messages had landed with the EU: that the UK wanted a deal and was prepared to work hard to get one; but also that the Government was prepared to leave without one if necessary.

> There had been absolute clarity with the EU about the aspects of the current Withdrawal Agreement that were unacceptable. The backstop was fundamentally undemocratic. It bound the UK into EU laws over which it had no say and tilted the balance of the Good Friday Agreement away from the UK by giving Dublin a greater say over matters in Northern Ireland.'

Concluding, the PM said:

> 'Progress with the EU should not be exaggerated, but it was substantial. Whilst there was a good chance that a deal could be secured, there was also a high chance that it could not. Success would require a united and determined approach. Everyone joining the Government had done so on the understanding that the UK might have to leave the EU without a deal. There were no plans for an early General Election. This would not be right for the British people: they had faced an awful lot of electoral events in recent years. They wanted the Government to deliver Brexit and a strong domestic agenda.'

[**17**] On the same day, the PM wrote to Conservative MPs along similar lines.

LORD ORDINARY'S DECISION

[**18**] The Lord Ordinary refused the prayer of the petition for the principal reason that the provision of advice to the Queen on the prorogation of Parliament was not justiciable. The exercise of some prerogative powers in some circumstances was justiciable, but in others it was not. The power to advise the Queen in relation to the decision to prorogue Parliament was a political one. Its exercise could not be measured against legal standards. The accountability for the advice was to Parliament and, ultimately, the electorate, and not to the courts. The advice did not contravene the rule of law. It followed from the separation of powers that the courts would not interfere with Parliament's decisions on when to sit. It was not for the courts to devise restraints on prorogation beyond the limits which Parliament had set. Parliament could sit before and after the prorogation. It had recently, in the NIEFA 2019, provided for periods in which to do so.

[**19**] If the matter was justiciable, the Lord Ordinary was not persuaded that the reasons for the advice as disclosed in the documents provided by the respondent were unlawful. There had been no breach of the provision in the Claim of Right 1689 that 'Parliaments … be frequently called and allowed to sit'. The Claim of Right 1689 gave rise to no justiciable issue, but in any event there had been no breach. The Lord Ordinary was not persuaded by the respondent's argument that the issue raised by the petition was academic.

[**20**] The petition was concerned with prorogation, not with the legal requirements for Brexit. The fact that Parliament may not be sitting for five weeks did not of itself have any direct effect on individuals' EU law rights. The Lord Ordinary agreed with the respondent's analysis of *R (on the application of Miller) v Secretary of State for Exiting the European Union, Re Agnew's application for judicial review (reference by the A-G for Northern Ireland), Re McCord's application for judicial review (reference by the Court of Appeal (Northern Ireland))* [2017] UKSC 5, [2017] 1 All ER 593, [2018] AC 61 and the subsequent legislation. It would not be unlawful for the UK to leave the EU with no deal unless there was further

legislation. Withdrawal from the EU had been approved by Parliament unconditionally (European Union (Notification of Withdrawal) Act 2017, s 1(1)).

PRELIMINARY MATTERS

[21] *In limine*, the petitioners moved for an order for the production of unredacted versions of the four documents produced by the respondent (*supra*). The redactions purported to have been made on the basis of irrelevance, legal privilege and the Law Officers' advice convention. The petitioners did not know whether these redactions had been properly made. No claim of public interest immunity had been advanced. It was a breach of the right to a fair trial for the respondent to produce redacted documents. Once the documents had been produced, any privilege had been waived (*Scottish Lion Insurance Co Ltd v Goodrich Corp* [2011] CSIH 18, 2011 SC 534, at para [48]). The court had an inherent power to override an objection by the Government to the production of documents based on public interest grounds (*Glasgow Corp v Central Land Board* 1956 SC (HL) 1 at 9 and 11; *Somerville v Scottish Ministers* (*HM Advocate General for Scotland intervening*) [2007] UKHL 44, 2008 SC (HL) 45, [2007] 1 WLR 2734 (at para [155])).

[22] The BBC, the Times and the Sun made an application for access to the four documents produced by the respondent, the pleadings and the written arguments for the Lord Advocate and the respondent. This was on the basis of the principle of open justice (*Dring* (*on behalf of the Asbestos Victims Support Group*) *v Cape Intermediate Holdings Ltd* (*Media Lawyers Association intervening*) [2019] UKSC 38, [2019] 3 WLR 429 and *Guardian News and Media Ltd v City of Westminster Magistrates' Court* (*United States Government, interested party*) [2012] EWCA Civ 420, [2012] 3 All ER 551, [2013] QB 618). There required to be public scrutiny of the way in which the courts decided cases. The public had to be able to understand why decisions had been taken. It was difficult, if not impossible, to know what was going on without the written material. The court required to carry out a fact specific balancing exercise involving the principle of open justice on the one hand and the risk of harm to the judicial process or the legitimate interests of others on the other hand. The principle of open justice applied equally in Scotland (*A v British Broadcasting Corp* [2014] UKSC 25, [2014] 2 All ER 1037, [2015] AC 588; *British Broadcasting Corp, petitioners* [2012] HCJ 10, 2012 SCCR 354, 2012 SLT 476).

[23] The respondent opposed the application for production of unredacted versions of the documents. These had been produced in response to the duty of candour which rested upon the Government. They were available *quantum valeat*; the respondent's position remaining the lack of justiciability of the issue. The reclaiming motion ought to be determined on the basis of the documents which had been produced to the Lord Ordinary. Although the petitioners had opposed the lodging of the documents, they had not asked the Lord Ordinary to order production of unredacted versions. The court could not determine whether unredacted versions should be produced without looking at these versions or appointing a commissioner to do so. Counsel had seen the unredacted versions and could state, on his professional responsibility, that the redactions had been properly made.

[24] RCS 4.11 provides that any person having an interest may inspect a writ lodged with the court. A writ includes a petition and answers (RCS 1.3). There is no difficulty in the press having access to the pleadings. At the start of the proceedings, therefore, the court provided these, including the Lord Advocate's

written intervention, to the press. It is common practice for the press to have access to the pleadings at the stage of any final hearing. That is not to say that publication of their contents will thereby be privileged (*Macleod v Justices of the Peace of Lewis* (1892) 20 R 218).

[**25**] In relation to the written notes of argument in a reclaiming motion, these are lodged in accordance with the timetable in RCS 38.13(2)(c). In terms of the Practice Note (No 3 of 2011) para 86, they are intended to be a 'concise summary of the submissions to be developed'. They, or parts of them, are routinely adopted by the party at the start of the oral argument, but not always covered in that argument. They still form part of the submission to the court. They will often assist the press in understanding the core elements of a party's cause. In the absence of special circumstances, they too will be open for inspection. Parties may, in accordance with past practice, assist in facilitating access to those documents by the press. The court will continue to do so.

[**26**] In a reclaiming motion, it is normal for the court to proceed on the basis of the same documents as were provided to the Lord Ordinary (*Scotch Whisky Association v Lord Advocate* [2016] CSIH 77, 2017 SC 465, 2017 SCLR 410, Lord President (Carloway), delivering the opinion of the court, at para [109]), although it can look at new material if it is satisfied that it is in the interests of justice to do so. Even in a case of urgency, as the present proceedings undoubtedly are, the court would not expect to be considering an application of this nature, which could have been made to the Lord Ordinary, at the stage of the Summar Roll hearing. It would normally require a formal application for a commission and diligence and then scrutiny of the documents by the Lord Ordinary to determine whether the redactions are justified on the bases proffered (*Somerville v Scottish Ministers* (*supra*), Lord Rodger at para [155]). In that context, the court can, of course, override any objections from the Government based upon public interest considerations. It could reject the assurance by counsel that the material had been properly excluded for the reasons stated. The test is whether 'production of the full version of the document to the petitioners is necessary for disposing fairly of the proceedings' (*ibid* para [156]).

[**27**] The court is not satisfied that this test has been met. The redactions appear to be justified on the bases stated. The court sees no reason not to accept the assurance given by counsel. It is certainly borne out by the leaking, following the Summar Roll hearing, of the redacted part of the PM's handwritten note. It is satisfied that the relevant parts of the material have been properly disclosed in terms of the obligation of candour. It will therefore refuse the application for production of unredacted versions given both the timing of the application and the absence of any need for this to be done in order to decide the issues fairly. The redacted versions will be available to the press.

SUBMISSIONS

Petitioners

[**28**] The petitioners sought a declarator in terms of the petition, together with an order reducing the Order in Council and an interdict prohibiting the Government from proroguing Parliament. Scots and English law were not necessarily the same as regards the use of prerogative powers (*Admiralty Comrs v Blair's Trustees* 1916 SC 247 at 266). If there was any difference, the law that was more limiting of executive power should be preferred. Parliamentary

sovereignty was fundamental (*R* (*on the application of Jackson*) *v A-G* [2005] UKHL 56, [2005] 4 All ER 1253, [2006] 1 AC 262 (at paras [9] and [126])). The Government had no inherent power to legislate. The prerogative encompassed the residual powers which Parliament had left vested in the Government. It remained only where the situation was not covered by statute (*Burmah Oil Co* (*Burma Trading*) *Ltd v Lord Advocate, Burmah Oil Co* (*Burma Concessions*) *Ltd v Lord Advocate, Burmah Oil Co* (*Overseas*) *Ltd v Lord Advocate, Burmah Oil Co* (*Pipe Lines*) *Ltd v Lord Advocate* [1964] 2 All ER 348 at 354, [1965] AC 75 at 101). It was displaced where there was a corresponding power conferred by statute (*A-G v De Keyser's Royal Hotel Ltd* [1920] AC 508 at 526, [1920] All ER Rep 80 at 85–86). It could not be used to defeat rights which had been created by Parliament (*R* (*Miller*) *v Secretary of State for Exiting the European Union* (*supra*), paras [44], [45] and [63]).

[29] The Government was politically accountable to Parliament in the exercise of its powers. The Government would be acting unlawfully if it curtailed political accountability (*Moohan v Lord Advocate* [2014] UKSC 67, [2015] 2 All ER 361, [2015] AC 901 (at para [35])). The proper constitutional relationship between the executive and the courts was one of respect. The Government's political accountability to Parliament and its legal accountability to the courts were not mutually exclusive. They could overlap (*R* (*on the application of Barclay*) *v Secretary of State for Justice and Lord Chancellor* [2014] UKSC 54, [2014] 1 All ER 429, [2015] AC 276 (at para [57])). The Government had to obey the law as declared by the courts (*Edwards v Cruickshank* (1840) 3 D 282 at 306–307, endorsed in *R* (*on the application of Bancoult*) *v Secretary of State for Foreign and Commonwealth Affairs* [2008] UKHL 61, [2008] 4 All ER 1055, [2009] AC 453 (at para [106])). This protected the individual from arbitrary government (*Wightman v Secretary of State for Exiting the European Union* [2018] CSIH 62, 2019 SC 111, [2019] 1 CMLR 795 (at para [67])). The rule of law, as enforced by the courts, was the ultimate control upon which the constitution was based (*R* (*Jackson*) *v A-G* (*supra*) at para [107]). The court had to provide an effective remedy against constitutional violations (*Teh Cheng Poh v Public Prosecutor, Malaysia* [1980] AC 458 at 473, [1979] 2 WLR 623 at 633–634; Bankton *Institutes* IV, xxiii, 18). The courts could enforce the law by interdict and contempt proceedings (*Beggs v Scottish Ministers* [2007] UKHL 3, [2007] 1 WLR 455, 2007 SCLR 287 (at para [9])). The Lord Ordinary had abrogated his constitutional function in determining that, in relation to prorogation, the Government was above the law. The court was the only umpire available to ensure a balance of power. Parliament had no power to stop itself being suspended. If the Lord Ordinary was right and the court had no power, the only option to prevent tyranny would be to 'take to the street'.

[30] Scottish constitutional law involved the subordination of Government to the law. This could be traced back to Buchanan's *De jure regni apud Scotos* (1567). The power of the sovereign was, by immemorial tradition, restricted by the laws and customs of the people. This was different from England. The two approaches were reflected in the reformations in each country and the approach to the appointment of the clergy. The kings of Scotland had no prerogative distinct from supremacy above the law (Rutherford *Rex Lex* (1660) question XLIII).

[31] The Claim of Right 1689 (affirmed by the Act of the Scottish Parliament of 1703: APS xi 104, c 3) set limitations on the sovereign's power. That power could not be used to contravene the law. Parliaments had to be called frequently and allowed to sit in order to redress grievances and to amend,

strengthen and preserve the law. Although the court could not enter into forbidden areas such as foreign policy, decisions or inaction could be reviewed if they were irrational (cf *R* (*on the application of Sandiford*) *v Secretary of State for Foreign and Commonwealth Affairs* [2014] UKSC 44, [2014] 4 All ER 843, [2014] 1 WLR 2697 (at paras [50], [52] and [65])). Certain prerogative powers, including (at that time) the dissolution of Parliament, were not justiciable, but others may be (*Council of Civil Service Unions v Minister for the Civil Service* [1984] 3 All ER 935 at 955–956, [1985] AC 374 at 417–418; *R v Secretary of State for the Home Dept, ex p Bentley* [1993] 4 All ER 442, [1994] QB 349 and *R v Secretary of State for Foreign and Commonwealth Affairs, ex p Everett* [1989] 1 All ER 655, [1989] QB 811). The power to prorogue Parliament was accordingly justiciable and reviewable on grounds of irrationality and other judicial review principles (*R* (*Sandiford*) *v Foreign Secretary* (*supra*)). It was at least not unfettered. The Government could not use the prerogative to affect individuals (*A-G v De Keyser's Royal Hotel* (*supra*) [1920] AC 508 at 567–568, [1920] All ER Rep 80 at 105–106). The power was lawfully exercised only if it was consistent with constitutional principle. It had to be exercised for a proper purpose. Prorogation was subject to the ordinary principles of legality, rationality and procedural impropriety as with other Governmental action (*R* (*Bancoult*) *v Secretary of State for Foreign and Commonwealth Affairs* (*supra*) at paras [35], [105], [122] and [141]).

[**32**] The Government was obliged to 'co-operate and to make candid disclosure, by way of affidavit, of the relevant facts and (so far as they are not apparent from contemporaneous documents which have been disclosed) the reasoning behind the decision challenged in the judicial review proceedings' (*Belize Alliance of Conservation Non-Governmental Organisations v Dept of the Environment* (*No 2*) [2004] UKPC 6, (2004) 64 WIR 68, [2004] Env LR 38 (at para [86]); *McGeoch, petitioner* [2013] CSOH 6, 2013 Scot (D) 13/1, 2013 SLT 183 (at para [64])). The PM had not done so (cf *R* (*on the application of I*) *v Secretary of State for the Home Dept* [2010] EWCA Civ 727, [2010] All ER (D) 244 (Jun) (at para [55])). A full and accurate explanation of the facts was required (*R* (*on the application of Quark Fishing Ltd*) *v Secretary of State for Foreign and Commonwealth Affairs* [2002] EWCA Civ 1409, [2002] All ER (D) 450 (Oct) (at para [50])). The respondent had no pleadings on the matter. At the same time, as the respondent had pled that the petitioners had no reasonable apprehension that the Government intended to prorogue Parliament with the intention of denying sufficient time for debate, the Government was in fact doing precisely that. Adverse inferences should be drawn concerning the veracity of the reasons for prorogation advanced in the documentation (*R* (*on the application of Das*) *v Secretary of State for the Home Dept* [2014] EWCA Civ 45, [2014] 1 WLR 3538 (at para [80])). Anxious scrutiny of these reasons was required, given that fundamental rights and the constitution were in issue (*R v Ministry of Defence, ex p Smith* [1996] 1 All ER 257 at 263, [1996] QB 517 at 554–555; *Wightman v Secretary of State for Exiting the European Union* (Case C-621/18) EU: C: 2018:999, [2019] QB 199, [2019] 1 CMLR 973 (at para 64); *Wightman* (*supra*) at para [53]). The power had been exercised 'for an alien purpose or in a wholly unreasonable manner' (*Pepper* (*Inspector of Taxes*) *v Hart* [1993] 1 All ER 42 at 68, [1993] AC 593 at 639); preventing parliamentary scrutiny of a no deal Brexit. It was the 'paramount duty' of the court to recognise this abuse of power (*R v Secretary of State for the Home Dept, ex p Fire Brigades Union* [1995] 2 All ER 244 at 271, [1995] 2 AC 513 at 571).

[**33**] Parliament was not given to passing legislation idly. An Act, when in force, will have practical consequences (*M v Scottish Ministers* [2012] UKSC 58, [2012] 1 WLR 3386, 2013 SC (UKSC) 139 (at para [34])). The prorogation was unlawful because it ran contrary to Parliamentary intention in passing ss 9, 10 and 13 of the European Union (Withdrawal) Act 2018, which provide that Parliament must have the time and opportunity to give effect to any withdrawal, deal or no deal, and to respect the British-Irish Agreements of 1998 and 2007. It was only once Parliament had passed the necessary statute that the Government had the authority to effect the withdrawal. Only in this way would the constitution be maintained (*AXA General Insurance Ltd v Lord Advocate* [2011] UKSC 46, (2011) 122 BMLR 149, [2012] 1 AC 868 (at [153])). The prorogation was vitiated by an error of law as it was predicated on the idea that the Government had the authority to create a no deal Brexit. The art 50 process required a partnership between the Government and Parliament. Primary legislation was required to conclude the process (*Wightman* (*supra*) at para [54]). None of the existing provisions, whether express or by implication (*R* (*on the application of Morgan Grenfell & Co Ltd*) *v Special Comr of Income Tax* [2002] UKHL 21, [2002] 3 All ER 1, [2003] 1 AC 563 (at para [45]); *R* (*on the application of Black*) *v Secretary of State for Justice* [2017] UKSC 81, [2018] 2 All ER 212, [2018] AC 215 (at paras [36](3) and (4))), authorised a no deal Brexit. Given that prorogation was aimed at facilitating a no deal Brexit, which was unlawful in the absence of Parliamentary sanction, the prorogation itself was unlawful.

[**34**] The petitioners moved for *interim* interdict preventing prorogation which was scheduled for Monday 9 September 2019 on the basis that they had established a *prima facie* case and the balance of convenience favoured its grant.

The Lord Advocate

[**35**] The Lord Advocate maintained that the Lord Ordinary had erred in concluding that the prorogation was not justiciable. It was disproportionate to any justification advanced. This was apt for judicial review on the basis of familiar standards and involved an assessment of its impact on recognised legal interests. The question was always whether a particular exercise of prerogative power was reviewable. For example, if it had been procured by bribery, it would be. Although the Lord Ordinary had found that scrutiny of the prorogation lay with Parliament and the electorate, it was in its nature that it deprived Parliament, during the period of prorogation, [of] the ability to exercise accountability. That was why the courts could not reject the challenge as *per se* not justiciable. The courts had a responsibility, when circumstances required, to protect Parliament from an abuse of Government power. If the prorogation had been until a date after 31 October 2019, the court would have been entitled to scrutinise that decision closely because of the effect which it would have on the principle of responsible government. It would have to ask whether, having regard to its duration, the prorogation was rationally connected and proportionate to the justification advanced.

[**36**] It was a cardinal principle of the constitution that the Government was accountable to Parliament. This was no less fundamental than that of parliamentary sovereignty (*R* (*Miller*) *v Secretary of State for Exiting the European Union* (*supra*) at para [249]). The courts should not overlook the constitutional importance of ministerial accountability to Parliament (*ibid* para [240]). The effect of the prorogation was to insulate the Government entirely from any accountability to Parliament. Although the power to prorogue lay with the PM,

the lawfulness of the exercise of that power lay with the courts. Just as with the sole question in *R* (*Miller*) *v Secretary of State for Exiting the European Union* (*supra*) at para [4], the question here was whether, as a matter of constitutional law, the prorogation, in the context of the anticipated Brexit, was unlawful.

[**37**] Prerogative powers existed for the public benefit and not that of the executive (Sales *Crown Powers, the Royal Prerogative and Fundamental Rights* (c 4) in Wilberg and Elliot (ed) *The Scope and Intensity of Substantive Review* (2015)). The public interest was promoted by allowing Parliament to carry out its role without let or hindrance. The courts had jurisdiction to review an Order in Council made on the advice of the Government (*R* (*Barclay*) *v Lord Chancellor* (*supra*) at para [58]; *R* (*Bancoult*) *v Secretary of State for Foreign and Commonwealth Affairs* (*supra*)). Just as the courts could control legislative action to protect individual rights (*AXA v Lord Advocate* (*supra*) at paras [50]–[51], [153] and [169]), so they should review Government action which undermines a fundamental constitutional principle (Craig *Prorogation: Constitutional Principle and Law, Fact and Causation* (Oxford University Hub)).

[**38**] The decision to prorogue for five weeks was an abuse of power. It was disproportionate to the declared purpose of paving the way for a Queen's Speech. That could be achieved by a prorogation of a few days. Just as there was a sliding scale, in which the cogency of the justification required for interfering with a right will be proportionate to its perceived importance and the extent of the interference (*Pham v Secretary of State for the Home Dept* [2015] UKSC 19, [2015] 3 All ER 1015, [2015] 1 WLR 1591 (at paras [105]–[106])), so there was a similar scale concerning justification for executive action which interfered with a fundamental principle of the constitution; that of responsible government.

Respondent

[**39**] The respondent's primary submission was that the Lord Ordinary was correct in deeming the issue to be not justiciable. There were no judicial or manageable standards by which the courts could assess the lawfulness of ministerial advice to prorogue Parliament. The issue was one of high policy and politics and not of law. Parliament could regulate its own sittings by legislating in specific contexts. Prorogation was governed by constitutional conventions which the courts did not enforce. Parliament had decided on what controls it should impose on prorogation. There was nothing unconstitutional in the Government acting within those limits. It would be unconstitutional for the courts to impose an additional control. Only the sovereign could prorogue Parliament in exercise of the Royal prerogative (Prorogation Act 1867 s 1). Parliament had expressly preserved the prorogation prerogative except in specific contexts.

[**40**] The issue was not justiciable because it was political (*Shergill v Khaira* [2014] UKSC 33, [2014] 3 All ER 243, [2015] AC 359 (at para [40]); *A v Secretary of State for the Home Dept, X v Secretary of State for the Home Dept* [2004] UKHL 56, [2005] 3 All ER 169, [2005] 2 AC 68 (at para [29])). The principle was longstanding. It was doubtful whether the tests of irrationality, impartiality or fettering of discretion could be applied to the exercise of prerogative powers (*Council of Civil Service Unions v Minister for the Civil Service* (*supra*) [1984] 3 All ER 935 at 951, [1985] AC 374 at 411; *R* (*on the application of Wheeler*) *v Office of the Prime Minister* [2008] EWHC 1409 (Admin), [2008] All ER (D) 333 (Jun) (at para [34]); *R* (*on the application of McClean*) *v First Secretary of State*

[2017] EWHC 3174 (Admin), [2018] 1 Costs LO 37 (at paras [21] and [22]); *R (Sandiford) v Secretary of State for Foreign Affairs* (*supra*)). Issues of high policy and political judgment were not ones with which the courts were equipped to grapple or had the means to determine. Constitutional arrangements, which involved the exercise of political judgment, permitted a flexible response (*Robinson v Secretary of State for Northern Ireland* [2002] UKHL 32, [2002] NI 390 (at para [12])). They could not be measured against public law standards. There was no measure by which the court could determine the sufficiency of time for proper consideration of the Brexit issue.

[41] The court could not begin to rule on whether sufficient time was being afforded to Parliament to debate a particular issue. That was a matter for Parliament to determine, as it had done in setting the procedures under the NIEFA 2019. The petition was inviting the court to go beyond what Parliament had already determined and to superimpose additional requirements. That was an interference with the political and legislative processes and was constitutionally inappropriate.

[42] There were wider political considerations, including the separation of powers, which dictated that the courts would not interfere with Parliamentary proceedings, rules and privileges. The courts and Parliament had to respect each other's roles and jurisdictions (*Coulson v HM Advocate* [2015] HCJAC 49, 2015 SCCR 219; cf *Adams v Guardian Newspapers Ltd* [2003] ScotCS 131, 2003 SC 425, 2003 SCLR 593 (at paras [13] and [17])). Parliament had control over its dissolution and prorogation. It had legislated for the former and had done so for prorogation in certain circumstances (Succession to the Crown Act 1707 s 5; Reserve Forces Act 1996 s 52(8); Civil Contingencies Act 2004 s 28; NIEFA 2019 s 3). The exercise of a prerogative power was not immune from review, but this depended upon the subject matter and the context of the power and the challenge (*Council of Civil Service Unions v Minister for the Civil Service* (*supra*) [1984] 3 All ER 935 at 948 and 956, [1985] AC 374 at 407 and 418; *R v Secretary of State for Foreign and Commonwealth Affairs, ex p Everett* (*supra*) [1989] 1 All ER 655 at 660, [1989] QB 811 at 820; *R v Secretary of State for the Home Dept, ex p Bentley* (*supra*) [1993] 4 All ER 442 at 452–453, [1994] QB 349 at 363). Matters of high policy, including prorogation were examples (see also *R v Wilde* (1670) 1 Lev 296, (1670) 83 ER 415).

[43] Prorogation was governed by constitutional convention. There required to be a new session of Parliament each year, although this was flexible. The existing session had lasted for more than two years. Political conventions were not enforceable (*R (Miller) v Secretary of State for Exiting the European Union* (*supra*) at [141]). They were not legal restrictions (see *Adegbenro v Akintola* [1963] 3 All ER 544, [1963] AC 614).

[44] The existence of prerogative powers was recognised in the same way in Scotland and England. Their scope was the same (*Burmah Oil Co (Burma Trading) Ltd v Lord Advocate* (*supra*)). There was no difference in the law of parliamentary privilege (*Adams v Guardian Newspapers* (*supra*) at para [13]). In both jurisdictions there were settled limits on the circumstances in which it was appropriate for the court to grant an advisory declarator (*Wightman* (*supra*) at para [24] under reference to *AXA v Lord Advocate* (supra) at para [170]). The issue of justiciability necessarily involved considerations of whether the issue was legal or political (*Gibson v Lord Advocate* 1975 SC 136 at 144; *Lord Gray's Motion* [2002] 1 AC 124 at 141, (2000) SC (HL) 46 at 61).

[45] Secondly, the issue was academic because, in terms of the NIEFA 2019, Parliament would be sitting before 31 October 2019. In addition, the Order in

Council meant that Parliament would be sitting in both September and October. The petitioners' complaint was therefore restricted to the number of days available. It was not for the courts to determine this.

[**46**] Thirdly, the petitioner's claim was unsustainable on its merits. The complaints of unconstitutional action were not matters of law (see Dicey *The Law of the Constitution* (8th edn) 293). The Claim of Right 1689 set no mandatory periods during which Parliament had to sit and nothing remotely sufficient to require the additional sittings beyond the NIEFA 2019. It provided no legal standard to measure the lawfulness of the decision to prorogue at any particular time or for any particular reason. It was for Parliament to decide whether the provision in the Claim of Right was to be further defined as the English Parliament had done in the Meeting of Parliament Act 1694 (applied to the UK Parliament by the Succession of the Crown Act 1707). The Claim of Right did not require Parliament to be in permanent session. There was nothing in the European Union (Withdrawal) Act 2018, the NIEFA 2019 or the Fixed-term Parliaments Act 2011 which would be frustrated by prorogation at any time for any reason.

[**47**] HM the Queen in Parliament was sovereign in the sense that Parliament could enact whatever it wished, subject to its own self-imposed restraints such as the European Communities Act 1972 and the Human Rights Act 1998 (*R* (*Jackson*) *v A-G* (*supra*) at para [159]). There was a distinction between enacted law and resolutions of either or both Houses of Parliament; the latter having no legal effect. The Government and the courts had to act in conformity with the will of Parliament as expressed in legislation. Neither the courts nor the Government could act to undermine legislation, including provisions for Brexit and the NIEFA 2019.

[**48**] There was no substance to the petitioners' argument that a no deal Brexit required authorisation by further primary legislation and thus parliamentary time. Withdrawal had already been authorised by the European Union (Notification of Withdrawal) Act 2017. Article 50 meant that Brexit would occur on the expiry of the relevant period with or without a deal. If the petitioners were correct, they would cease to have a relevant complaint. The provisions in the European Union (Withdrawal) Act 2018 were, in relation to the withdrawal agreement then extant, spent. They had no application to a no deal Brexit.

[**49**] The considerations which the PM took into account in seeking a prorogation were not justiciable. Nonetheless, in accordance with the duty of candour, the reasons were set out in the documentation. They were lawful. The decision was taken having regard, *inter alia*, to the fact that Parliament would be sitting extensively in the period leading up to 31 October 2019, having already made extensive legislative provision on the issue. The decision was: (a) to enable the new Government to set out its legislative agenda in a Queen's Speech; (b) to end the extraordinarily long Parliamentary session in a practical way, having regard to the traditional Parliamentary recess for party conferences; (c) based upon specific political considerations referred to in the documents; and (d) to reflect the fact that the timetable would afford time both before and after the Queen's Speech to debate Brexit, having regard to the European Council meeting on 17–18 October 2019.

DECISION

[**50**] The decision under review, which seems to have been made by the Prime Minister alone, is that to request HM the Queen to exercise her

prerogative to prorogue Parliament. A prerogative decision may be the subject of a judicial review (*R (Bancoult) v Secretary of State for Foreign and Commonwealth Affairs* [2008] 4 All ER 1055, [2009] 1 AC 453, Lord Rodger at para [106], endorsing *Edwards v Cruickshank* (1840) 3 D 282, Lord President (Hope) at 306–307). Whether the issue is ultimately justiciable will depend upon the subject matter (*Council of Civil Service Unions v Minister for the Civil Service*, Lord Scarman [1984] 3 All ER 935 at 948, [1985] AC 374 at 407, Lord Roskill [1984] 3 All ER 935 at 956, [1985] AC 374 at 418). As a generality, decisions which are made on the basis of legitimate political considerations alone are not justiciable (*Shergill v Khaira* [2014] 3 All ER 243, [2015] AC 359, Lords Neuberger, Sumption and Hodge at para [40]; *Gibson v Lord Advocate* 1975 SC 136, Lord Keith at 144). It is not possible to apply to such decisions the public law tests of reasonableness (*Council of Civil Service Unions v Minister for the Civil Service* (*supra*) Lord Diplock [1984] 3 All ER 935 at 951, [1985] AC 374 at 411), impartiality (*R (on the application of McClean) v First Secretary of State* [2017] EWHC 3174 (Admin), [2018] 1 Costs LO 37, Sales LJ at paras [21] and [22]) or fettering of discretion (*R (Sandiford) v Secretary of State for Foreign and Commonwealth Affairs* [2014] 4 All ER 843, [2014] 1 WLR 2697). In this case, if the challenge was based upon these judicial review considerations or similar matters, it would not be justiciable. If the reasons for the decision were based upon legitimate political considerations, including a desire to see that Brexit occurs, they would not be challengeable. However, that is not the contention.

[**51**] The contention is that the reasons which have been proffered by the PM in public (to prepare for a new legislative programme and to cover the period of the party conferences) are not the true ones. The real reason, it is said, is to stymie Parliamentary scrutiny of Government action. Since such scrutiny is a central pillar of the good governance principle which is enshrined in the constitution, the decision cannot be seen as a matter of high policy or politics. It is one which attempts to undermine that pillar. As such, if demonstrated to be true, it would be unlawful. This is not because of the terms of the Claim of Right 1689 or of any speciality of Scots constitutional law, it follows from the application of the common law, informed by applying 'the principles of democracy and the rule of law' (*Moohan v Lord Advocate* [2015] 2 All ER 361, [2015] AC 901, Lord Hodge at para [35]). The terms of the Claim of Right are not breached simply because Parliament does not sit for a month or so. Parliament has, throughout the year, been allowed to sit.

[**52**] There is some force in the contention that the court should leave it to Parliament to decide whether to challenge the prorogation. Parliament could, if there were time to do so, enact legislation which would have the effect of removing the prorogation before it began. It has not done that in the days which were available. In practical terms, this is not surprising given the intensity of the political debate in recent times; in particular the moves by the opposition parties and some Conservative MPs to enact a Bill designed to prevent a no deal Brexit (European Union (Withdrawal) (No 6) Bill which, on 9 September 2019, became the European Union (Withdrawal) (No 2) Act 2019). This requires the PM to seek an extension to the art 50 exit date for a further four months to 31 January 2020 if no withdrawal agreement is secured by 19 October 2019. Because the prorogation goes to the root of Parliament's ability to sit, and thus prevents Parliament from performing its central role in scrutinising Government action, the court must have a concurrent jurisdiction (see *R (Barclay) v Lord Chancellor* [2014] 1 All ER 429, [2015] AC 276, Lady Hale

at para [57]) to prevent this occurring and to enable Parliament to sit, should it choose to do so. Parliament is, of course, free to pass legislation which overrides a court's decision. It can decide not to sit.

[**53**] The circumstances demonstrate that the true reason for the prorogation is to reduce the time available for Parliamentary scrutiny of Brexit at a time when such scrutiny would appear to be a matter of considerable importance, given the issues at stake. This is in the context of an anticipated no deal Brexit, in which case no further consideration of matters by Parliament is required. The art 50 period, as extended, will have expired and withdrawal will occur automatically.

[**54**] This conclusion on the true reason stems from a number of factors. First, the prorogation was sought in a clandestine manner during a period in which litigation concerning the prospect of prorogation occurring was extant. Although it is possible to argue about exactly what was meant by the respondent's fifth plea-in-law (see *supra* para [8]), it is not unreasonable to comment that even the respondent's legal team appear to have been kept in the dark about what was about to happen. Secondly, the decision to prorogue in the manner sought was taken against the background of the discussions in which it was being suggested that MPs, and thus Parliament, would be unable to prevent a no deal Brexit if time was simply allowed to elapse, without further legislation, until the exit date. Put shortly, prorogation was being mooted specifically as a means to stymie any further legislation regulating Brexit.

[**55**] Thirdly, there is remarkably little said about the reason for the prorogation in the respondent's pleadings. Although the court would not expect an affidavit from a Government minister or official testifying to the reason (cf the procedure in England: *Belize Alliance of Conservation Non-Governmental Organisations v Dept of the Environment (No 2)* [2004] UKPC 6, (2004) 64 WIR 68, [2004] Env LR 38, Lord Walker, delivering the opinion of the minority, at para [86]) it would expect averments in the respondent's answers setting out that reason. Such averments would require to be based upon information provided to counsel and to proceed upon counsel's responsibility (*McGeoch, petitioner* [2013] CSOH 6, 2013 Scot (D) 13/1, 2013 SLT 183, Lord Brodie at para [64]).

[**56**] Fourthly, there was, and is, no practical reason for a prorogation for what is, in modern times, an extraordinary length of time (5 weeks instead of about 7 days). The Memorandum of 15 August 2019, which does not emanate from a member of the civil service, does not state that there is any such reason. It says that prorogation could occur as early as 9 to 12 September; there already being matters scheduled for the first week in September and additional time was needed for the 'wash-up' of extant Bills. There would be a requirement for Parliament to sit both before and after the EU Council meeting on 17–18 October in order to approve any Brexit deal (2018 Act s 13), hence a Queen's Speech at about that time; 14 October being selected. The references in the memorandum and the PM's handwritten note state that the number of sitting days lost, having regard to the party conferences, may be relatively small. This does not acknowledge that the party conferences are normally covered by a period of recess, which Parliament itself has set. Parliament may elect not to recess or, if in recess, to recall itself. Similarly, the sitting following the Queen's Speech is required at least in part to debate the Government's legislation programme as set out in that speech. Presumably, the sittings required by the Northern Ireland (Executive Formation etc) Act 2019 are

primarily designed to deal with issues relating to that subject matter and not for scrutiny of other matters. None of this justifies losing the days, which might be available, to no apparent purpose, other than not to have time available for Parliamentary scrutiny of Government action and, in particular, the ongoing Brexit procedure.

[**57**] At the Cabinet meeting, the tenor of the PM's remarks, and the discussion around them, point to the various factors being used publicly to deflect from the real reason for the prorogation (see *Porter v Magill* [2001] UKHL 67, [2002] 1 All ER 465, [2002] 2 AC 357, Lord Scott at para [144]). That reason, as is reflected in the frequent references to it in the papers, centred on Brexit and not the intervention of the party conferences or the new legislative programme.

[**58**] The fact that there will be some days in September and October during which Parliament will be sitting, and thus potentially some time to discuss Brexit, does not detract from the general position that the prorogation is intended unlawfully to restrict that time. The court is not dictating the days on which Parliament should sit. That is a matter for Parliament to decide. It is merely holding that a particular attempt to restrict the available days is unlawful.

[**59**] Having regard to the substantial effect of the prorogation on the ability of Parliament to scrutinise Government action, the matter cannot be considered academic. However, the proroguing of Parliament does not have a direct consequence on individual legal rights. The issue is not justiciable on that basis and the petitioner's argument to the opposite effect on this point is rejected.

[**60**] The court should for these reasons allow the reclaiming motion and grant a declarator that the advice to prorogue Parliament on a day between 9 and 12 September until 14 October, and hence any prorogation which followed thereon, is unlawful and thus null and of no effect.

LORD BRODIE.

[**61**] This is a reclaiming motion against an interlocutor of the Lord Ordinary dated 4 September 2019 refusing a petition for judicial review by means of which the petitioners sought:

> (1) a declarator that it is *ultra vires et separatim* unconstitutional for any Minister of the Crown, including the Prime Minister, with the intention and aim of denying before Exit Day sufficient time for proper parliamentary consideration of the withdrawal of the United Kingdom from the European Union, to purport to advise the Queen to prorogue the Union Parliament.
>
> (2) interdict against Ministers of the Crown from advising the Queen, with the view or intention of denying before Exit Day sufficient time for proper parliamentary consideration of the withdrawal of the United Kingdom from the European Union, to prorogue the Union Parliament and for interdict *ad interim*.
>
> (3) such further orders (including an order for expenses) as may seem to the court to be just and reasonable in all the circumstances of the case.

[**62**] An order for intimation and service of the petition was made on 31 July 2019, the Advocate General for Scotland being named as respondent in the schedule for service and the Prime Minister as an interested party. Answers were lodged by the respondent. Permission to proceed was granted on

8 August. On 13 August parties were allowed to adjust their respective pleadings until 23 August and to adjust their pleadings in response until 27 August. Parties were appointed to intimate and lodge in process no later than 4pm on 30 August all affidavits and other documents to be relied on. On 3 September the Lord Advocate was granted leave to intervene by way of written submission (at the summar roll hearing before the Inner House a written submission in the reclaiming motion was supplemented by a short oral submission by Mr Mure QC on behalf of the Lord Advocate).

[**63**] Short as that timetable may be thought to be, it was to an extent overtaken by events. Statement 51 of the petition, which can be seen as encapsulating the petitioners' complaint is in the following terms:

> 'That in light of the public statements made by among others the current Prime Minister and, separately, in light of the refusal by the current Leader of the House of Commons to rule out the possibility of the UK Government seeking to advise the Queen to prorogue the Union Parliament the petitioners are reasonably apprehensive that the UK Government intends to advise the Queen – whether as part of a process either ending a session of Parliament in preparation for the State Opening of Parliament, or dissolving Parliament and summoning a new Parliament following a General Election – to prorogue the Union Parliament in advance of Exit Day so as to deny the Union Parliament an adequate opportunity to scrutinise the terms of any exit of the United Kingdom from the European Union and hold to account the Government as is its role on behalf of the people of the United Kingdom. …'

These averments were denied by the respondent. However, on 28 August 2019 the Queen, on the advice of the Privy Council, pronounced the following order:

> 'It is this day ordered by Her Majesty in Council that the Parliament be prorogued on a day no earlier than Monday the 9th day of September and no later than Thursday the 12th day of September 2019 to Monday the 14th day of October 2019, to be then holden for the despatch of divers urgent and important affairs, and that the Right Honourable the Lord High Chancellor of Great Britain do cause a Commission to be prepared and issued in the usual manner for proroguing the Parliament accordingly.'

[**64**] Accordingly, when the petition came before the Lord Ordinary for a substantive hearing on 3 September 2019, reflecting the fact that, on the petitioners' interpretation of events, their apprehension had become a reality with the making of the Order in Council, their motion to the Lord Ordinary was:

> (1) to pronounce a declarator that it is *ultra vires et separatim* unconstitutional for any Minister of the Crown, including the Prime Minister, with the intention and aim of denying before Exit Day sufficient time for proper parliamentary consideration of the withdrawal of the United Kingdom from the European Union, to purport to advise the Queen to prorogue the Union Parliament;
>
> (2) to order reduction of the Order in Council of 28 August 2019;
>
> (3) to interdict Ministers of the Crown in right of the United Kingdom from acting upon the Order in Council of 28 August 2019 proroguing the Union Parliament.

THE GROUNDS OF CHALLENGE

[**65**] In their petition the petitioners present two grounds of challenge to the lawfulness of the Order in Council of 28 August 2019 proroguing Parliament (the 'Order').

[**66**] The first ground is summarised at statements 37 to 42 of the petition. Put short, it might be stated in two propositions which are to be found in that part of the petition: (i) the UK Government, as the executive, is on all matters politically accountable and answerable to the Union Parliament; and (ii) in advising the Queen to prorogue the Union Parliament prior to Exit Day [by making the Order] with a view to denying the Union Parliament sufficient time properly to consider issues around the withdrawal of the United Kingdom from the European Union would undermine the United Kingdom's system of constitutional and democratic government in respect of the principle of the political accountability of the executive to the legislature and its legal accountability to the courts.

[**67**] The second ground of challenge is that prorogation of Parliament for a period of some five weeks consequent on the Order would frustrate the will of Parliament as expressed in at least two statutes: the European Union (Withdrawal) Act 2018 (the 'EUWA 2018') and the Northern Ireland (Executive Formation etc) Act 2019 ('NIEFA'). It is to this, the second ground, that I will first turn.

THE SECOND GROUND OF CHALLENGE

[**68**] In my opinion, the second ground of challenge can be dealt with briefly; and rejected.

[**69**] The argument based on EUWA 2018 is as follows. Article 50 of the Treaty on European Union (2007/C 326/01) ('TEU') provides inter alia:

> '1. Any Member State may decide to withdraw from the Union in accordance with its own constitutional requirements.
>
> 2. A Member State which decides to withdraw shall notify the European Council of its intention. … [T]he Union shall negotiate and conclude an agreement with that State, setting out the arrangements for its withdrawal …
>
> 3. The Treaties shall cease to apply to the State in question from the date of entry into force of the withdrawal agreement or, failing that, two years after the notification referred to in paragraph 2, unless the European Council, in agreement with the Member State concerned, unanimously decides to extend this period.'

[**70**] What art 50 terms 'an agreement with [the withdrawing] State, setting out the arrangements for its withdrawal' has come to be generally referred to as 'a deal' and, conversely, the absence of any such agreement as 'no deal'. A withdrawal agreement reached by the government requires ratification by Parliament in terms of s 13 of EUWA 2018. It is the petitioners' contention that the effect of s 13 of the Act, as read with s 1(1) of the European Union (Notification of Withdrawal) Act 2017 and the European Union (Withdrawal) Act 2019 is that:

> '… in the absence of express Parliamentary discussion and specific Parliamentary approval for such a course, it is unlawful for the Government (relying on the automatic effect of EU law and its own failure) to allow the United Kingdom to leave the European Union by

default, without a deal. Ministers accordingly require the authority of Parliament in the form of new primary legislation expressly allowing for it, before they can lawfully take the course of allowing for such a "no deal Brexit". The Government is therefore obliged to ensure that Parliament is sitting for such no deal authorising legislation to be considered by Parliament and, if so advised, passed before Exit Day.'

[**71**] The respondent disputed that interpretation of s 13. It is directed at parliamentary approval of a withdrawal agreement; it has no application to an exit from the EU without a deal because in these circumstances there would be no deal to be approved. The Lord Ordinary agreed with that interpretation. I express no concluded opinion on the matter. On the face of it s 13 is about approval of a deal. To come to a concluded view on the proper interpretation of the legislation would require a much more detailed examination than has been or is possible in the time available. More critically, as Mr Johnston QC submitted on behalf of the respondent, s 13 of EUWA 2018 is irrelevant to the issues in the petition. If, contrary to the respondent's interpretation, it requires parliamentary approval for a no deal exit then the petitioners' principal concern, a no deal exit by default, cannot occur. I would add that, again, the petition would appear to have been overtaken by events in that the European Union (Withdrawal) (No 6) Bill received Royal Assent, on 9 September 2019, and became the European Union (Withdrawal) (No 2) Act 2019. That Act provides that unless Ministers have sought and obtained parliamentary approval either of a withdrawal agreement or of leaving the European Union without an agreement by 19 October 2019 then the Prime Minister must seek a further extension of the art 50 notice period until 31 January 2020.

[**72**] The NIEFA argument is based on the requirement of s 3 of that Act for a Minister to report periodically to the House of Commons until December 2019 on the progress of talks on restoring the Northern Ireland Assembly. The petitioners aver that this indicated the clear intention and purpose of Parliament to ensure that it continued to sit throughout September to December 2019 to ensure, among other things, Parliament's continued scrutiny of the process of the UK's withdrawal from the European Union and to maintain the accountability of the Government on this issue. I do not accept that. NIEFA illustrates that Parliament can and does regulate when it will sit. The provisions of NIEFA are very specific as to the days when Parliament must sit in the period until December 2019, assuming no dissolution but irrespective of prorogation. It can be taken to have been Parliament's intention to sit on these days but it cannot be taken that it was Parliament's intention to sit on other days. Just what business Parliament considers in addition to the progress of talks on restoring the Northern Ireland Assembly will be for Parliament to determine but there is nothing in NIEFA to prevent Parliament standing prorogued for other than the specified days. However, I do not go the distance of accepting that by passing the bill that became NIEFA, Parliament must be taken to have 'occupied the ground', as it was put by Mr Johnston for the respondent, if by that he meant having comprehensively determined all the days when it must sit before December 2019, but as to the petitioners' suggestion that a more extensive parliamentary intention can be implied from NIEFA than what is specifically stated I agree with the respondent and the Lord Ordinary.

THE FIRST GROUND OF CHALLENGE

[**73**] The first ground of challenge gives rise to two broad questions: first, whether this court in exercise of its supervisory jurisdiction can reduce the Order; second, whether it should.

[**74**] In order to answer these two questions in the affirmative, as the petitioners would wish, the court must be satisfied that the advice given to the Sovereign by the relevant members of the Privy Council in respect of the making of the Order was in some way unlawful, however that unlawfulness is characterised; 'abuse of power', '*ultra vires*', 'unconstitutional', 'improper purpose' and 'irrational' were among the expressions used in the course of submissions.

THE PETITIONERS' SUBMISSION IN SUPPORT OF THE FIRST GROUND OF CHALLENGE

[**75**] There are three pillars to the State: Parliament, the Executive, and the courts. While its sovereignty may not be absolute, Parliament is sovereign. The Executive must act within the powers permitted it by Parliament, and for the purposes for which those powers were left with it by Parliament. The Executive is politically accountable to Parliament for exercise of its powers. Through its exercise of prerogative power the Executive may prorogue Parliament but if and so far as the Executive were to use this power in order to avoid being held accountable to Parliament or to impede Parliament from exercising control over the Executive that would be unlawful. The proper constitutional relationship of the Executive and the courts is one of mutual respect; the courts will respect all acts of the Executive within its lawful province, and the Executive will respect all decisions of the courts as to what its lawful province is. As the Executive is politically accountable to Parliament, the Executive is legally accountable to the courts. The government of the United Kingdom is subject to the rule of law and it is the function of the courts to ensure the rule of law by providing an effective remedy against any constitutional violation. It is the law (and accordingly a matter for courts in enforcing the rule of law) that parliaments be called and allowed to sit: the Claim of Right Act 1689, as subsequently confirmed. It is therefore clear that the Executive's power to prorogue Parliament is a matter which is justiciable before the courts and is reviewable on grounds of irrationality or breach of other judicial review principles (cf *A-G v De Keyser's Royal Hotel Ltd* [1920] AC 508 at 567–568, [1920] All ER Rep 80 at 105–106, *R (on the application of Sandiford) v Secretary of State for Foreign and Commonwealth Affairs* [2014] UKSC 44, [2014] 4 All ER 843, [2014] 1 WLR 2697 (at paras [50] and [65])). The Executive's exercise of the power of prorogation of Parliament is accordingly not unlimited or unfettered. Exercise of the power is lawful only if it is consistent with constitutional principle. The power can only be exercised for a proper purpose. Even if it is exercised for a proper purpose, it is subject to review on the ordinary principles of legality, rationality and procedural propriety. In the present case the Prime Minister has declined to give a proper and complete account of the Executive's true reasons for exercising the prerogative to prorogue Parliament for the period specified in the Order. This refusal by the Prime Minister to explain the decision-making and reasoning underlying the exercise of the power at the present time mean that the court should draw inferences of fact against the respondent. In particular it is proper in these circumstances for the court critically to examine and sceptically to question the reasoning and justification given for the exercise of the power to

prorogue Parliament in his letter of 28 August 2019 to MPs (that the decision was not driven by Brexit, and that the Prime Minister wished to press ahead with a new agenda and to prepare for its presentation in a Queen's Speech) (*R* (*on the application of Das*) *v Secretary of State for the Home Dept* [2014] EWCA Civ 45, [2014] 1 WLR 3538, Beatson LJ at para [80] approving the approach taken by Sales J, as he then was, at first instance). Such an approach of anxious scrutiny was appropriate as requiring the Executive to demonstrate that the most compelling of justifications existed for an exercise of the power to prorogue where it will have profoundly intrusive and distortive effects on the constitution. It is in any event clear that the Executive's exercise of the power in the present case has been vitiated by its use for an improper purpose and in an unreasonable manner namely: to prevent or impede Parliament holding the Executive politically to account in the run up to Exit Day; to prevent or impede Parliament from legislating on the United Kingdom's exit from the European Union; and to allow the Executive, notwithstanding that it has no Parliamentary mandate to do so, to pursue a policy of No Deal Brexit without further Parliamentary interference. The Executive has purported to use the power intending to silence and disempower Parliament for the crucial period in the immediate run up to Exit Day. Prorogation used in this way seeks to curtail Parliament's capacity to exercise the totality of legislative authority. Where, as in the present case, the Executive so abuses its power of prorogation of Parliament, it is the paramount duty of the court to say so.

THE LORD ADVOCATE'S SUBMISSION IN SUPPORT OF THE FIRST GROUND OF CHALLENGE

[**76**] The question was whether, having regard to its effects in all the circumstances, this particular decision to prorogue was one that calls for the intervention of the court. In the particular context the decision to advise and procure the prorogation of Parliament for five weeks at this time may properly be characterised as an abuse of executive power which calls for intervention. It is an existential question: whether Parliament is to sit. The Executive is accountable to Parliament but once the Executive has suspended Parliament that mechanism for democratic accountability is removed and yet it is said that a closing down of the possibility of scrutiny of the Executive is non-justiciable. The abuse of power lies in the timing and duration of the prorogation, its effect on a fundamental constitutional principle – namely, accountable or responsible government – and a marked absence of any compelling justification offered in that regard by the Prime Minister for that timing and length. While the UK Government has publically stated that the purpose of prorogation at this time is to bring the current session of Parliament to an end, a period of five weeks is disproportionate for that purpose. It was the role of the courts to protect Parliament. It would be odd if the court disqualified itself just because political judgement is involved. Merely because a question is in the political sphere does not mean that it is not justiciable. The real issue was how the courts should carry out their review, in other words what is the appropriate standard and intensity of review. The structure of analysis that the intervener invites the court to apply is a familiar one. It involves the court assessing the impact of the decision under review on a recognised legal interest, here the constitutional principle of responsible government; in applying scrutiny to the justification advanced by the UK Government; and in addressing whether the interference is rationally connected to the justification; and whether that impact is proportionate to the justification advanced. These are all questions

which are apt for judicial determination. The constitutional right of Parliament to sit is so important that it requires enforcement in the court. In these circumstances the intervener invites the court to reduce the Order.

THE LORD ORDINARY'S OPINION

[**77**] In refusing the petition, the Lord Ordinary essentially accepted the submissions made to him on behalf of the respondent. Review of the exercise of some prerogative powers was justiciable in some cases but not in others. Whether the exercise of prerogative power is reviewable depends on the subject matter of the power or its exercise and the context of the power and of the challenge. Some functions exercised or decisions taken are non-justiciable. Among them are matters of high policy and political judgement. The courts do not have the tools or standards to assess the legality of such matters. That is political territory and decision-making which cannot be measured against legal standards but rather only by political judgements. It could not be said that the prorogation contravened the rule of law, thus making the claim justiciable. The Prime Minister had the *vires* to advise the Sovereign as to the exercise of the royal prerogative. Parliament is master of its own proceedings. It is not for the courts to devise restraints on prorogation beyond those which Parliament has chosen to provide. The Lord Ordinary saw force in the submission by counsel for the respondent that the petitioners' claim that the Claim of Right Act 1689 had been contravened was non-justiciable but he preferred to decide that issue on the more straightforward ground that there was nothing to support any breach of the provisions of the Act.

DISCUSSION

[**78**] The petitioners seek to challenge the exercise of the royal prerogative in order to prorogue Parliament.

[**79**] A session of a Parliament can only be brought to an end by an exercise of the royal prerogative (hence the Order); formerly this was done at the end of the session by the monarch in person but now it is prorogued by a commission for the purpose under the Great Seal; the effect of prorogation is to put an end with certain exceptions to all proceedings then current and to suspend any sitting of Parliament or its committees for the period of prorogation (see Erskine May's *Parliamentary Practice* (24th edn, 2011) pp 144–145).

[**80**] The Order was made by the Queen but, as appears on its face, in making the Order she was acting in council, in other words with the advice of ministers. In reality the Sovereign never acts by himself, but only through the medium of ministers or executive servants and accordingly a challenge to an order in council is properly directed against the responsible ministers or their law officer (*Edwards v Cruickshank* (1840) 3 D 282, Lord President Hope at pp 306–307, quoted with approval by Lord Rodger in *R* (*on the application of Bancoult*) *v Secretary of State for Foreign and Commonwealth Affairs* [2008] UKHL 61, [2008] 4 All ER 1055, [2009] AC 453 (at para [106]); cf *Teh Cheng Poh v Public Prosecutor, Malaysia* [1980] AC 458 at 473, [1979] 2 WLR 623 at 633–634). As a matter of procedure an order in council may be quashed by decree of the Court of Session in an action or petition directed against the Advocate General for Scotland (Crown Suits (Scotland) Act 1857, *R* (*Bancoult*) at para [106]).

[**81**] While the respondent submits that this is all a matter of high politics and therefore not a matter for the courts, a certain amount is conceded or otherwise not a matter for argument. The petitioners have been granted

permission to proceed. Their standing to bring the petition has accordingly been acknowledged by the court and indeed was expressly accepted by the respondent. Also accepted was that, as a matter of generality, this court has jurisdiction to review an exercise of power derived from the royal prerogative. There is no procedural difficulty in this court granting a decree the effect of which is to nullify the Order. While the court was reminded of the separation of powers, I did not understand the proposition that review of the Order would in some way constitute contempt of Parliament to be pressed. Thus, while we heard much from Mr O'Neill on behalf of the petitioners which was both interesting and stirring about a particularly Scottish tradition of holding the Crown, in its various manifestations, to account, for present purposes (and not having actually identified any material differences between the applicable Scots law and the corresponding English law) Mr O'Neill was, to an extent, pushing at an open door; however only to an extent. The Lord Ordinary has held that the petitioner's first ground of challenge is not justiciable; that prorogation of Parliament in terms of the Order is not contrary to the rule of law; that as Parliament is master of its own proceedings, the courts will not interfere; and that there has been no contravention of the Claim of Right Act 1689. He has refused the petition. Counsel for the respondent submits that he was right to do so.

[**82**] I shall address these points in turn, although there is a degree of inter-dependence among them.

Not justiciable

[**83**] Without pretending to define the concept, I would see a question to be justiciable if it is capable of practical determination by reference to legal principles in a court of law. If it is not capable of determination in that manner it is not justiciable. I have suggested that the first ground of challenge gives rise to two issues: whether this court can reduce the Order; and second, whether it should. Both involve a question of justiciability in that in order for this or any other court to find those whom the respondent represents to have acted unlawfully the court must be satisfied that there are sufficiently precise and applicable legal principles by reference to which the lawfulness of making the Order can be judged; and the court must further be satisfied that on the material available to it by applying the relevant principles it should conclude that advising the Queen to make the Order was an unlawful act. The Lord Ordinary captured the notion of justiciability, or at least non-justiciability rather more succinctly than I have been able to do when he indicated that where the court does not have the tools or standards to assess the legality of a matter then it is not justiciable. In doing so the Lord Ordinary was echoing the 'lack of judicial or manageable standards' referred to in the joint judgment of Lords Neuberger, Sumption and Hodge in *Shergill v Khaira* [2014] UKSC 33, [2014] 3 All ER 243, [2015] AC 359 (at para [40]) (and see also the other authorities cited by the respondent: *Council of Civil Service Unions v Minister for the Civil Service* [1984] 3 All ER 935 at 951, [1985] AC 374 at 411, *A v Secretary of State for the Home Dept, X v Secretary of State for the Home Dept* [2004] UKHL 56, [2005] 3 All ER 169, [2005] 2 AC 68 (at para [29]), *R (on the application of Wheeler) v Office of the Prime Minister* [2008] EWHC 1409 (Admin), [2008] All ER (D) 333 (Jun), *R (on the application of McClean) v First Secretary of State* [2017] EWHC 3174 (Admin), [2018] 1 Costs LO 37 (DC) (at paras [21] and [22]), *Robinson v Secretary of State for Northern Ireland* [2002] UKHL 32, [2002] NI 390 (at para [12])).

[**84**] The Lord Ordinary correctly recognised that review of the exercise of some prerogative powers was justiciable in some instances but not so in respect of other powers or other instances; it will depend on the nature of the power, the circumstances and context of its exercise, any established practice or undertaking giving rise to an expectation, and the precise way in which a particular challenge is formulated (*R* (*Sandiford*) at paras [50]–[52] and authorities cited there). However, while questions of justiciability in judicial review are not confined to applications to review exercises of the royal prerogative they are more likely to arise in such cases because of the relatively amorphous nature of common law prerogative powers in comparison to the more closely defined powers conferred by statute.

[**85**] An illustration of circumstances in which a court may conclude that a question or issue is not justiciable is provided by the line of argument in the present case that the making of the Order contravenes the provisions of the Claim of Right Act 1689. It is a statute but also a document of its time. It lacks the precision to be expected of modern legislation. The passage founded on by the petitioners reads as follows:

> 'That for redress of all grievances and for the amending strenthneing and preserving of the lawes Parliaments ought to be frequently called and allowed to sit and the freedom of speech and debate secured to the members'.

As I understand it, the Lord Ordinary rejected the petitioners' contention that making the Order contravened the 1689 Act on the basis that a particular prorogation of Parliament, taken in isolation, does not amount to breach of a requirement that Parliament be 'allowed to sit'. However counsel for the respondent had also argued that, given the terms of the relevant text, the question of whether the requirement that Parliament be 'allowed to sit' was not justiciable. Like the Lord Ordinary, I see the force of that argument. Where in practice the sitting of Parliament is commonly adjourned and prorogued, by reference to what criteria and what materials can a court determine that in a particular instance Parliament has not been 'allowed to sit'? Moreover, if this is brought into contention, how can a court decide that the 'redress of all grievances and for the amending strenthneing and preserving of the lawes' or 'freedom of speech and debate' have been subverted or prevented?

[**86**] As matters stood when the petition was first presented (31 July 2019) I am inclined to the view that the petitioners were not in a position to frame a justiciable question or at least had not done so. The events up to that date which are recorded by your Lordship in the chair provided context, but I do not consider that a court asked to consider the petition on 31 July 2019 would have had the materials or the 'judicial or manageable standards' available to it to conclude that the petitioners had a reasonable apprehension that Parliament was to be prorogued in such a way as to be unlawful. It was then the apprehension of the petitioners that Parliament was to be denied 'sufficient time for proper parliamentary consideration of the withdrawal of the United Kingdom from the European Union'. It does not appear to me that a court has the capability to determine what time is sufficient for Parliament or what consideration is proper for Parliament when the matter for consideration is the withdrawal of the United Kingdom from the European Union.

[**87**] The landscape changed, however, with the making of the Order, the issue of the Prime Minister's letter to MPs on 28 August 2019 and the

disclosure to the court of copies of the three redacted documents referred to by your Lordship in the chair which were apparently exhibited to the witness statement of Jonathan Guy Jones dated 2 September 2019 in the proceedings *R* (*on the application of Miller*) *v Prime Minister* before the Queen's Bench Division of the High Court in England (Exhibit JGJ/1, Exhibit JGJ/2, and Exhibit JGJ/3). The making of the Order meant that prorogation was no longer a matter of apprehension; it would happen. Moreover, the dates and the period of prorogation were known. The Prime Minister's letter set out his explanation for the prorogation. The redacted documents provided material bearing on the thinking of the Prime Minister and his advisers, which, taken with the whole circumstances, including the Prime Minister's public statements, might allow a court to draw inferences as to whether the Prime Minister's explanation disclosed his whole or indeed his principal reasons for proroguing Parliament at this time.

[**88**] As to the use to be made of the redacted documents, I respectfully associate myself with the position of your Lordship in the chair. It was submitted by Mr O'Neill on behalf of the petitioners that it was simply not open to a party to put in documents to support his case in redacted form where the redaction was at his hand; any claim of privilege or confidentiality had to be taken as having been waived. Mr O'Neill was also critical of the absence of any affidavit, whether to explain the documents or otherwise to support the reasons for advising the Queen to make the Order. It was for the Prime Minister, submitted Mr O'Neill, to commit to a position on oath and render himself liable to cross-examination. I do not agree with Mr O'Neill on any of these points. In my opinion it is open to a court to look at any documentary production which is tendered to it and give it such weight as the court considers that it is worth. If a party has redacted certain portions in the way that these documents have been redacted (portions blacked out) then it is clear that the court is not being provided with the full text of the original. The court can take that into account. Redaction may mean that certain inferences should be drawn. However, I do not consider that a party should not be allowed to produce a document in redacted form or to rely on it, for what it is worth. Similarly I do not consider that a document cannot be produced and relied on where it is evident that it is part of or originally intended to be read with another document, such as an affidavit. Counsel for the respondent explained that the three documents had been produced on the advice of the Treasury Solicitor in discharge of what he saw to be a duty of candour to the court. The redactions had been made on the basis of legal professional privilege, the convention as to Law Officers' advice and relevancy. I see no reason why not to accept the good faith and professional diligence of the Treasury Solicitor and of counsel when he advised that he had satisfied himself that redactions had been properly made. Indeed, while there may be cases when the court will have to probe more deeply, I would see every reason for the court to be prepared to rely on what is said by professional civil servants and counsel who understand what is meant by accurate information and their duty to present it to the court. In an age of special or political advisers who may not share that understanding and the diffusion of 'messaging', to use an expression in the cabinet minute, responsible conduct and adherence to the highest standards is to be encouraged.

[**89**] When regard is had to all the material now before the court, it is my opinion that the petitioners are entitled to be sceptical of the proposition that the reason for making the Order was simply in order to prepare a new

legislative agenda for announcement in a Queen's Speech at the beginning of the next session of the Parliament. Further, I consider that they are entitled to ask the court to infer, as I would infer, as submitted on behalf of the petitioners, that the principal reason for the advice to the Queen to make the Order for the prorogation of Parliament was to prevent or impede Parliament holding the Executive politically to account in the run up to Exit Day; to prevent or impede Parliament from legislating on the United Kingdom's exit from the European Union; and to allow the Executive to pursue a policy of no deal Brexit without further Parliamentary interference. My reasons for inferring that are as follows. The Prime Minister has made it very clear that his principal policy objective is to achieve a withdrawal of the United Kingdom from the European Union on 31 October 2019 irrespective of the consequences of such a withdrawal and therefore irrespective of the making of a withdrawal agreement with the European Union with a view to ameliorating some of the adverse effects of withdrawal (that there will be adverse effects would seem to be accepted by the Prime Minister, given his expressed wish to negotiate an agreement). If withdrawal by 31 October 2019 means a no deal Brexit then the Prime Minister is prepared to accept that. He would prefer to be 'dead in a ditch' to not achieving that objective. However, the Prime Minister does not command a majority in Parliament for this policy objective if it comes at the price of no deal. A sitting Parliament, carrying out its constitutional functions including the passing of legislation, therefore presents the potential to interfere with the Prime Minister's policy objective. As it happens, this was to be demonstrated during the two days of the hearing of the reclaiming motion, but it had been anticipated for some time before that. What was also anticipated, not just by the petitioners but in public statements by at least one member of the present cabinet, that a means of preventing such interference would be to prorogue Parliament (and the speaker said he was willing to procure that). It is now known that a prorogation of some five weeks between 9 September and 14 October was being planned at least as early as 15 August. That planning would seem to have been conducted in conditions of some secrecy. That Parliament was to be prorogued was only announced after the Order was made, on 28 August. That was so, as your Lordship in the chair observes, despite the fact that the petitioners' application with its averments of apprehension of a prorogation had been initiated on 31 July without any subsequent acknowledgement in the respondent's pleadings that the apprehension was well founded. As your Lordship observes, it would appear to have been thought appropriate to keep the respondent's legal advisers in the dark about what was planned. Of significance is the length of the prorogation. The note from Nikki da Costa to the Prime Minister (Exhibit JGJ/1) states that the usual length of prorogation is usually under 10 days, although occasions of longer periods are there identified. For the reasons given by Professor Paul Craig in *Prorogation: Constitutional Principle and Law, Fact and Causation* Oxford Human Rights Hub, 31 August 2019, presenting and initiating a new legislative agenda would not appear to require a five week prorogation of Parliament. That the Prime Minister was conscious that an inference might be drawn that the true purpose of the prorogation was other than it was claimed to be appears from the cabinet minute (Exhibit JGJ/3). He is there recorded as saying that it was 'important to emphasise that this decision to prorogue Parliament for a Queen's speech was not driven by Brexit considerations …'. The point was picked up in discussion during which it was observed that—

> 'any messaging should emphasise that the plan for a Queen's Speech was not intended to reduce parliamentary scrutiny or minimise Parliament's opportunity to make clear its views on Brexit. … Therefore, any suggestion that Government was using this as a tactic to frustrate Parliament should be rebutted; …'

One can protest too much, but even if Parliament is to be given an opportunity 'to make clear its views' that does not mean that it is intended that it should have the opportunity to do anything about them.

[**90**] In my opinion the justiciability question should be approached on the basis that what is challenged by the petitioners is 'a tactic to frustrate Parliament', to use the shorthand of the cabinet minute. Can and should this court declare this tactic unlawful?

[**91**] I can see that just because a government has resorted to a procedural manoeuvre in order to achieve its purpose does not mean that there is necessarily scope for judicial review. Procedural manoeuvres are the stuff of politics, whether conducted in Parliament or in lesser bodies. However, when the manoeuvre is quite so blatantly designed 'to frustrate Parliament' at such a critical juncture in the history of the United Kingdom I consider that the court may legitimately find it to be unlawful. There are undoubted difficulties in the courts applying its supervisory jurisdiction to an exercise of the royal prerogative within the political sphere, but Mr Johnston for the respondent did not go the distance of saying that there could never be a case which would justify intervention. He accepted that a two year prorogation of Parliament might be amenable to review. Here, the prorogation is only five weeks (and it is to be borne in mind that in practice the reduction of sitting days will be less because of the traditional adjournment of Parliament during the political party conference season). However, it is a lengthy prorogation at a particularly sensitive moment when time would seem to be of the essence. In my opinion Mr Mure QC for the Lord Advocate (whose analysis I accept) was right to point to the dictum of Lord Sumption in *Pham v Secretary of State for the Home Dept* [2015] UKSC 19, [2015] 3 All ER 1015, [2015] 1 WLR 1591 (at paras [105]–[106]):

> '… in reality [there is] a sliding scale, in which the cogency of the justification required for interfering with a right will be proportionate to its perceived importance and the extent of the interference.'

Here there has been interference with Parliament's right to sit, should it wish to. The petitioners want to protect that right. If Parliament does not wish to be so protected it can decide accordingly but the petitioners want to give it the opportunity to determine whether and when it is to sit between now and 31 October. The petitioners submit that as yet Parliament has not had that opportunity, notwithstanding the legislative activity that was going on during the hearing of the reclaiming motion. What has led me to conclude that the court is entitled to find the making of the Order unlawful is the extreme nature of the case. A formulation to which I have been attracted is found in Ch 14, *Crown Powers, the Royal Prerogative and Fundamental Rights*, in Wilberg & Elliott *The Scope and Intensity of Substantive Review* (Hart, 2015) at p 374 where the author of the chapter, Sales LJ, as he then was, refers to a group of authorities where the courts had been prepared to review exercises of the Crown's common law and prerogative powers. The formulation is: 'these are egregious cases where there is a clear failure to comply with generally accepted standards of behaviour of public authorities'. I see this as an egregious case. Mr O'Neill

came to submit that the essence of the illegality here was irrationality (as had been the cases with the cases referred to by Sales LJ). Mr O'Neill may be right about that, although I would see it as having to do with improper purpose. At all events, I consider the Order to be unlawful and that making it was contrary to the rule of law.

Parliament the master of its own proceedings

[**92**] Clearly Parliament is the master of its own proceedings but, as I would see it, what the petitioners seek to achieve is to allow it to act as such.

No breach of the Claim of Right Act 1689

[**93**] As previously touched on, I would agree with the Lord Ordinary on this point.

CONCLUSION

[**94**] I respectfully agree with your Lordship in the chair. The Order was unlawful and thus null and of no effect. The court should grant an order to that effect.

LORD DRUMMOND YOUNG.

INTRODUCTION

[**95**] I am grateful to your Lordship in the chair for setting out the factual background to this case. I agree with your Lordship that the reclaiming motion should be allowed and that this court should pronounce a declarator that it was *ultra vires et separatim* unconstitutional for any Minister of the Crown to purport to advise the Queen to prorogue the United Kingdom Parliament in the manner of the Order in Council reportedly pronounced on 28 August 2019.

[**96**] The critical question is whether the Government's decision to prorogue Parliament embodied in the Order in Council of 28 August was a proper exercise of the executive's power. It is a matter of agreement that the power to prorogue Parliament falls within the royal prerogative. The prerogative extends to other matters, notably foreign policy, the defence of the realm and the prerogative of mercy. Nevertheless, the power to prorogue Parliament differs from other prerogative powers in important respects. Principal among these is the fact that prorogation raises in an acute form the relationship between the executive and the legislature. That is obviously a matter of fundamental constitutional importance. Parliament is the democratically elected organ of government, and the government, the executive, is answerable to Parliament and will normally attempt to obtain majority support there. Prorogation has the effect of suspending the operation of the democratically elected body, leaving the executive for the time being free of political (as against legal) control. In this connection there is an important distinction between prorogation and Parliament's going into recess. During a recess, Parliament may reconvene itself at any time. Prorogation, by contrast, is an act of the executive, not of Parliament, and Parliament can do nothing during the period of prorogation to bring it to an end.

[**97**] In considering whether the exercise of the power to prorogue Parliament has been properly exercised, three features of the constitutional system of the United Kingdom are in my opinion of central importance: the sovereignty of Parliament, the accountability of the executive to Parliament,

and the rule of law. I will begin with a brief consideration of those principles. Thereafter I will consider whether the exercise by the executive of the power to prorogue Parliament is subject to control by the courts, and if so in what circumstances and in what manner the courts may control the exercise of the power. Finally, on the basis that the courts do have such a power, I will consider the particular decision to prorogue Parliament that is in issue in the present case: the circumstances in which the decision to prorogue has arisen, the reasons given for the decision, and whether in all the circumstances the exercise of the power is *intra vires* of the government.

Parliamentary sovereignty

[**98**] Under the constitutional system of the United Kingdom Parliament is the sovereign institution. Its sovereignty is exercised through the enactment of Acts of Parliament, which represent law binding on all persons, including the executive and other official institutions. The principle has been described as—

> 'the right to make or unmake any law whatever; and, further, that no person or body is recognized by the law … as having a right to override or set aside the legislation of Parliament.' Dicey's *Introduction to the Study of the Law of the Constitution* (8th edn, 1915) at p 38.

In the recent decision of the UK Supreme Court in *R (on the application of Miller) v Secretary of State for Exiting the European Union, Re Agnew's application for judicial review (reference by the A-G for Northern Ireland), Re McCord's application for judicial review (reference by the Court of Appeal (Northern Ireland))* [2017] UKSC 5, [2017] 1 All ER 593, [2018] AC 61, the majority of the court described Parliamentary sovereignty as 'a fundamental principle of the UK constitution', and affirmed that the legislative power of the Crown is today exercised only through Parliament: see paras [40]–[46]. Thus it is Parliament, and Parliament alone, that is empowered to effect changes in the law of the United Kingdom, either directly in an Act of Parliament or indirectly by authorizing subordinate legislation through an Act of Parliament.

The executive and Parliament

[**99**] Thus the enactment of statute law is a vital function of Parliament. Parliament has a second equally important function, namely that of holding the executive to account. The policies and actions of the government are subject to scrutiny in Parliament by Members of Parliament. The United Kingdom operates by a system of representative democracy, and it is Members of Parliament, representing the interests of their constituents and the wider interests of the country, who are responsible for ensuring that the executive operates in the national interest. In particular, Parliament is responsible for ensuring that the policies of the executive are properly considered in a democratic body, and that the actions of the executive are subject to critical scrutiny, with representatives of the government reporting on and explaining those actions. In this way Parliament performs the fundamental role of protecting the country from the arbitrary exercise or abuse of executive power. The importance of the latter function is obvious, both in the abstract and in the light of the events during the 17th century that gave rise to the principle of Parliamentary sovereignty.

The rule of law

[**100**] The importance of the rule of law should be self-evident: a system of democratic government that pays proper respect to the rights of citizens must be based on a system of rules, and those rules must be properly interpreted and consistently applied. Otherwise government is liable to descend into tyranny or anarchy. The doctrine of the sovereignty of Parliament emerged from the constitutional conflicts of the 17th century, and in particular from the settlement effected by the Revolution of 1688–90. The principle was recognized in various statutes that followed the Revolution, notably the Claim of Right Act 1689 (c 28) in Scotland, the Bill of Rights 1688 (1 Will & Mar Sess 2 c 2) and the Act of Settlement 1700 (12 & 13 Will 3 c 2) in England and Wales, and the Acts of Union of 1706 (6 Ann c 11) and 1707 (c 7) in England and Wales and in Scotland respectively. Central to the Revolution settlement, however, was the principle of the rule of law. Thus the introductory clause of the Claim of Right Act refers to King James VII's invading the fundamental constitution of the kingdom, altering it from 'a legall limited monarchy to ane Arbitrary Despotick power', and asserting an absolute power to annul and disable laws. The Bill of Rights likewise refers to the King's assuming and exercising a power of dispensing with and suspending laws without the consent of Parliament. Those two statutes reflect the fact that the rule of law is fundamental to the constitutional system of the United Kingdom.

[**101**] The maintenance of the rule of law – determining what the law is and ensuring that it is consistently applied and if necessary enforced – is a primary function of the judiciary. That is a task that must obviously be carried out with scrupulous impartiality and objectivity. Judicial independence is central to that function. The executive cannot be judge of its own powers; independent courts must be able to consider the exercise of those powers in order to determine whether such exercise is or is not *intra vires*.

JUDICIAL CONTROL OF THE POWER TO PROROGUE

[**102**] The primary submission for the respondent was that the petitioners' challenge to the exercise of the power to prorogue Parliament was non-justiciable. In my opinion this contention must be rejected. The rule of law requires that any act of the executive, or any other public institution, must be liable to judicial scrutiny to ensure that it is within the scope of the legal power under which it is exercised. The boundaries of any legal power are necessarily a matter for the courts, and the courts must have jurisdiction to determine what those boundaries are and whether they have been exceeded. That jurisdiction is constitutionally important, and in my opinion the courts should not shrink from exercising it. Consequently, if the expression 'non-justiciable' means that the courts have no jurisdiction to consider whether a power has been lawfully exercised, it is a concept that is incompatible with the rule of law and contrary to fundamental features of the constitution of the United Kingdom.

[**103**] When pressed on the meaning of the expression 'non-justiciable', counsel for the respondent conceded that in some circumstances the court might hold that the power to prorogue Parliament had not been validly exercised: for example, if Parliament were prorogued for two years, or if the governing party lost its majority at a general election and immediately thereafter attempted to prorogue Parliament. In my opinion that concession was properly made. What the concession acknowledges, however, is that the power to prorogue Parliament is subject to judicial review by the courts. For

the reasons stated in the last paragraph I am of opinion that this is inevitable: the courts must have jurisdiction to determine whether any power, under the prerogative or otherwise, has been legally exercised.

The grounds for judicial control

[**104**] The grounds for judicial control of the exercise of prerogative powers are in my opinion broadly the same as those used in other cases of judicial review of executive action, subject to one important qualification, that the court should not interfere with the substantive political grounds for the exercise of prerogative power provided that the power is used for a proper purpose. The grounds for judicial review are well known and do not require to be restated; they include *ultra vires* in the narrow sense and the use of a power for an improper purpose: something that does not fall within the purposes that the power, construed objectively, is intended to achieve. Those grounds are legal in nature, however, and do not normally go to policy questions, including political matters. In judicial review, the primary decision maker is a body or person other than the court, and the court only has jurisdiction to review the legality of a decision, not its merits. In relation to the prorogation of Parliament, this feature is particularly important, as a decision to prorogue Parliament is likely to be based on political considerations. This may make it difficult to apply standards such as proportionality, which does involve consideration of the merits of a decision. Nevertheless, standards of review are flexible, and in appropriate circumstances it would be possible for a court to hold that a decision by the executive to exercise a prerogative power is one that no reasonable person in that position could exercise: see, for example, *Pham v Secretary of State for the Home Dept* [2015] UKSC 19, [2015] 3 All ER 1015, [2015] 1 WLR 1591, in particular at paras [105]–[107]. For present purposes, it is not necessary to go so far; it is sufficient to hold that the court has jurisdiction to consider whether the exercise of a power, including a prerogative power, is *ultra vires*, or whether such a power is used for a purpose that is objectively outwith its intended scope.

[**105**] Counsel for the respondent submitted that the court should not interfere with the present decision to prorogue Parliament on the ground that it amounted to 'high policy'. The expression 'high policy' has not, so far as I am aware, been judicially defined; it has been used in a number of cases, but generally as a convenient label in a case where the court considers that the executive decision in question is too political for the court to interfere with. The court must not stray into the political aspects of any executive decision, especially one in exercise of the prerogative, but in my opinion it must still apply legal standards in the manner described in the last paragraph.

Parliamentary control

[**106**] It does not follow, that the actions of the executive, and in particular its use of prerogative powers, are subject to no political control. Political control over such actions is exercised by Parliament through its scrutiny of the actions of government. This includes such matters as Parliament's power to call for debates on controversial matters or to question ministers about their decisions. As I have indicated, parliamentary scrutiny of executive decisions is one of the essential features of the constitutional arrangements of the United Kingdom. Thus the government is held to account in two distinct ways: legally by the courts and politically, or on policy grounds, by Parliament. With the

prorogation of Parliament, however, this leads to a paradox. The proroguing of Parliament suspends the operation of the body that is responsible for subjecting the executive to critical scrutiny. Consequently during the period of prorogation formal political scrutiny of the executive cannot take place. This in my opinion makes it particularly important that the courts should ensure that the power to prorogue Parliament is only used in a proper manner and for proper purposes. The courts cannot subject the actings of the executive to political scrutiny, but they can and should ensure that the body charged with performing that task, Parliament, is able to do so.

[**107**] On the subject of prorogation, I should note one further matter. Prorogation is an act of the executive acting through the Crown. Parliament has no power to revoke it. This should be contrasted with Parliament's going into recess. That is a decision of Parliament itself, and a recess can be revoked by Parliament at any time. Recesses take place regularly, for example, during the summer and over the party conference season in the autumn. The power to reconvene Parliament at any time provides important flexibility. This is absent from prorogation. This explains in part why prorogation is in practice normally only used for very short periods, generally to begin a new Parliamentary session.

Previous cases of prorogation

[**108**] So far as I am aware the prorogation of Parliament has never been the subject of judicial challenge. Prorogation is used regularly to bring sittings of Parliament to an end and begin a new session. When that occurs, however, the suspension of Parliament usually only lasts for a few days. Furthermore, we were not referred to any case where prorogation was used at a time of acute political controversy in such a way that Parliamentary debate was suspended for several weeks during a critical period. In my opinion the standard use of prorogation to begin a new Parliamentary session is not in any way a precedent for the prorogation that is now proposed. Occasionally prorogation has been used for other purposes, to achieve political objectives rather than merely the routine change in sessions of Parliament. We were referred to one particular example of this, the two prorogations that occurred in 1948 to enable the Bill that ultimately became the Parliament Act 1949 to pass through Parliament notwithstanding opposition by the House of Lords. The Bill had been rejected by the House of Lords, and was likely to be rejected by them on subsequent votes. At that time, under the Parliament Act 1911, it was only a rejection of a bill by the House of Lords in three consecutive sessions that permitted use of the Parliament Act procedure to pass the bill notwithstanding its rejection by the Lords. Prorogation was therefore used to provide for three sessions of Parliament in quick succession, to enable the Bill to proceed to Royal assent. The use of prorogation in that way was not challenged in the courts, perhaps for obvious reasons. What this case illustrates is that the examples where prorogation has been used for more than formal purposes are highly unusual, and cannot serve as a precedent for later use of the power.

THE GOVERNMENT'S DECISION TO PROROGUE PARLIAMENT EFFECTED BY THE ORDER IN COUNCIL OF 28 AUGUST 2019

[**109**] As already noted, the primary question in the present case is whether the government's decision to prorogue Parliament, as effected by the Order in Council of 28 August 2019, was *intra vires* of the Crown's prerogative powers,

and in particular whether it was a proper exercise of the power of prorogation. It is a matter of agreement that the decision to prorogue, although effected by the Crown through an Order in Council, results from a decision of the government. In considering whether that decision was a proper exercise of the power to prorogue, it is essential in my opinion to have regard to the legal and political context in which it was made.

[**110**] Central to that context is the notice that has been given by the United Kingdom in terms of art 50 of the Treaty on European Union to leave that body. After extensions, it is now due to take effect on 31 October 2019. The effect of the decision in *R (Miller) v Secretary of State for Exiting the European Union*, *supra*, was that legislation was required to effect the United Kingdom's withdrawal from the European Union, and that was in due course enacted by Parliament, in the form of the European Union (Withdrawal) Act 2018 (2018 c 16). Section 13 of that Act provides that the terms of any withdrawal agreement between the United Kingdom and the European Union require Parliamentary approval in order to become law within the United Kingdom. If, however, no such approval is obtained, the result will be that the United Kingdom's withdrawal still takes effect, but without any formal arrangements to govern the future relationship between the United Kingdom and European Union – on a so-called 'no deal' basis. If a withdrawal agreement is not approved by Parliament, that is the default position.

[**111**] This is potentially a matter of great importance. The law of the European Union covers large areas of legal practice. The European Union (Withdrawal) Act provides that EU legislation will continue in force in the United Kingdom, but of itself that has no effect on the international relationships of the United Kingdom with the remaining member states of the EU, and to a considerable extent with third countries, where trading and other relationships are at present governed by EU treaties. Those international problems cover a number of important areas of law. These include international trade, financial services, transport, customs, trading standards (which at present apply internationally), nuclear energy, immigration, asylum, criminal justice, particularly in the area of extradition, and the recognition of foreign judgments and other legal acts.

[**112**] The United Kingdom government has engaged in negotiations with the European Union over the terms of a withdrawal agreement, and ultimately concluded such an agreement in the early part of 2019. For the agreement to take effect, however, it required to be approved by Parliament. On three occasions Parliament refused to give its approval by substantial majorities. Notwithstanding those defeats in Parliament the government, with a new Prime Minister and government, has continued to negotiate with the European Union over the terms of a proposed withdrawal agreement to take effect after 31 October 2019. The change of government has been significant, however, because the present Prime Minister has declared that he would be willing to withdraw from the EU without a withdrawal agreement, a view that appears to be supported by a majority of his government. His predecessor, by contrast, had negotiated a withdrawal agreement and focussed on trying to have that approved by Parliament, although in that she was unsuccessful. Extensive preparations are currently being made for withdrawal from the EU on 31 October, including legislation and administrative arrangements to deal with the possibility that the United Kingdom might leave the EU without any withdrawal agreement. So far those arrangements, together with the legislation, have been the subject of Parliamentary scrutiny.

The decision to prorogue and parliamentary scrutiny

[**113**] In these circumstances, it is obvious that the United Kingdom's withdrawal from the European Union, and the terms on which that withdrawal is effected, if any, are a matter of immense national importance. It is therefore not surprising that within Parliament the matter has been the subject of extensive debate and a great deal of controversy. It has become apparent that a majority of Members are opposed to the United Kingdom's leaving the EU without a withdrawal agreement. This has resulted in the passing of legislation that will compel the Prime Minister to seek an extension to the withdrawal process if no agreement is reached with the EU before 19 October 2019, in the form of the European Union (Withdrawal) (No 2) Act 2019, which received Royal assent on 9 September 2019.

[**114**] Apart from legislation, however, it is apparent that the United Kingdom's withdrawal from the EU and its future relationship with the EU are the subject of vigorous debate and controversy. The controversy goes beyond the terms of any withdrawal agreement or the lack of it. It extends to the arrangements that will be put in place in the United Kingdom either to implement a future withdrawal agreement or to address the consequences of withdrawal on a 'no-deal' basis. These are themselves complex matters, and preparations for a 'no-deal' withdrawal are widely reported as involving a great deal of work by the civil service. At such a time Parliament's second essential constitutional function, the scrutiny of the executive, is of paramount importance.

[**115**] The decision to prorogue Parliament was given effect by the Order in Council of 28 August 2019. Its effect is that Parliament will be prorogued from Monday 9 September. A Queen's Speech will take place on Monday 14 October. During the intervening period of five weeks, Parliament will sit on certain days by virtue of provisions of the Northern Ireland (Executive Formation etc) Act 2019 (c 22), but these are limited in number and are in any event related to the formation of an executive in Northern Ireland. The effect of prorogation will accordingly be to prevent Parliament from sitting, except to a very limited extent, during the five-week period between 9 September and 14 October. The United Kingdom is due to leave the European Union on 31 October. Consequently the effect of prorogation is to reduce the sitting time of Parliament by five weeks during the period of approximately seven weeks between the date when prorogation takes effect and Britain's leaving the EU. That is clearly a material reduction in the time available for Parliamentary debate. That is so even if the sittings mandated by the Northern Ireland (Executive Formation etc) Act 2019 are taken into account; these are clearly of limited utility.

[**116**] The effect of proroguing Parliament is to prevent, or at least to limit severely, the ability of Parliament to perform its essential function of holding the executive to account. During a vital period of five weeks Parliament will be prevented from performing that function. Seven weeks after Parliament is prorogued the United Kingdom is scheduled to leave the European Union, with or without a withdrawal agreement. Such lack of scrutiny may be convenient for the government. Nevertheless, it is taking place at a time when matters of great national importance fall to be decided. It extends over most of the period during which Parliamentary debate or the questioning of ministers in Parliament might have a practical effect in relation to the basis of which the United Kingdom might leave the EU. When regard is had both to the circumstances at the time of prorogation and its duration, I am of opinion that

it is incumbent on the government to show that it has a valid reason for proroguing Parliament in that manner. In reaching that conclusion, I have particular regard to the fundamental constitutional importance of Parliamentary scrutiny of executive action.

[**117**] Prorogation has the effect of bringing Parliamentary scrutiny to an end, and thus in the event of challenge any reason for proroguing must be supplied to the court. If no reason is given, in the present circumstances I am of opinion that the decision to prorogue Parliament for five weeks out of the seven remaining before the United Kingdom is scheduled to leave the European Union leads inevitably to the conclusion that the reason for prorogation was to prevent Parliamentary scrutiny of the government. I find it impossible to see that it could serve any other rational purpose. The respondent's pleadings say almost nothing about the reason for the prorogation, and the court was not provided with any other formal statement of the reasons. It was provided, however, with the documentation behind the decision to prorogue, and I will now consider the reasons disclosed by that documentation.

The reasons given for prorogation

[**118**] Three documents were made available. The first is a memorandum from Nikki da Costa, the Prime Minister's Director of Legislative Affairs, dated 15 August 2019. This is set out in the opinion of your Lordship in the chair. I would draw attention to the following passage:

> 'RECOMMENDATION
>
> 2. Are you content for your PPS to approach the Palace with a request for prorogation to begin within the period Monday 9th September to Thursday 12th September, and for a Queen's Speech on Monday 14th October?
>
> DEADLINE
>
> 3. 16 August – with only two months until 14th October it would be wise to open discussions this week, with the aim of securing confirmation next week. …'

The memorandum goes on to discuss a number of other factors, including political considerations and precedents for prorogation. Next to the recommendation quoted above there is a tick and the word 'yes'; we were informed that these were written by the Prime Minister.

[**119**] The memorandum of 15 August was accompanied by the Prime Minister's comments, made on 16 August:

> '(1) The whole September session is a rigmarole introduced [redaction] to show the public that MPs were earning their crust
>
> (2) So I don't see anything especially shocking about this prorogation
>
> (3) As Nikki notes, it is OVER THE CONFERENCE SEASON so that the sitting days lost are actually very few.'

The tenor of these comments suggests a desire to excuse the length of the prorogation. It is perhaps worth observing that the September session is an established feature of modern Parliamentary procedure. During the period of the party conferences in the early autumn Parliament goes into recess; it is not prorogued. This means that if necessary it can resume sitting at any time.

[**120**] In neither the memorandum nor the Prime Minister's comments is any actual reason for the prorogation given other than a desire to begin a new

session of Parliament with, as is customary, a Queen's Speech in which the government's legislative programme is set out. Reference is made to the fact that the legislative programme for the present session of Parliament is nearly at an end, which would provide a valid reason for starting a new session. No attempt is made, however, to explain why a prorogation of five weeks is necessary at a time of acute national controversy. The critical complaint about the prorogation is not the fact that it occurred; short prorogation is regularly used to start new Parliamentary sessions. The complaint rather relates to the length of the period during which Parliament is to be prorogued, without any power to resume sitting during that period.

[**121**] The second document made available, also emanating from Nikki da Costa, is a memorandum to the Prime Minister dated 23 August 2019 headed 'ANNOUNCING THE QUEEN'S SPEECH'. This document is concerned primarily with the timing of announcements made in connection with the prorogation and the intention to announce a new session of Parliament with a Queen's Speech on 14 October. Attached to it is an annex, Annex B, which appears to contain text for an announcement by the Prime Minister. In Annex B it is stated that Parliament has been in session for an especially long time, 340 sitting days; but that had involved 'too much drift for too long'; and that the Prime Minister intended to bring forward a new legislative agenda for the period before and after leaving the European Union. The main part of the legislative programme is said to be a Withdrawal Agreement Bill, and it was intended to have that bill passed before 31 October. Once again, the tenor of the document suggests that the need for a new legislative programme is being put forward as the reason for prorogation, but no attempt is made to explain why a prorogation of five weeks is required for this purpose.

[**122**] The third document that was made available was the minutes of a Cabinet meeting held on 28 August. Your Lordship in the chair has set out the terms of this document at some length. Once again, no reason is given for the length of the period during which Parliament is to be prorogued. It is noted that the timetable gave Parliament 'ample time to debate Brexit in the period before the October European Council on 17–18 October, and again in the run up to the UK's departure date on 31 October'. In relation to those timings, the available periods are between 14 October, when the Queen's Speech was to be delivered, and 17 October. That ignores the fact that discussion of the Queen's Speech is likely to take a substantial part of that period. In any event it does not provide any justification as to why the prorogation requires to start five weeks before that, especially if anything said in Parliament is to have an effect on the United Kingdom's negotiating position at the European Council meeting. Similarly, in relation to the period between the Council meeting and the date, 31 October, when the United Kingdom is scheduled to leave the European Union, the time involved is not great, and it is difficult to understand how any debate at that late stage would have a significant effect on the terms of departure from the EU.

Conclusion as to the purpose of proroguing Parliament

[**123**] In my opinion nothing in these documents can be said to provide any rational explanation as to why Parliament must be prorogued as early as 9 September for a period of five weeks. Nor has any other explanation been provided for the length of the prorogation, beyond references to the need to begin a new session of Parliament to promote a new legislative programme.

That, of course, does not explain the length of the prorogation; merely the fact that prorogation is required. In these circumstances I have come to the conclusion that the only inference that can properly be drawn on an objective basis is that the government, and the Prime Minister in particular, wished to restrict debate in Parliament for as long as possible during the period leading up to the European Council meeting on 17–18 October and the scheduled date of Britain's departure from the European Union.

[**124**] It would be wrong to speculate as to whether this is because the government wishes to persuade the European Union to accept a withdrawal agreement that differs from the agreement previously concluded or whether the government is truly intent on achieving departure from the European Union without a withdrawal agreement. In either event, the matter clearly calls for Parliamentary scrutiny. The effect of the prorogation under consideration, in particular its length, is that proper Parliamentary scrutiny is rendered all but impossible. As I have noted, I consider that the inference must inevitably be drawn, on a strictly objective basis, that that was the purpose of the prorogation. In my opinion that is not a proper purpose for proroguing Parliament. I accordingly conclude that the decision to prorogue contained in the Order in Council of 28 August 2019 was not a proper exercise of the prerogative power. It follows that the prorogation was *ultra vires*. In my opinion the court should pronounce a declarator to that effect.

[**125**] Finally, I should express concurrence with the views of your Lordship in the chair on the question of redaction of documents supplied and the proposition that proroguing Parliament does not have a direct effect on individual legal rights.

Reclaiming motion allowed.

Appeals

R (on the application of Miller) v Prime Minister

The claimant, Gina Miller, appealed from the judgment of the Divisional Court (Lord Burnett CJ, Sir Terence Etherton MR and Dame Victoria Sharp P) of 11 September 2019 ([2019] EWHC 2381 (QB), [2019] All ER (D) 24 (Sep) (set out above)) dismissing her claim seeking judicial review of the decision of the United Kingdom Prime Minster, the Rt Hon Boris Johnson MP, to advise Her Majesty the Queen to prorogue Parliament from a date between 9 and 12 September until 14 October 2019. The following parties intervened: (1) the Lord Advocate on behalf of the Scottish Government; (2) Raymond McCord; (3) Counsel General for Wales; (4) Sir John Major KG, CH; (5) Baroness Chakrabarti CBE, PC; and (6) the Public Law Project. The facts are set out in the judgment of the court.

Cherry and others v Advocate General for Scotland

The Advocate General for Scotland appealed from the judgment of the First Division, Inner House, Court of Session (Scotland) (Lord President (Carloway), Lord Brodie and Lord Drummond Young) of 13 September 2019 ([2019] CSIH 49 (set out above)) allowing the reclaiming motion (appeal) of the petitioners and reclaimers, Joanna Cherry QC MP and 78 others, against the decision of the Lord Ordinary (Lord Doherty) in the Outer House, Court of Session of 4 September 2019 ([2019] CSOH 70 (set out above)) refusing their petition for

judicial review against the decision of the United Kingdom Prime Minster, the Rt Hon Boris Johnson MP, to advise Her Majesty the Queen to prorogue Parliament from a date between 9 and 12 September until 14 October 2019. The following parties intervened: (1) the Lord Advocate on behalf of the Scottish Government; (2) Raymond McCord; (3) Counsel General for Wales; (4) Sir John Major KG, CH; (5) Baroness Chakrabarti CBE, PC; and (6) the Public Law Project. The facts are set out in the judgment of the court.

Lord Pannick QC, Tom Hickman QC and *Warren Fitt* (instructed by *Mishcon de Reya LLP*) for the claimant in the *Miller* case.

Sir James Eadie QC, David Blundell, Christopher Knight and *Richard Howell* (instructed by the *Government Legal Department*) for the Prime Minister.

Lord Keen of Elie QC and *Andrew Webster QC* (instructed by the *Office of the Advocate General for Scotland*) for the Advocate General.

Aidan O'Neill QC, David Welsh and *Sam Fowles* (instructed by *Balfour and Manson LLP*) for the petitioners in the *Cherry* case.

James Wolffe QC (Lord Advocate), *James Mure QC* and *Christine O'Neill* (instructed by the *Legal Department of the Scottish Government*) for the first intervener.

Ronan Lavery QC, Conan Fegan BL and *Richard Smyth* (instructed by *McIvor Farrell Solicitors*) for the second intervener.

Michael Fordham QC, Celia Rooney and *Hollie Higgins* (instructed by the *Welsh Government Legal Services Department*) for the third intervener.

Lord Garnier QC, Tom Cleaver and *Anna Hoffmann* (instructed by *Herbert Smith Freehills LLP*) for the fourth intervener.

Deok Joo Rhee QC and *Catherine Dobson* (instructed by *Howe and Co*) for the fifth intervener (written submissions only).

Thomas de la Mare QC, Daniel Cashman and *Alison Pickup* (instructed by the *Public Law Project*) for the sixth intervener (written submissions only).

Judgment was reserved.

24 September 2019. The following judgment was delivered.

LADY HALE P AND LORD REED DP GIVING THE JUDGMENT OF THE COURT.

[**1**] It is important to emphasise that the issue in these appeals is not when and on what terms the United Kingdom is to leave the European Union. The issue is whether the advice given by the Prime Minister to Her Majesty the Queen on 27 or 28 August 2019 that Parliament should be prorogued from a date between 9 and 12 September until 14 October was lawful. It arises in circumstances which have never arisen before and are unlikely ever to arise again. It is a 'one off'. But our law is used to rising to such challenges and supplies us with the legal tools to enable us to reason to a solution.

WHAT IS PROROGATION?

[**2**] Parliamentary sittings are normally divided into sessions, usually lasting for about a year, but sometimes less and sometimes, as with the current session, much longer. Prorogation of Parliament brings the current session to an end. The next session begins, usually a short time later, with the Queen's Speech. While Parliament is prorogued, neither House can meet, debate and pass legislation. Neither House can debate Government policy. Nor may

members of either House ask written or oral questions of Ministers. They may not meet and take evidence in committees. In general, Bills which have not yet completed all their stages are lost and will have to start again from scratch in the next session of Parliament. In certain circumstances, individual Bills may be 'carried over' into the next session and pick up where they left off. The Government remains in office and can exercise its powers to make delegated legislation and bring it into force. It may also exercise all the other powers which the law permits. It cannot procure the passing of Acts of Parliament or obtain Parliamentary approval for further spending.

[**3**] Parliament does not decide when it should be prorogued. This is a prerogative power exercised by the Crown on the advice of the Privy Council. In practice, as noted in the House of Commons Library Briefing Paper (No 8589, 11 June 2019), 'this process has been a formality in the UK for more than a century: the Government of the day advises the Crown to prorogue and that request is acquiesced to'. In theory the monarch could attend Parliament and make the proclamation proroguing it in person, but the last monarch to do this was Queen Victoria in 1854. Under current practice, a proclamation is made by Order in Council a few days before the actual prorogation, specifying a range of days within which Parliament may be prorogued and the date on which the prorogation would end. The Lord Chancellor prepares a commission under the great seal instructing the Commissioners accordingly. On the day chosen for the prorogation, the Commissioners enter the House of Lords; the House of Commons is summoned; the command of the monarch appointing the Commission is read; and Parliament is formally prorogued.

[**4**] Prorogation must be distinguished from the dissolution of Parliament. The dissolution of Parliament brings the current Parliament to an end. Members of the House of Commons cease to be Members of Parliament. A general election is then held to elect a new House of Commons. The Government remains in office but there are conventional constraints on what it can do during that period. These days, dissolution is usually preceded by a short period of prorogation.

[**5**] Dissolution used also to be a prerogative power of the Crown but is now governed by the Fixed-term Parliaments Act 2011. This provides for general elections to be held every five years and for an earlier election to be held in only two circumstances: either the House of Commons votes, by a majority of at least two-thirds of the number of seats (including vacant seats) in the House, to hold an early election; or the House of Commons votes that it has no confidence in Her Majesty's Government and no-one is able to form a Government in which the House does have confidence within 14 days. Parliament is dissolved 25 days before polling day and cannot otherwise be dissolved. The Act expressly provides that it does not affect Her Majesty's power to prorogue Parliament (s 6(1)).

[**6**] Prorogation must also be distinguished from the House adjourning or going into recess. This is decided, not by the Crown acting on the advice of the Prime Minister, but by each House passing a motion to that effect. The Houses might go into recess at different times from one another. In the House of Commons, the motion is moved by the Prime Minister. In the House of Lords, it is moved by the Lord Speaker. During a recess, the House does not sit but Parliamentary business can otherwise continue as usual. Committees may meet, written Parliamentary questions can be asked and must be answered.

THE RUN-UP TO THIS PROROGATION

[**7**] As everyone knows, a referendum was held (pursuant to the European Union Referendum Act 2015) on 23 June 2016. The majority of those voting voted to leave the European Union. Technically, the result was not legally binding. But the Government had pledged to honour the result and it has since been treated as politically and democratically binding. Successive Governments and Parliament have acted on that basis. Immediately after the referendum, Mr David Cameron resigned as Prime Minister. Mrs Theresa May was chosen as leader of the Conservative party and took his place.

[**8**] The machinery for leaving the European Union is contained in art 50 of the Treaty on European Union. This provides that any member state may decide to withdraw from the Union 'in accordance with its own constitutional requirements'. That member state is to notify the European Council of its intention. The Union must then negotiate and conclude an agreement with that member state, 'setting out the arrangements for its withdrawal, taking account of the framework for its future relationship with the Union'. The European Union treaties will cease to apply to that state when the withdrawal agreement comes into force or, failing that, two years after the notification unless the European Council, in agreement with the member state, unanimously decides to extend this period.

[**9**] On 2 October 2016, Mrs May announced her intention to give notice under art 50 before the end of March 2017. Mrs Gina Miller and others challenged her power to do so without the authority of an Act of Parliament. That challenge succeeded: *R (on the application of Miller) v Secretary of State for Exiting the European Union, Re Agnew's application for judicial review (reference by the A-G for Northern Ireland), Re McCord's application for judicial review (reference by the Court of Appeal (Northern Ireland))* [2017] UKSC 5, [2017] 1 All ER 593, [2018] AC 61. Parliament responded by passing the European Union (Notification of Withdrawal) Act 2017, which received royal assent on 16 March 2017 and authorised the Prime Minister to give the notification. Mrs May did so on 29 March 2017.

[**10**] That Parliament was dissolved on 3 May 2017 and a general election was held on 8 June 2017. The result was that Mrs May no longer had an overall majority in the House of Commons, but she was able to form a Government because of a 'confidence and supply' agreement with the Democratic Unionist Party of Northern Ireland. Negotiations for a withdrawal agreement with the European Council proceeded.

[**11**] Meanwhile, Parliament proceeded with some of the legislative steps needed to prepare United Kingdom law for leaving the Union. The European Union (Withdrawal) Act 2018 came into force on 26 June 2018. In brief, it defined 'exit day' as 29 March 2019, but this could be extended by statutory instrument (s 20). From that day, it repealed the European Communities Act 1972, the Act which had provided for our entry into what became the European Union, but it preserved much of the existing EU law as the law of the United Kingdom, with provision for exceptions and modifications to be made by delegated legislation. Crucially, s 13 requires Parliamentary approval of any withdrawal agreement reached by the Government. In summary it provides that a withdrawal agreement may only be ratified if (a) a Minister of the Crown has laid before Parliament a statement that political agreement has been reached, a copy of the negotiated withdrawal agreement and a copy of the framework for the future relationship; (b) the House of Commons has approved the withdrawal agreement and future framework; (c) the House of

Lords has, in effect, taken note of them both; and (d) an Act of Parliament has been passed which contains provision for the implementation of the withdrawal agreement.

[**12**] A withdrawal agreement, setting out terms for a 'smooth and orderly exit from the European Union' and a political declaration, setting out a framework for the future relationship, to be negotiated by the end of 2020, were concluded on 25 November 2018. However, the agreement was rejected three times by the House of Commons, on 15 January 2019 (by 432 to 202 votes), on 12 March 2019 (by 391 to 242 votes) and on 29 March 2019 (by 344 to 286 votes).

[**13**] On 20 March 2019, the Prime Minister had asked the European Council to extend the notification period. This was granted only until 12 April 2019. However, on 8 April 2019, the European Union (Withdrawal) Act 2019 was passed. This required a Minister of the Crown to move a motion, that day or the next, that the House of Commons agrees to the Prime Minister seeking an extension to a specified date and, if the motion was passed, required the Prime Minister to seek that extension. Pursuant to that Act, the Prime Minister sought an extension, which on 10 April 2019 was granted until 31 October 2019. The regulation changing the 'exit day' was made the next day (European Union (Withdrawal) Act 2018 (Exit Day) (Amendment) (No 2) Regulations 2019, SI 2019/859). Thus the current position, under both art 50 of the Treaty on European Union and the European Union (Withdrawal) Act 2018 is that the United Kingdom will leave the Union on 31 October 2019 whether or not there is a withdrawal agreement (but this is now subject to the European Union (Withdrawal) (No 2) Act 2019: see para [22] below).

[**14**] Mrs May resigned as leader of the Conservative party on 7 June 2019 and stood down as Prime Minister on 24 July, after the Conservative party had chosen Mr Boris Johnson as its leader. Mr Johnson has on many occasions made it clear that he believes that the European Council will only agree to changes in the withdrawal agreement if they think that there is a genuine risk that the United Kingdom will leave without any such agreement. He appointed Mr Michael Gove Cabinet Office Minister with a view to preparing for a 'no deal' exit. Yet it was also clear that a majority of the House of Commons would not support withdrawal without an agreement.

THIS PROROGATION

[**15**] On 28 August 2019, Mr Jacob Rees-Mogg, Lord President of the (Privy) Council and Leader of the House of Commons, Baroness Evans of Bowes Park, Leader of the House of Lords, and Mr Mark Spencer, Chief Whip, attended a meeting of the Privy Council held by the Queen at Balmoral Castle. An Order in Council was made ordering that 'the Parliament be prorogued on a day no earlier than Monday the 9th day of September and no later than Thursday the 12th day of September 2019 to Monday the 14th day of October 2019' and that the Lord Chancellor 'do cause a Commission to be prepared and issued in the usual manner for proroguing the Parliament accordingly'. We know that in approving the prorogation, Her Majesty was acting on the advice of the Prime Minister. We do not know what conversation passed between them when he gave her that advice. We do not know what conversation, if any, passed between the assembled Privy Counsellors before or after the meeting. We do not know what the Queen was told and cannot draw any conclusions about it.

[**16**] We do know the contents of three documents leading up to that advice, annexed to a witness statement from Jonathan Jones, Treasury Solicitor and Head of the Government Legal Department. His evidence is that his department had made clear to all relevant departments, including the Prime Minister's Office, the requirement to make thorough searches for and to produce all information relevant to Mrs Miller's claim.

[**17**] The first document is a Memorandum dated 15 August 2019 from Nikki da Costa, Director of Legislative Affairs in the Prime Minister's Office, to the Prime Minister and copied to seven other people, including Sir Mark Sedwill, Cabinet Secretary, and Dominic Cummings, Special Adviser. The key points made in the Memorandum are:

- This had been the longest session since records began. Because of this, they were at the very end of the legislative programme of the previous administration. Commons and Lords business managers were asking for new Bills to ensure that Parliament was using its time gainfully. But if new Bills were introduced, the session would have to continue for another four to six months, or the Bills would fall at the end of the session.
- Choosing when to end the session – ie prorogue – was a balance between 'wash up' – completing the Bills which were close to Royal Assent – and 'not wasting time that could be used for new measures in a fresh session'. There were very few Bills suitable for 'wash-up', so this pointed to bringing the session to a close in September. Asking for prorogation to commence within the period 9 to 12 September was recommended.
- To start the new session with a Queen's Speech would be achievable in the week beginning 14 October but any earlier 'is extremely pressured'.
- Politically, it was essential that Parliament was sitting before and after the EU Council meeting (which is scheduled for 17–18 October). If the Queen's Speech were on 14 October, the usual six-day debate would culminate in key votes on 21 and 22 October. Parliament would have the opportunity to debate the Government's overall approach to Brexit in the run up to the EU Council and then vote on it once the outcome of the Council was known.
- It must be recognised that 'prorogation, on its own and separate of a Queen's Speech, has been portrayed as a potential tool to prevent MPs intervening prior to the UK's departure from the EU on 31st October'. The dates proposed sought to provide reassurance by ensuring that Parliament would sit for three weeks before exit and that a maximum of seven days were lost apart from the time usually set aside for the conference recess.
- The usual length of a prorogation was under ten days, though there had been longer ones. The present proposal would mean that Parliament stood prorogued for up to 34 calendar days but, given the conference recess, the number of sitting days lost would be far less than that.
- The Prime Minister ticked 'Yes' to the recommendation that his PPS approach the Palace with a request for prorogation to begin within the period Monday 9 September to Thursday 12 September and for a Queen's Speech on Monday 14 October.

[**18**] The second document is the Prime Minister's handwritten comments on the Memorandum, dated 16 August. They read:

> '(1) The whole September session is a rigmarole introduced [words redacted] t [sic] show the public that MPs were earning their crust.
>
> (2) So I don't see anything especially shocking about this prorogation.

(3) As Nikki nots [sic], it is OVER THE CONFERENCE SEASON so that the sitting days lost are actually very few.'

[**19**] The third document is another Memorandum from Nikki da Costa, dated 23 August, again to the Prime Minister and copied to five people, including Sir Mark Sedwill and Dominic Cummings. This sets out the proposed arrangements, including a telephone call between the Prime Minister and Her Majesty at 6.00 pm on Tuesday 27 August, formally to advise prorogation, the Privy Council meeting the next day, a cabinet meeting by conference call after that, and a press notice after that. Draft remarks for the Cabinet meeting and a draft letter to MPs (approved by the Chief Whip) were annexed.

[**20**] We also have the Minutes of the Cabinet meeting held by conference call at 10.05 am on Wednesday 28 August, after the advice had been given. The Prime Minister explained that it was important that they were 'brought up to speed' on the decisions which had been taken. It was also 'important to emphasise that this decision to prorogue Parliament for a Queen's Speech was not driven by Brexit considerations: it was about pursuing an exciting and dynamic legislative programme to take forward the Government's agenda'. He also explained that the timetable did not conflict with the statutory responsibilities under the Northern Ireland (Executive Formation etc) Act 2019 (as it happens, the timetable for Parliamentary sittings laid down in s 3 of that Act requires that Parliament sit on 9 September and, on one interpretation, no later than 14 October). He acknowledged that the new timetable would impact on the sitting days available to pass the Northern Ireland Budget Bill and 'potentially put at risk the ability to pass the necessary legislation relating to decision-making powers in a no deal scenario'. In discussion at the Cabinet meeting, among the points made was that 'any messaging should emphasise that the plan for a Queen's Speech was not intended to reduce parliamentary scrutiny or minimise Parliament's opportunity to make clear its views on Brexit. … Any suggestion that the Government was using this as a tactic to frustrate Parliament should be rebutted'. In conclusion, the Prime Minister said that 'there were no plans for an early General Election. This would not be right for the British people: they had faced an awful lot of electoral events in recent years'.

[**21**] That same day, the Prime Minister sent a letter to all MPs updating them on the Government's plans for its business in Parliament, stressing his intention to 'bring forward a new bold and ambitious domestic legislative agenda for the renewal of our country after Brexit'.

[**22**] On 3 September Parliament returned from its summer recess. The House of Commons passed a motion that MPs should take control of the order paper – in other words decide for themselves what business they would transact. On 4 September what became the European Union (Withdrawal) (No 2) Act 2019 passed all its stages in the House of Commons. On 6 September the House of Lords suspended its usual rules so that the Bill could be passed. It received Royal Assent on Monday 9 September. The import of the Act is to require the Prime Minister on 19 October to seek, by a letter in the form scheduled to the Act, an extension of three months from the European Council, unless by then Parliament has either approved a withdrawal agreement or approved leaving without one.

THESE PROCEEDINGS

[**23**] Meanwhile, on 30 July 2019, prompted by the suggestion made in academic writings in April and also by some backbench MPs, and not denied by

members of the Government, that Parliament might be prorogued so as to avoid further debate in the run-up to exit day, a cross party group of 75 MPs and members of the House of Lords, together with one QC, had launched a petition in the Court of Session in Scotland claiming that such a prorogation would be unlawful and seeking a declaration to that effect and an interdict to prevent it. This was met by averments that the petition was hypothetical and premature and that there was no reasonable or even hypothetical apprehension that the UK Government intended to advise the Queen to prorogue the Westminster Parliament with the intention of denying before Exit Day any further Parliamentary consideration of withdrawal from the Union. This denial was repeated in revised Answers dated 23 and 27 August. On 27 August the Petition was amended to claim that it would be unlawful to prorogue Parliament with the intention to deny 'sufficient time for proper consideration' of withdrawal. On 2 September, the Answers were amended to deny that there was any reasonable apprehension of that.

[**24**] On 30 August, the Lord Ordinary, Lord Doherty, refused an application for an interim interdict to prevent the now very far from hypothetical prorogation and set the date of 3 September for the substantive hearing: [2019] CSOH 68. On 4 September, he refused the petition, on the ground that the issue was not justiciable in a court of law: [2019] CSOH 70. The Inner House (Lord Carloway, Lord President, Lord Brodie and Lord Drummond Young) heard the appeal later that week, delivered their decision with a summary of their reasons on 11 September, and their full judgments were published on Friday, 13 September: [2019] CSIH 49. They allowed the appeal, holding that the advice given to Her Majesty was justiciable, that it was motivated by the improper purpose of stymying Parliamentary scrutiny of the executive, and that it and the prorogation which followed it were unlawful and thus null and of no effect. They gave permission to appeal to this court.

[**25**] Meanwhile, as soon as the prorogation was announced, Mrs Gina Miller launched proceedings in the High Court in England and Wales, seeking a declaration that the Prime Minister's advice to her Majesty was unlawful. Those proceedings were heard by a Divisional Court (Lord Burnett of Maldon, Lord Chief Justice of England and Wales, Sir Terence Etherton, Master of the Rolls, and Dame Victoria Sharp, President of the Queen's Bench Division) on 5 September and their judgment was delivered on 11 September: [2019] EWHC 2381 (QB). They dismissed the claim on the ground that the issue was not justiciable. They granted a 'leap-frog' certificate so that the case could come directly to this court.

[**26**] This Court heard the appeals in *Cherry* and in *Miller* over 17 to 19 September. In addition to the written and oral submissions of the principal parties, we had written and oral submissions from the Lord Advocate, for the Scottish Government; from the Counsel General for Wales, for the Welsh Government; from Mr Raymond McCord, who has brought proceedings in Northern Ireland raising various issues relating to Brexit, but has not been permitted to proceed to challenge the lawfulness of the prorogation given that the Scottish and English challenges were already well-advanced; and from Sir John Major, a former Prime Minister with first-hand experience of prorogation. We have also received written submissions from Baroness Chakrabarti, shadow Attorney General, for Her Majesty's Opposition, and from the Public Law Project. We are grateful to everyone for the speed with which they have produced their submissions and all the other documents in the case. In view of the grave constitutional importance of the matter, and the

disagreement between the courts in England and Wales and Scotland, we convened a panel of 11 Justices, the maximum number of serving Justices who are permitted to sit.

[**27**] Both cases raise the same four issues, although there is some overlap between the issues:

(1) Is the question of whether the Prime Minister's advice to the Queen was lawful justiciable in a court of law?

(2) If it is, by what standard is its lawfulness to be judged?

(3) By that standard, was it lawful?

(4) If it was not, what remedy should the court grant?

IS THE QUESTION OF WHETHER THE PRIME MINISTER'S ADVICE TO THE QUEEN WAS LAWFUL JUSTICIABLE IN A COURT OF LAW?

[**28**] Counsel for the Prime Minister in the *Miller* proceedings, and the Advocate General as representing the United Kingdom Government in the *Cherry* proceedings, have argued that the court should decline to consider the challenges with which these appeals are concerned, on the basis that they do not raise any legal question on which the courts can properly adjudicate: that is to say, that the matters raised are not justiciable. Instead of the Prime Minister's advice to Her Majesty being reviewable by the courts, they argue that he is accountable only to Parliament. They conclude that the courts should not enter the political arena but should respect the separation of powers.

[**29**] As we have explained, that argument was rejected by the Inner House in the *Cherry* proceedings, but was accepted by the Divisional Court in the *Miller* proceedings. In the view of the Divisional Court, the Prime Minister's decision that Parliament should be prorogued at the time and for the duration chosen, and his advice to Her Majesty to that effect, were inherently political in nature, and there were no legal standards against which to judge their legitimacy.

[**30**] Before considering the question of justiciability, there are four points that we should make clear at the outset. First, the power to order the prorogation of Parliament is a prerogative power: that is to say, a power recognised by the common law and exercised by the Crown, in this instance by the sovereign in person, acting on advice, in accordance with modern constitutional practice. It is not suggested in these appeals that Her Majesty was other than obliged by constitutional convention to accept that advice. In the circumstances, we express no view on that matter. That situation does, however, place on the Prime Minister a constitutional responsibility, as the only person with power to do so, to have regard to all relevant interests, including the interests of Parliament.

[**31**] Secondly, although the courts cannot decide political questions, the fact that a legal dispute concerns the conduct of politicians, or arises from a matter of political controversy, has never been sufficient reason for the courts to refuse to consider it. As the Divisional Court observed in para [47] of its judgment, almost all important decisions made by the executive have a political hue to them. Nevertheless, the courts have exercised a supervisory jurisdiction over the decisions of the executive for centuries. Many if not most of the constitutional cases in our legal history have been concerned with politics in that sense.

[**32**] Two examples will suffice to illustrate the point. The 17th century was a period of turmoil over the relationship between the Stuart kings and Parliament, which culminated in civil war. That political controversy did not

deter the courts from holding, in the *Case of Proclamations* (1610) 12 Co Rep 74, (1610) 77 ER 1352, that an attempt to alter the law of the land by the use of the Crown's prerogative powers was unlawful. The court concluded (1610) 12 Co Rep 74 at 76, (1610) 77 ER 1352 at 1354 that 'the King hath no prerogative, but that which the law of the land allows him', indicating that the limits of prerogative powers were set by law and were determined by the courts. The later 18th century was another troubled period in our political history, when the Government was greatly concerned about seditious publications. That did not deter the courts from holding, in *Entick v Carrington* (1765) 19 State Tr 1029, (1765) 95 ER 807, that the Secretary of State could not order searches of private property without authority conferred by an Act of Parliament or the common law.

[**33**] Thirdly, the Prime Minister's accountability to Parliament does not in itself justify the conclusion that the courts have no legitimate role to play. That is so for two reasons. The first is that the effect of prorogation is to prevent the operation of ministerial accountability to Parliament during the period when Parliament stands prorogued. Indeed, if Parliament were to be prorogued with immediate effect, there would be no possibility of the Prime Minister's being held accountable by Parliament until after a new session of Parliament had commenced, by which time the Government's purpose in having Parliament prorogued might have been accomplished. In such circumstances, the most that Parliament could do would amount to closing the stable door after the horse had bolted. The second reason is that the courts have a duty to give effect to the law, irrespective of the minister's political accountability to Parliament. The fact that the minister is politically accountable to Parliament does not mean that he is therefore immune from legal accountability to the courts. As Lord Lloyd of Berwick stated in the *Fire Brigades Union* case (*R v Secretary of State for the Home Dept, ex p Fire Brigades Union* [1995] 2 All ER 244 at 273, [1995] 2 AC 513 at 572–573):

> 'No court would ever depreciate or call in question ministerial responsibility to Parliament. But as Professor Sir William Wade points out in Wade and Forsyth *Administrative Law* (7th edn, 1994) p 34, ministerial responsibility is no substitute for judicial review. In *IRC v National Federation of Self-Employed and Small Businesses Ltd* [1981] 2 All ER 93 at 107, [1982] AC 617 at 644 Lord Diplock said:
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> > "It is not, in my view, a sufficient answer to say that judicial review of the actions of officers or departments of central government is unnecessary because they are accountable to Parliament for the way in which they carry out their functions. They are accountable to Parliament for what they do so far as regards efficiency and policy, and of that Parliament is the only judge; they are responsible to a court of justice for the lawfulness of what they do, and of that the court is the only judge." '

[**34**] Fourthly, if the issue before the court is justiciable, deciding it will not offend against the separation of powers. As we have just indicated, the court will be performing its proper function under our constitution. Indeed, by ensuring that the Government does not use the power of prorogation unlawfully with the effect of preventing Parliament from carrying out its proper functions, the court will be giving effect to the separation of powers.

[**35**] Having made those introductory points, we turn to the question whether the issue raised by these appeals is justiciable. How is that question to

be answered? In the case of prerogative powers, it is necessary to distinguish between two different issues. The first is whether a prerogative power exists, and if it does exist, its extent. The second is whether, granted that a prerogative power exists, and that it has been exercised within its limits, the exercise of the power is open to legal challenge on some other basis. The first of these issues undoubtedly lies within the jurisdiction of the courts and is justiciable, as all the parties to these proceedings accept. If authority is required, it can be found in the decision of the House of Lords in the case of *Council of Civil Service Unions v Minister for the Civil Service* [1984] 3 All ER 935, [1985] AC 374. The second of these issues, on the other hand, may raise questions of justiciability. The question then is not whether the power exists, or whether a purported exercise of the power was beyond its legal limits, but whether its exercise within its legal limits is challengeable in the courts on the basis of one or more of the recognised grounds of judicial review. In the *Council of Civil Service Unions* case, the House of Lords concluded that the answer to that question would depend on the nature and subject matter of the particular prerogative power being exercised. In that regard, Lord Roskill mentioned [1984] 3 All ER 935 at 956, [1985] AC 374 at 418 the dissolution of Parliament as one of a number of powers whose exercise was in his view non-justiciable.

[**36**] Counsel for the Prime Minister rely on that dictum in the present case, since the dissolution of Parliament under the prerogative, as was possible until the enactment of the Fixed-term Parliaments Act 2011, is in their submission analogous to prorogation. They submit that prorogation is in any event another example of what Lord Roskill described as 'excluded categories', and refer to later authority which treated questions of 'high policy' as forming another such category (*R v Secretary of State for Foreign and Commonwealth Affairs, ex p Everett* [1989] 1 All ER 655 at 660, [1989] QB 811 at 820). The court has heard careful and detailed submissions on this area of the law, and has been referred to many authorities. It is, however, important to understand that this argument only arises if the issue in these proceedings is properly characterised as one concerning the lawfulness of the exercise of a prerogative power within its lawful limits, rather than as one concerning the lawful limits of the power and whether they have been exceeded. As we have explained, no question of justiciability, whether by reason of subject matter or otherwise, can arise in relation to whether the law recognises the existence of a prerogative power, or in relation to its legal limits. Those are by definition questions of law. Under the separation of powers, it is the function of the courts to determine them.

[**37**] Before reaching a conclusion as to justiciability, the court therefore has to determine whether the present case requires it to determine where a legal limit lies in relation to the power to prorogue Parliament, and whether the Prime Minister's advice trespassed beyond that limit, or whether the present case concerns the lawfulness of a particular exercise of the power within its legal limits. That question is closely related to the identification of the standard by reference to which the lawfulness of the Prime Minister's advice is to be judged. It is to that matter that we turn next.

BY WHAT STANDARD IS THE LAWFULNESS OF THE ADVICE TO BE JUDGED?

[**38**] In principle, if not always in practice, it is relatively straightforward to determine the limits of a statutory power, since the power is defined by the text of the statute. Since a prerogative power is not constituted by any document, determining its limits is less straightforward. Nevertheless, every prerogative power has its limits, and it is the function of the court to

determine, when necessary, where they lie. Since the power is recognised by the common law, and has to be compatible with common law principles, those principles may illuminate where its boundaries lie. In particular, the boundaries of a prerogative power relating to the operation of Parliament are likely to be illuminated, and indeed determined, by the fundamental principles of our constitutional law.

[**39**] Although the United Kingdom does not have a single document entitled 'The Constitution', it nevertheless possesses a Constitution, established over the course of our history by common law, statutes, conventions and practice. Since it has not been codified, it has developed pragmatically, and remains sufficiently flexible to be capable of further development. Nevertheless, it includes numerous principles of law, which are enforceable by the courts in the same way as other legal principles. In giving them effect, the courts have the responsibility of upholding the values and principles of our constitution and making them effective. It is their particular responsibility to determine the legal limits of the powers conferred on each branch of government, and to decide whether any exercise of power has transgressed those limits. The courts cannot shirk that responsibility merely on the ground that the question raised is political in tone or context.

[**40**] The legal principles of the constitution are not confined to statutory rules, but include constitutional principles developed by the common law. We have already given two examples of such principles, namely that the law of the land cannot be altered except by or in accordance with an Act of Parliament, and that the Government cannot search private premises without lawful authority. Many more examples could be given. Such principles are not confined to the protection of individual rights, but include principles concerning the conduct of public bodies and the relationships between them. For example, they include the principle that justice must be administered in public (*Scott v Scott* [1913] AC 417, [1911–13] All ER Rep 1), and the principle of the separation of powers between the executive, Parliament and the courts (*Ex p Fire Brigades Union* [1995] 2 All ER 244 at 267–268, [1995] 2 AC 513 at 567–568). In their application to the exercise of governmental powers, constitutional principles do not apply only to powers conferred by statute, but also extend to prerogative powers. For example, they include the principle that the executive cannot exercise prerogative powers so as to deprive people of their property without the payment of compensation (*Burmah Oil Co* (*Burma Trading*) *Ltd v Lord Advocate, Burmah Oil Co* (*Burma Concessions*) *Ltd v Lord Advocate, Burmah Oil Co* (*Overseas*) *Ltd v Lord Advocate, Burmah Oil Co* (*Pipe Lines*) *Ltd v Lord Advocate* [1964] 2 All ER 348, [1965] AC 75).

[**41**] Two fundamental principles of our constitutional law are relevant to the present case. The first is the principle of Parliamentary sovereignty: that laws enacted by the Crown in Parliament are the supreme form of law in our legal system, with which everyone, including the Government, must comply. However, the effect which the courts have given to Parliamentary sovereignty is not confined to recognising the status of the legislation enacted by the Crown in Parliament as our highest form of law. Time and again, in a series of cases since the 17th century, the courts have protected Parliamentary sovereignty from threats posed to it by the use of prerogative powers, and in doing so have demonstrated that prerogative powers are limited by the principle of Parliamentary sovereignty. To give only a few examples, in the *Case of Proclamations* the court protected Parliamentary sovereignty directly, by holding that prerogative powers could not be used to alter the law of the

land. Three centuries later, in the case of *A-G v De Keyser's Royal Hotel Ltd* [1920] AC 508, [1920] All ER Rep 80, the court prevented the Government of the day from seeking by indirect means to bypass Parliament, in circumventing a statute through the use of the prerogative. More recently, in the *Fire Brigades Union* case, the court again prevented the Government from rendering a statute nugatory through recourse to the prerogative, and was not deflected by the fact that the Government had failed to bring the statute into effect. As Lord Browne-Wilkinson observed in that case [1995] 2 All ER 244 at 254, [1995] 2 AC 513 at 552, 'The constitutional history of this country is the history of the prerogative powers of the Crown being made subject to the overriding powers of the democratically elected legislature as the sovereign body'.

[**42**] The sovereignty of Parliament would, however, be undermined as the foundational principle of our constitution if the executive could, through the use of the prerogative, prevent Parliament from exercising its legislative authority for as long as it pleased. That, however, would be the position if there was no legal limit upon the power to prorogue Parliament (subject to a few exceptional circumstances in which, under statute, Parliament can meet while it stands prorogued). An unlimited power of prorogation would therefore be incompatible with the legal principle of Parliamentary sovereignty.

[**43**] In our view, it is no answer to these points to say, as counsel for the Prime Minister argued, that the court should decline to consider extreme hypothetical examples. The court has to address the argument of counsel for the Prime Minister that there are no circumstances whatsoever in which it would be entitled to review a decision that Parliament should be prorogued (or ministerial advice to that effect). In addressing that argument, it is perfectly appropriate, and necessary, to consider its implications. Nor is it any answer to say that there are practical constraints on the length of time for which Parliament might stand prorogued, since the Government would eventually need to raise money in order to fund public services, and would for that purpose require Parliamentary authority, and would also require annual legislation to maintain a standing army. Those practical constraints offer scant reassurance.

[**44**] It must therefore follow, as a concomitant of Parliamentary sovereignty, that the power to prorogue cannot be unlimited. Statutory requirements as to sittings of Parliament have indeed been enacted from time to time, for example by the Statute of 1362 (36 Edward III c 10), the Triennial Acts of 1640 and 1664, the Bill of Rights 1688, the Scottish Claim of Right 1689, the Meeting of Parliament Act 1694, and most recently the Northern Ireland (Executive Formation etc) Act 2019, s 3. Their existence confirms the necessity of a legal limit on the power to prorogue, but they do not address the situation with which the present appeals are concerned.

[**45**] On the other hand, Parliament does not remain permanently in session, and it is undoubtedly lawful to prorogue Parliament notwithstanding the fact that, so long as it stands prorogued, Parliament cannot enact laws. In modern practice, Parliament is normally prorogued for only a short time. There can be no question of such a prorogation being incompatible with Parliamentary sovereignty: its effect on Parliament's ability to exercise its legislative powers is relatively minor and uncontroversial. How, then, is the limit upon the power to prorogue to be defined, so as to make it compatible with the principle of Parliamentary sovereignty?

[**46**] The same question arises in relation to a second constitutional principle, that of Parliamentary accountability, described by Lord Carnwath in his

judgment in the first *Miller* case as no less fundamental to our constitution than Parliamentary sovereignty (*R* (*on the application of Miller*) *v Secretary of State for Exiting the European Union* [2017] UKSC 5, [2017] 1 All ER 593, [2018] AC 61 (para [249])). As Lord Bingham of Cornhill said in the case of *Bobb v Manning* [2006] UKPC 22, [2006] 4 LRC 735 (para [13]), 'The conduct of government by a Prime Minister and Cabinet collectively responsible and accountable to Parliament lies at the heart of Westminster democracy'. Ministers are accountable to Parliament through such mechanisms as their duty to answer Parliamentary questions and to appear before Parliamentary committees, and through Parliamentary scrutiny of the delegated legislation which ministers make. By these means, the policies of the executive are subjected to consideration by the representatives of the electorate, the executive is required to report, explain and defend its actions, and citizens are protected from the arbitrary exercise of executive power.

[47] The principle of Parliamentary accountability has been invoked time and again throughout the development of our constitutional and administrative law, as a justification for judicial restraint as part of a constitutional separation of powers (see, for example, *Nottinghamshire CC v Secretary of State for the Environment* [1986] 1 All ER 199 at 204, [1986] AC 240 at 250), and as an explanation for non-justiciability (*Mohammed v Ministry of Defence, Rahmatullah v Ministry of Defence, Iraqi Civilians v Ministry of Defence* [2017] UKSC 1, [2017] 3 All ER 179, [2017] AC 649 (para [57])). It was also an animating principle of some of the statutes mentioned in para [44], as appears from their references to the redress of grievances. As we have mentioned, its importance as a fundamental constitutional principle has also been recognised by the courts.

[48] That principle is not placed in jeopardy if Parliament stands prorogued for the short period which is customary, and as we have explained, Parliament does not in any event expect to be in permanent session. But the longer that Parliament stands prorogued, the greater the risk that responsible government may be replaced by unaccountable government: the antithesis of the democratic model. So the same question arises as in relation to Parliamentary sovereignty: what is the legal limit upon the power to prorogue which makes it compatible with the ability of Parliament to carry out its constitutional functions?

[49] In answering that question, it is of some assistance to consider how the courts have dealt with situations where the exercise of a power conferred by statute, rather than one arising under the prerogative, was liable to affect the operation of a constitutional principle. The approach which they have adopted has concentrated on the effect of the exercise of the power upon the operation of the relevant constitutional principle. Unless the terms of the statute indicate a contrary intention, the courts have set a limit to the lawful exercise of the power by holding that the extent to which the measure impedes or frustrates the operation of the relevant principle must have a reasonable justification. That approach can be seen, for example, in *R* (*on the application of UNISON*) *v Lord Chancellor* [2017] UKSC 51, [2017] 4 All ER 903, [2017] 3 WLR 409 (paras [80]–[82] and [88]–[89]), where earlier authorities were discussed. A prerogative power is, of course, different from a statutory power: since it is not derived from statute, its limitations cannot be derived from a process of statutory interpretation. However, a prerogative power is only effective to the extent that it is recognised by the common law: as was said in the *Case of Proclamations*, 'the King hath no prerogative, but that which the law of the land

allows him'. A prerogative power is therefore limited by statute and the common law, including, in the present context, the constitutional principles with which it would otherwise conflict.

[**50**] For the purposes of the present case, therefore, the relevant limit upon the power to prorogue can be expressed in this way: that a decision to prorogue Parliament (or to advise the monarch to prorogue Parliament) will be unlawful if the prorogation has the effect of frustrating or preventing, without reasonable justification, the ability of Parliament to carry out its constitutional functions as a legislature and as the body responsible for the supervision of the executive. In such a situation, the court will intervene if the effect is sufficiently serious to justify such an exceptional course.

[**51**] That standard is one that can be applied in practice. The extent to which prorogation frustrates or prevents Parliament's ability to perform its legislative functions and its supervision of the executive is a question of fact which presents no greater difficulty than many other questions of fact which are routinely decided by the courts. The court then has to decide whether the Prime Minister's explanation for advising that Parliament should be prorogued is a reasonable justification for a prorogation having those effects. The Prime Minister's wish to end one session of Parliament and to begin another will normally be enough in itself to justify the short period of prorogation which has been normal in modern practice. It could only be in unusual circumstances that any further justification might be necessary. Even in such a case, when considering the justification put forward, the court would have to bear in mind that the decision whether to advise the monarch to prorogue Parliament falls within the area of responsibility of the Prime Minister, and that it may in some circumstances involve a range of considerations, including matters of political judgment. The court would therefore have to consider any justification that might be advanced with sensitivity to the responsibilities and experience of the Prime Minister, and with a corresponding degree of caution. Nevertheless, it is the court's responsibility to determine whether the Prime Minster has remained within the legal limits of the power. If not, the final question will be whether the consequences are sufficiently serious to call for the court's intervention.

CONCLUSIONS ON JUSTICIABILITY

[**52**] Returning, then, to the justiciability of the question of whether the Prime Minister's advice to the Queen was lawful, we are firmly of the opinion that it is justiciable. As we have explained, it is well established, and is accepted by counsel for the Prime Minister, that the courts can rule on the extent of prerogative powers. That is what the court will be doing in this case by applying the legal standard which we have described. That standard is not concerned with the mode of exercise of the prerogative power within its lawful limits. On the contrary, it is a standard which determines the limits of the power, marking the boundary between the prerogative on the one hand and the operation of the constitutional principles of the sovereignty of Parliament and responsible government on the other hand. An issue which can be resolved by the application of that standard is by definition one which concerns the extent of the power to prorogue, and is therefore justiciable.

THE ALTERNATIVE GROUND OF CHALLENGE

[**53**] In addition to challenging the Prime Minister's advice on the basis of the effect of the prorogation which he requested, Mrs Miller and Ms Cherry also

seek to challenge it on the basis of the Prime Minister's motive in requesting it. As we have explained, the Prime Minister had made clear his view that it was advantageous, in his negotiations with the EU, for there to be a credible risk that the United Kingdom might withdraw without an agreement unless acceptable terms were offered. Since there was a majority in Parliament opposed to withdrawal without an agreement, there was every possibility that Parliament might legislate to prevent such an outcome. In those circumstances, it is alleged, his purpose in seeking a prorogation of such length at that juncture was to prevent Parliament from exercising its legislative functions, so far as was possible, until the negotiations had been completed.

[**54**] That ground of challenge raises some different questions, in relation to justiciability, from the ground based on the effects of prorogation on Parliament's ability to legislate and to scrutinise governmental action. But it is appropriate first to decide whether the Prime Minister's advice was lawful, considering the effects of the prorogation requested and applying the standard which we have set out. It is only if it was, that the justiciability of the alternative ground of challenge will need to be considered.

WAS THE ADVICE LAWFUL?

[**55**] Let us remind ourselves of the foundations of our constitution. We live in a representative democracy. The House of Commons exists because the people have elected its members. The Government is not directly elected by the people (unlike the position in some other democracies). The Government exists because it has the confidence of the House of Commons. It has no democratic legitimacy other than that. This means that it is accountable to the House of Commons – and indeed to the House of Lords – for its actions, remembering always that the actual task of governing is for the executive and not for Parliament or the courts. The first question, therefore, is whether the Prime Minister's action had the effect of frustrating or preventing the constitutional role of Parliament in holding the Government to account.

[**56**] The answer is that of course it did. This was not a normal prorogation in the run-up to a Queen's Speech. It prevented Parliament from carrying out its constitutional role for five out of a possible eight weeks between the end of the summer recess and exit day on 31 October. Parliament might have decided to go into recess for the party conferences during some of that period but, given the extraordinary situation in which the United Kingdom finds itself, its members might have thought that parliamentary scrutiny of government activity in the run-up to exit day was more important and declined to do so, or at least they might have curtailed the normal conference season recess because of that. Even if they had agreed to go into recess for the usual three-week period, they would still have been able to perform their function of holding the government to account. Prorogation means that they cannot do that.

[**57**] Such an interruption in the process of responsible government might not matter in some circumstances. But the circumstances here were, as already explained, quite exceptional. A fundamental change was due to take place in the Constitution of the United Kingdom on 31 October 2019. Whether or not this is a good thing is not for this or any other court to judge. The people have decided that. But that Parliament, and in particular the House of Commons as the democratically elected representatives of the people, has a right to have a voice in how that change comes about is indisputable. And the House of Commons has already demonstrated, by its motions against leaving without an agreement and by the European Union (Withdrawal) (No 2) Act 2019, that it

a does not support the Prime Minister on the critical issue for his Government at this time and that it is especially important that he be ready to face the House of Commons.

[**58**] The next question is whether there is a reasonable justification for taking action which had such an extreme effect upon the fundamentals of our democracy. Of course, the Government must be accorded a great deal of b latitude in making decisions of this nature. We are not concerned with the Prime Minister's *motive* in doing what he did. We are concerned with whether there was a reason for him to do it. It will be apparent from the documents quoted earlier that no reason was given for closing down Parliament for five weeks. Everything was focussed on the need for a new Queen's Speech and the c reasons for holding that in the week beginning 14 October rather than the previous week. But why did that need a prorogation of five weeks?

[**59**] The unchallenged evidence of Sir John Major is clear. The work on the Queen's Speech varies according to the size of the programme. But a typical time is four to six days. Departments bid for the Bills they would like to have in the next session. Government business managers meet to select the Bills to be d included, usually after discussion with the Prime Minister, and Cabinet is asked to endorse the decisions. Drafting the speech itself does not take much time once the substance is clear. Sir John's evidence is that he has never known a Government to need as much as five weeks to put together its legislative agenda.

[**60**] Nor does the Memorandum from Nikki da Costa outlined in para [17] e above suggest that the Government needed five weeks to put together its legislative agenda. The memorandum has much to say about a new session and Queen's Speech but nothing about why so long was needed to prepare for it. The only reason given for starting so soon was that 'wash up' could be concluded within a few days. But that was totally to ignore whatever else f Parliament might have wanted to do during the four weeks it might normally have had before a prorogation. The proposal was careful to ensure that there would be some Parliamentary time both before and after the European Council meeting on 17–18 October. But it does not explain why it was necessary to curtail what time there would otherwise have been for Brexit related business. It does not discuss what Parliamentary time would be needed g to approve any new withdrawal agreement under s 13 of the European Union (Withdrawal) Act 2018 and enact the necessary primary and delegated legislation. It does not discuss the impact of prorogation on the special procedures for scrutinising the delegated legislation necessary to make UK law ready for exit day and achieve an orderly withdrawal with or without a withdrawal agreement, which are laid down in the European Union h (Withdrawal) Act 2018. Scrutiny committees in both the House of Commons and the House of Lords play a vital role in this. There is also consultation with the Scottish Parliament and the Welsh Assembly. Perhaps most tellingly of all, the memorandum does not address the competing merits of going into recess and prorogation. It wrongly gives the impression that they are much the same. The Prime Minister's reaction was to describe the September sitting as a j 'rigmarole'. Nowhere is there a hint that the Prime Minister, in giving advice to Her Majesty, is more than simply the leader of the Government seeking to promote its own policies; he has a constitutional responsibility, as we have explained in para [30] above.

[**61**] It is impossible for us to conclude, on the evidence which has been put before us, that there was any reason – let alone a good reason – to advise Her

Majesty to prorogue Parliament for five weeks, from 9 or 12 September until 14 October. We cannot speculate, in the absence of further evidence, upon what such reasons might have been. It follows that the decision was unlawful.

REMEDY

[**62**] Mrs Miller asks us to make a declaration that the advice given to Her Majesty was unlawful and we can certainly do that. The question is whether we should do more than that, in order to make it crystal clear what the legal consequences of that holding are. The Inner House did go further and declared, not only that the advice was unlawful, but that 'any prorogation which followed thereon, is unlawful and thus null and of no effect'. The essential question is: is Parliament prorogued or is it not?

[**63**] The Government argues that we cannot answer that question, or declare the prorogation null and of no effect, because to do so would be contrary to art 9 of the Bill of Rights of 1688, an Act of the Parliament of England and Wales, or the wider privileges of Parliament, relating to matters within its 'exclusive cognisance'. The prorogation itself, it is said, was 'a proceeding in Parliament' which cannot be impugned or questioned in any court. And reasoning back from that, neither can the Order in Council which led to it.

[**64**] Article 9 provides:

> 'That the Freedome of Speech and Debates or Proceedings in Parlyament ought not to be impeached or questioned in any Court or Place out of Parlyament.'

The equivalent provision in the Claim of Right of 1689, an Act of the Parliament of Scotland, is this:

> 'That for redress of all greivances and for the amending strenthneing and preserveing of the lawes Parliaments ought to be frequently called and allowed to sit and the freedom of speech and debate secured to the members'.

[**65**] The first point to note is that these are Acts of Parliament. It is one of the principal roles of the courts to interpret Acts of Parliament. A recent example of this Court interpreting art 9 is *R v Chaytor* [2010] UKSC 52, [2011] 1 All ER 805, [2011] 1 AC 684. The case concerned the prosecution of several Members of Parliament for allegedly making false expenses claims. They resisted this on the ground that those claims were 'proceedings in Parliament' which ought not to be 'impeached or questioned' in any court outside Parliament. An enlarged panel of nine Justices held unanimously that MPs' expenses claims were not 'proceedings in Parliament' nor were they in the exclusive cognisance of Parliament. There is a very full discussion of the authorities in the judgments of Lord Phillips of Worth Matravers P and Lord Rodger of Earlsferry which need not be repeated here.

[**66**] That case clearly establishes: (1) that it is for the court and not for Parliament to determine the scope of Parliamentary privilege, whether under art 9 of the Bill of Rights or matters within the 'exclusive cognisance of Parliament'; (2) that the principal matter to which art 9 is directed is 'freedom of speech and debate in the Houses of Parliament and in parliamentary committees. This is where the core or essential business of Parliament takes place' (para [47]). In considering whether actions outside the Houses and committees are also covered, it is necessary to consider the nature of their

connection to those and whether denying the actions privilege is likely to impact adversely on the core or essential business of Parliament; (3) that 'Exclusive cognisance refers not simply to Parliament, but to the exclusive right of each House to manage its own affairs without interference from the other or from outside Parliament' (para [63]); it was enjoyed by Parliament itself and not by individual members and could be waived or relinquished; and extensive inroads had been made into areas previously within exclusive cognisance.

[**67**] Erskine May *Parliamentary Practice* (25th edn, 2019) para 13.12 is to similar effect:

> 'The primary meaning of proceedings, as a technical parliamentary term, which it had at least as early as the 17th century, is some formal action, usually a decision, taken by the House in its collective capacity. While business which involves actions and decisions of the House are clearly proceedings, debate is an intrinsic part of that process which is recognised by its inclusion in the formulation of article IX. An individual member takes part in a proceeding usually by speech, but also by various recognised forms of formal action, such as voting, giving notice of a motion, or presenting a petition or report from a committee, most of such actions being time-saving substitutes for speaking.'

[**68**] The prorogation itself takes place in the House of Lords and in the presence of Members of both Houses. But it cannot sensibly be described as a 'proceeding in Parliament'. It is not a decision of either House of Parliament. Quite the contrary: it is something which is imposed upon them from outside. It is not something upon which the Members of Parliament can speak or vote. The Commissioners are not acting in their capacity as members of the House of Lords but in their capacity as Royal Commissioners carrying out the Queen's bidding. They have no freedom of speech. This is not the core or essential business of Parliament. Quite the contrary: it brings that core or essential business of Parliament to an end.

[**69**] This court is not, therefore, precluded by art 9 or by any wider Parliamentary privilege from considering the validity of the prorogation itself. The logical approach to that question is to start at the beginning, with the advice that led to it. That advice was unlawful. It was outside the powers of the Prime Minister to give it. This means that it was null and of no effect: see, if authority were needed, *R (on the application of UNISON) v Lord Chancellor* [2017] UKSC 51, [2017] 4 All ER 903, [2017] 3 WLR 409 (para [119]). It led to the Order in Council which, being founded on unlawful advice, was likewise unlawful, null and of no effect and should be quashed. This led to the actual prorogation, which was as if the Commissioners had walked into Parliament with a blank piece of paper. It too was unlawful, null and of no effect.

[**70**] It follows that Parliament has not been prorogued and that this court should make declarations to that effect. We have been told by counsel for the Prime Minister that he will 'take all necessary steps to comply with the terms of any declaration made by the court' and we expect him to do so. However, it appears to us that, as Parliament is not prorogued, it is for Parliament to decide what to do next. There is no need for Parliament to be recalled under the Meeting of Parliament Act 1797. Nor has Parliament voted to adjourn or go into recess. Unless there is some Parliamentary rule to the contrary of which we are unaware, the Speaker of the House of Commons and the Lord Speaker can take immediate steps to enable each House to meet as soon as possible to

decide upon a way forward. That would, of course, be a proceeding in Parliament which could not be called in question in this or any other court. *a*

[**71**] Thus the Advocate General's appeal in the case of *Cherry* is dismissed and Mrs Miller's appeal is allowed. The same declarations and orders should be made in each case.

b

Appeal in the Miller case allowed. Appeal in the Cherry case dismissed.

Wendy Herring Barrister.

STAND ON GUARD FOR THEE

Ethical considerations in preparedness planning for pandemic influenza

November 2005

University of Toronto
Joint Centre for Bioethics

Innovative. Interdisciplinary. International.
Improving health care through bioethics.

A report of the
University of Toronto Joint Centre for Bioethics
Pandemic Influenza Working Group

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Key Points

- Plans to deal with an influenza pandemic need to be founded on widely held ethical values, so that people understand in advance the kinds of choices that will have to be made. Decision makers and the public need to be engaged in the discussions about ethical choices, so plans reflect what most people will accept as fair, and good for public health.

- The Pandemic Influenza Working Group at the University of Toronto Joint Centre for Bioethics (JCB) has developed a 15-point ethical guide for planning and decision-making for a pandemic.

- The JCB Working Group has identified four key ethical issues that need to be addressed in pandemic planning, and made specific recommendations for each. The four major issues are:
    1. health workers' duty to provide care during a communicable disease outbreak;
    2. restricting liberty in the interest of public health by measures such as quarantine;
    3. priority setting, including the allocation of scarce resources such as vaccines and antiviral medicines; and
    4. global governance implications, such as travel advisories.

- The JCB Working Group recommends that all pandemic plans have an ethical component, and offers the ethical guide contained in this paper for use in

developing such a component.

A. INTRODUCTION

When an influenza pandemic strikes the world many people, ranging from government and medical leaders to health care workers, will face a host of difficult decisions that will affect people's freedoms and their chances of survival. There will be choices about the level of risk health care workers should face while caring for the sick, the imposition of restrictive measures such as quarantines, the allocation of limited resources such as medicines, and the use of travel restrictions and other measures to contain the spread of disease.

Governments and health care leaders have been working on pandemic plans in many parts of the world. However, most of their communication to the public has focussed on technical issues, such how to obtain, stockpile and distribute medicines, and the assignment of duties.

Planners have not generally communicated the ethical underpinnings of their choices in a clear manner. But ethical issues have surfaced in public debates, often in the news media. Should people purchase their own stockpiles of antiviral drugs such as Tamiflu, or should they accept governments' decisions on how to allocate such medications? When medications are distributed, should children come before or after health care and emergency services workers, or decision makers such politicians?

Government and health care leaders need to make the values behind their decisions public. They should discuss the values with people who could be affected, ranging from health care workers, who will find themselves on the front lines, to government officials, who are making decisions about the allocation of limited resources, to the public at large, because people will be affected in many ways. They need to do this in advance of a health crisis, not when people are lining up at emergency ward doors.

Openly discussing the choices and confirming that they are based on ethical values that are shared by members of a society brings important benefits. If ethics are clearly built into pandemic plans in an open and transparent manner, and with buy-in from multiple sectors of society, the plans carry greater trust, authority and legitimacy. Advance discussions of such issues can help to address fears of the unknown. People will be more likely to cooperate, and accept difficult decisions made by their leaders for the common good. It is a goal of this paper to provide guidance and to spur a broad public discussion of the often difficult ethical issues underlying decisions.

This fall the World Health Organization (WHO) issued a checklist for influenza pandemic preparedness planning, calling on planners to deal with ethical issues, and to use an ethical framework. The WHO said a framework might deal with such issues as quarantines, the allocation of scarce resources and compulsory vaccinations. The Province of Ontario in Canada built a significant ethics

component into its *Ontario Health Plan for an Influenza Pandemic* of June 2005. The Toronto Academic Health Science Network, made up of all the teaching hospitals in Toronto, is working on a collaborative pandemic plan that will include references to using an ethical framework. Although the JCB Working Group is aware of ethics sections in other plans, we are unaware of any that address the ethical issues in a clear and comprehensive fashion and that articulate the underlying principles and values.

The need for a clearly understood and widely accepted ethics approach to dealing with serious communicable disease outbreaks was underscored during the outbreak of Severe Acute Respiratory Syndrome (SARS) in early 2003. SARS showed the universal vulnerability of humans to communicable diseases, and the need for coordinated and cooperative responses across national borders. It also found that health care systems had generally not prepared themselves to deal with the hard ethical choices that rapidly arose.

Immediately after that outbreak, the JCB produced the report *Ethics and SARS: Learning Lessons from the Toronto Experience*. Since then the JCB has conducted much more detailed research, which is summarized in this paper, and will be published in more detail in separate papers.

Research found that as the SARS crisis became more severe, and restrictions were imposed, there were concerns over access to care and the allocation of medicines, access to safety equipment, who had to work and under what protections, and the sharing of vital information. People started raising the issues of whose values should prevail during a public health emergency.

Leaders in governments and health care systems had not previously developed an ethical framework or held prior consultations on to deal with the suite of ethical issues forced on them by SARS. Decision makers had to balance individual freedoms against the common good, fear for personal safety against the duty to treat the sick, and economic losses against the need to contain the spread of a deadly disease. Decisions had to be rapid, and were as transparent as possible given the limitations of the time. Therefore the lesson learned is to establish the ethical framework in advance, and to do it in a transparent manner.

One major finding of the JCB research was that people are more likely to accept such decisions if the decision-making processes are reasonable, open and transparent, inclusive, responsive and accountable, and if reciprocal obligations are respected. Although these principles can sometimes be difficult to implement during a crisis, SARS showed there are costs from not having an agreed-upon ethical framework, including loss of trust, low morale, fear and misinformation. SARS taught the world that if ethical frameworks had been more widely used to guide decision-making, this would have increased trust and solidarity within and between health care organizations.

SARS gave the world an advance warning of the need for ethical frameworks for decision-making during other communicable disease outbreaks, such as a flu pandemic. JCB research has identified critical issues and ethical principles that can be applied to pandemic planning. The Working Group recommends using these principles to develop a preventive ethics approach. This will have many benefits, including the reduction of conflicts during a crisis.

While much of the research was done in Canada, the lessons are generally applicable around the world. They should be part of the democratic process of making decisions that affect a society.

Following is a comprehensive ethical guide for planning for and dealing with major communicable disease outbreaks, such as pandemic influenza. The guide was developed with expertise from clinical, organizational and public health ethics, and validated through a stakeholder engagement process. It includes both substantive and procedural elements for ethical pandemic influenza planning. This can form the basis for applying the framework that the WHO has recommended. It can be a key planning tool for pandemic readiness.

Next comes a section exploring four key ethical issues that will arise during a flu pandemic. Drawing from the ethical framework, the group identified the applicable key ethical values for each issue, and provides recommendations for dealing with each. The recommendations are particularly addressed to governments and decision-making bodies, mainly in the health care sector, around the world. The key issues are:

1. health workers' duty to provide care during a communicable disease outbreak;

2. restricting liberty in the interest of public health by measures such as quarantine;

3. priority setting, including the allocation of scarce resources, such as vaccines and antiviral medicines; and

4. global governance implications, such as travel advisories.

These may not be the only ethical issues that the world will face in an influenza pandemic, but they are critically important issues that the Working Group has identified. Planners and decision-makers need to be vigilant for other ethical challenges that will need to be managed.

B. AN ETHICAL GUIDE FOR PANDEMIC PLANNING

Based on the SARS experience, the JCB Working Group has assembled an ethical guide for planning and decision-making that can be used both in advance of and during an influenza pandemic. This guide is composed of 15 ethical values, of which 10 are substantive values and five are procedural values. They should be seen as a package of interdependent values that are important in any democratic society.

B1. Ten substantive values to guide ethical decision-making for a pandemic influenza outbreak

Substantive value	**Description**
Individual liberty	In a public health crisis, restrictions to individual liberty may be necessary to protect the public from serious harm. Restrictions to individual liberty should: • be proportional, necessary, and relevant; • employ the least restrictive means; and • be applied equitably.
Protection of the public from harm	To protect the public from harm, health care organizations and public health authorities may be required to take actions that impinge on individual liberty. Decision makers should: • weigh the imperative for compliance; • provide reasons for public health measures to encourage compliance; and • establish mechanisms to review decisions.
Proportionality	Proportionality requires that restrictions to individual liberty and measures taken to protect the public from harm should not exceed what is necessary to address the actual level of risk to or critical needs of the community.
Privacy	Individuals have a right to privacy in health care. In a public health crisis, it may be necessary to override this right to protect the public from serious harm.
Duty to provide	Inherent to all codes of ethics for health care professionals is the duty to provide care and to respond to suffering. Health care

care	providers will have to weigh demands of their professional roles against other competing obligations to their own health, and to family and friends. Moreover, health care workers will face significant challenges related to resource allocation, scope of practice, professional liability, and workplace conditions.
Reciprocity	Reciprocity requires that society support those who face a disproportionate burden in protecting the public good, and take steps to minimize burdens as much as possible. Measures to protect the public good are likely to impose a disproportionate burden on health care workers, patients, and their families.
Equity	All patients have an equal claim to receive the health care they need under normal conditions. During a pandemic, difficult decisions will need to be made about which health services to maintain and which to defer. Depending on the severity of the health crisis, this could curtail not only elective surgeries, but could also limit the provision of emergency or necessary services.
Trust	Trust is an essential component of the relationships among clinicians and patients, staff and their organizations, the public and health care providers or organizations, and among organizations within a health system. Decision makers will be confronted with the challenge of maintaining stakeholder trust while simultaneously implementing various control measures during an evolving health crisis. Trust is enhanced by upholding such process values as transparency.
Solidarity	As the world learned from SARS, a pandemic influenza outbreak, will require a new vision of global solidarity and a vision of solidarity among nations. A pandemic can challenge conventional ideas of national sovereignty, security or territoriality. It also requires solidarity within and among health care institutions. It calls for collaborative approaches that set aside traditional values of self-interest or territoriality among health care professionals, services, or institutions.
Stewardship	Those entrusted with governance roles should be guided by the notion of stewardship. Inherent in stewardship are the notions of trust, ethical behaviour, and good decision-making. This implies that decisions regarding resources are intended to achieve the best patient health and public health outcomes given the unique circumstances of the influenza crisis.

B2. Five procedural values to guide ethical decision-making for a pandemic influenza outbreak

Procedural value	Description
Reasonable	Decisions should be based on reasons (i.e., evidence, principles, and values) that stakeholders can agree are relevant to meeting health needs in a pandemic influenza crisis. The decisions should be made by people who are credible and accountable.
Open and transparent	The process by which decisions are made must be open to scrutiny, and the basis upon which decisions are made should be publicly accessible.
Inclusive	Decisions should be made explicitly with stakeholder views in mind, and there should be opportunities to engage stakeholders in the decision-making process.
Responsive	There should be opportunities to revisit and revise decisions as new information emerges throughout the crisis. There should be mechanisms to address disputes and complaints.
Accountable	There should be mechanisms in place to ensure that decision makers are answerable for their actions and inactions. Defence of actions and inactions should be grounded in the 14 other ethical values proposed above.

Recommendations

1. National, provincial/state/territorial, and municipal governments, as well as the health care sector, should ensure that their pandemic plans include an ethical component.

2. National, provincial/state/territorial, and municipal governments, as well as the health care sector, should consider incorporating both substantive and procedural values in the ethical component of their pandemic plans.

C. FOUR KEY ETHICAL ISSUES

As a result of analyses of the SARS crisis, the JCB Working Group identified four key ethical issues that are expected to be very important during a pandemic flu outbreak. Below, each of these issues is described in turn to illustrate how this ethical guide can be used. Specific recommendations are included for each issue.

C1. Health workers' duty to provide care during a communicable disease outbreak

During SARS, some medical workers were afraid that they would be infected while caring for SARS patients, and that they would infect their families, friends and co-workers. The workers were torn between these fears and a sense of duty to their patients and solidarity with fellow workers. A flu pandemic will mean virtually all health care workers will face such difficult choices.

Overview

The duty to care for the sick is a primary ethical obligation for health care workers for a number of reasons, including:

1. the ability of physicians and health care workers to provide care is greater than that of the public, thus increasing their obligation to provide care.

2. by freely choosing a profession devoted to care for the ill, they assume risks.

3. the profession has a social contract that calls on members to be available in times of emergency. (In addition, they largely work in publicly supported systems in many countries.)

When SARS broke out, health care workers in a number of countries were on the firing line, and had to make decisions for which they were not always prepared. They faced an unknown and deadly communicable disease, a coronavirus for which there was no known effective treatment. They were rapidly forced to weigh serious and imminent health risks to themselves and their families against their duty to care for the sick. A significant number of health care workers were infected with SARS because of their work, and some died. Many workers were placed under work quarantine.

Workers generally showed heroism and altruism in the face of danger during the SARS outbreak, but some balked at caring for people infected with SARS, and a few were dismissed for failing to report for duty. Post-SARS, many health care workers raised concerns about the level of protection to themselves and their families. Some even left the profession.

A flu pandemic would put far greater pressures on health care systems around the world. Faced with a very serious disease for which there may be no absolute protection or cure, health care workers will find themselves facing overwhelming demands. They will be forced to weigh their duty to provide care against competing obligations, such as their duty to protect their own health and that of families and friends. Initially the primary care and emergency services workers will take the full brunt of responding to the flu, and therefore bear a disproportionate risk compared to more specialized care providers. There will likely be pressure on other health care providers to come to the front lines.

Some believe that under dire circumstances, professionals should have minimal self-regard and pursue their duties at potential cost to their own lives. By analogy, firefighters do not have the freedom to choose whether or not they have to face a particularly bad fire, and police do not get to select which dark alleys they walk down. Others claim that it is unreasonable to demand extreme heroism from health care workers as the norm, and even more unreasonable to demand that workers put the lives of their families at high risk or make themselves unavailable to care for them should they become ill.

At times like this, health care workers' ethical codes should provide important guidance on such issues as professional rights and responsibilities. It is important for health care professionals, from doctors to nurses to hospital and ambulance staff, to articulate codes or statements of ethical conduct in high-risk situations, so that everyone knows what to expect during times of communicable disease crises. These codes or statements should cover such issues as:

- how much risk should health care workers be required to take;
- their duty to care for the sick, and to care for themselves so they can continue to provide care; and
- their duty not to harm others by transmitting diseases.

There is currently a vacuum in this field. For example, the 2004 Canadian Medical Association (CMA) revised *Code of Ethics*, released a year after SARS, provides no clear guidance on the key ethical issues raised by communicable disease outbreaks, including the duty to care. The JCB Working Group has looked at a number of medical codes of ethics in other countries and found a similar lack of specific guidance on these issues.

In the past, particularly after the 1919 influenza pandemic, such issues were explicitly addressed by some codes. For example, the 1922 *CMA Code of Ethics* said: “When pestilence prevails, it is their (physicians') duty to face the danger, and to continue their labours for the alleviation of suffering, even at the jeopardy of their own lives.” The American Medical Association used similar language in its code of ethics from 1846 until the 1950s. The disappearance of this stringent demand from medical codes of ethics is unexplained, perhaps related to belief in recent decades that dangerous communicable diseases had been vanquished. The resurgence of communicable diseases for which there are no ready defences raises the need for clarity from the professions.

While much of the discussion post SARS has been about the duties of health care workers, there are other important ethical issues that need to be addressed, including reciprocity and solidarity. If workers are to take high risks, there is a duty upon society, in particular on their institutions, to support them. The institutions need to plan to help workers cope with the high stress of a pandemic, to acknowledge that their work is dangerous. For example, they need to provide for the health and safety of workers, and for the care of those who fall ill on duty. This might include an insurance fund for life and disability to cover health care workers who become sick or die as they place themselves in harm’s way. Also, there is a need for fair and workable human resource plans for emergency situations. Limitations imposed during SARS resulted in a loss of work for some health care workers. The imposition of employment restrictions should not result in financial hardship or job loss and should not unduly affect part-time staff.

The risk to care providers is not only physical, but also psychological. Senior decision makers and physicians will have to make many hard choices about care and the assignment of staff. They need to feel that they have the support of the highest levels of administration, including boards of directors.

Just after the SARS crisis, a JCB paper recommended a review of professional codes to help clarify professional duties and define the acceptable extent of professional obligation. That paper recommended that health care institutions develop ethical frameworks in collaboration with their workforce, establish explicit work expectations in times of communicable disease, and make them available to their staffs.

Ethical values and processes

Based on the guide of substantive values and process for ethical decision-making, the substantive values most applicable to this issue are: duty to provide care, reciprocity, trust, and solidarity.

All five procedural values apply: reasonable, open and transparent, inclusive, responsive, and accountable.

Recommendations

1. Professional colleges and associations should provide, by way of their codes of ethics, clear guidance to members in advance of a major communicable disease outbreak, such as pandemic flu. Existing mechanisms should be identified, or means should be developed, to inform college members as to expectations and obligations regarding the duty to provide care during a communicable disease outbreak.

2. Governments and the health care sector should ensure that:

    a. care providers' safety is protected at all times, and providers are able to discharge duties and receive sufficient support throughout a period of extraordinary demands; and

    b. disability insurance and death benefits are available to staff and their families adversely affected while performing their duties.

3. Governments and the health care sector should develop human resource strategies for communicable disease outbreaks that cover the diverse occupational roles, that are transparent in how individuals are assigned to roles in the management of an outbreak, and that are equitable with respect to the distribution of risk among individuals and occupational categories.

C2. Restricting liberty in the interest of public health by measures such as quarantine

During the SARS outbreak, a number of people, including health care staff, were ordered to remain at home to prevent spreading the disease. People faced the loss of income and possibly their jobs. The number of people affected could be far higher during a global flu pandemic, and people subject to restrictive measures will need to have their basic needs met, including some protection for their income and jobs.

Overview

Until a new flu vaccine is developed or other medications are found to control pandemic flu, restrictive measures may be one of the important public health tools to reduce spread of this communicable disease. Governments may need to limit three basic personal freedoms that we take from granted: mobility, freedom of assembly and privacy. They may close schools, cancel public gatherings and

sporting events, and impose quarantine, isolation and even detention, where needed.

During SARS, a significant number of people were placed in quarantine to control the spread of this disease, making it one of the largest quarantines in modern times. A major flu pandemic could result in very large numbers being subjected to such measures. These restrictions impose a heavy burden on those affected. People may be cut off from family, friends, work, shopping, entertainment, travel, and most other activities, including some forms of medical care. People may feel stigmatized if they are put into quarantine or identified as being affected by pandemic flu.

JCB research in the aftermath of SARS showed that people understood and accepted the need for restrictive measures for the control of communicable diseases. Most saw it as a form of civic duty, and were willing to make a sacrifice. However, our data also indicate that if decision makers expect full compliance with restrictive measures, the decisions need to be made in a fair manner, and people affected by such measures need support. Reciprocity requires society in turn to ensure that those affected receive adequate care, and do not suffer unfair economic penalties. If leaders expect people exposed to or suffering from communicable diseases to act in a manner that does not put others at risk, it is important that they create a social environment that does not leave people without supports.

For example, if quarantine is implemented, governments should ensure that people have adequate food supplies and are able to carry out essential functions. Their jobs should be protected, and they should not suffer an undue financial burden. Volunteer organizations will have a vital role to play, but since they are voluntary, they do not have the same ethical obligations as governments.

There will be related issues, including the privacy of personal information and the public needs to know about high risks of disease. In SARS, the outbreak in Canada was linked to a traveller from China, leading to some people boycotting Chinese businesses elsewhere.

The state has the right to override an individual’s right to privacy in cases of serious public health risks if revealing private medical information helps to protect public health. Governments also have an obligation to reduce stigmatization by respecting the value of privacy as much as possible, and by providing accurate information, and only the information that will give the public a realistic view of such key public health issues as the spreading of disease.

The world could face the possibility of other measures that could be used to contain the disease, including mandatory vaccination, surveillance cameras, monitoring devices, and even imprisonment for people who failed to comply with quarantine orders.

Restrictive measures are a reminder of the legitimate limits to our highly prized individual liberties. When making such decisions, leaders will need to balance individual freedoms against the common good of society, fear for personal safety against the duty to treat the sick, and economic losses against the need to contain the spread of a deadly disease. Authorities exercising public health powers should do so in a way that is relevant, legitimate, legal, proportional, and necessary. They should use the least restrictive methods that are reasonably available to limit individual liberties, and should apply restrictions without discrimination. People need to be fully informed about issues, including risks and benefits of public health measures.

Decision makers need to turn for guidance to documents such as charters of rights and freedoms and human rights legislation. They can look to the United Nations' Siracusa Principles, which are based upon human rights documents. The principles stipulate the extent to which state powers should be exercised in times of public health emergencies. The principles hold that public health may be invoked as grounds for limiting certain rights in order to manage a serious threat to the health of individuals or a population. These measures must be specifically aimed at preventing disease or injury, or providing care for the sick and injured. The actions taken must be legal, necessary, and proportional to the threat.

In November 2005, the American Medical Association issued guidelines for protecting patient rights if they have to be quarantined during an epidemic. An AMA spokesperson said: "…Physicians must do everything they can to protect the rights and privacy of patients without compromising the health of the public."

Ethical values and processes

Based on our guide of substantive values and process for ethical decision-making, the substantive values most applicable to this issue are: liberty, protection of public from harm, proportionality, privacy, and reciprocity.

All five procedural values apply: reasonable, open and transparent, inclusive, responsive, and accountable.

Recommendations

1. Governments and the health care sector should ensure that pandemic influenza response plans include a comprehensive and transparent protocol for the implementation of restrictive measures. The protocol should be founded upon the principles of proportionality and least restrictive means, should balance individual liberties with protection of public from harm, and should build in safeguards such as the right of appeal.

2. Governments and the health care sector should ensure that the public is aware of:

    a. the rationale for restrictive measures;
    b. the benefits of compliance; and
    c. the consequences of non-compliance.

3. Governments and the health care sector should include measures in their pandemic influenza preparedness plans to protect against stigmatization and to safeguard the privacy of individuals and/or communities affected by quarantine or other restrictive measures.

4. Governments and the health care sector should institute measures and processes to guarantee provisions and support services to individuals and/or communities affected by restrictive measures, such as quarantine orders, implemented during a pandemic influenza emergency. Plans should state in advance what backup support will be available to help those who are quarantined (e.g., who will do their shopping, pay the bills, and provide financial support in lieu of lost income). Governments should have public discussions of appropriate levels of compensation in advance, including who is responsible for compensation.

C3. Priority setting, including the allocation of scarce resources, such as vaccines and antiviral medicines

One of the side effects of SARS was that people scheduled for important treatments, such as cancer surgery, had their care postponed. A number of hospital beds, staff and equipment were redirected to the public health emergency. These kinds of decisions will be even more prevalent during a flu pandemic.

Overview

If the flu pandemic is as severe as some fear, there will be an extraordinarily high number of sick people around the world, all requiring care at the same time. This will be on top of the “normal” health care needs, which strain medical systems at the best of times. During a pandemic, the human and material resources of health care will be rapidly overwhelmed. There will be scarcities of medicines, equipment and health care workers in all countries, with less-developed nations facing some of the greatest scarcities. There will be cases of people who will have to forego medical care for other ailments, such as cancer and heart disease.

Decision makers will seek to maximize benefits for society while balancing obligations to individuals and individual needs. They will have to decide who gets access to vaccines, antiviral drugs, such as Tamiflu, ventilators, and other forms of care. They will use priority-setting processes, also known as rationing or resource allocation. This means that current societal expectations about access to health care will have to change in light of a public health crisis of major proportions.

Already there are signs of a public debate over choices. Some jurisdictions are stockpiling Tamiflu rather than allowing unlimited private sales. Most pandemic plans give priority for the use of antivirals and vaccines to health care workers and people in emergency services. Some plans state that once a vaccine is developed, children would be among the last to be immunized. This is based on experience with flu in the past, showing that after age 2, children are most likely to survive the virus. While these choices are justifiable, it would help to build public support by discussing them in a public manner.

People expect decisions to be reasonable, open and transparent, inclusive, responsive, and accountable. In the midst of a pandemic, when guidance will be incomplete, consequences uncertain, and information constantly changing, and where hour-by-hour decisions involve life and death, fairness is crucial. Experience shows that there is often disagreement on what principles should be used to make fair allocation decisions. This means that decision makers may have also to rely on a fair process to establish the legitimacy of priority setting decisions.

There is still time for many decisions to be made in consultation with stakeholders and the public. Although the organizational leaders would ultimately be accountable for making the priority setting decisions, a broader range of stakeholders should be engaged particularly as key informants through expert and broader stakeholder consultation. The stakeholders can range from employees and patient groups to institutional partners, community groups, and government officials.

People need to know in advance what to expect. An effective communications strategy should be developed to ensure a transparent priority setting process. The purpose of the communication strategy should be to ensure that stakeholders know and understand the scope and necessity of priority setting decision-making, the degrees of freedom within which priority setting would take place and the roles of various people. In addition, the rationales for priority setting decisions should be communicated to stakeholders, and should clearly demonstrate how these decisions are defensible in light of the priority setting criteria and available data and information.

Among the benefits of open communications about priority-setting:

- stakeholders feel engaged and understand the decision-making process;

- priorities can be justified and seen to be reasonable; and
- the process is perceived to be fair.

Ethical values and processes

Based on our guide of substantive values and process for ethical decision-making, the substantive values most applicable to this issue are: equity, trust, solidarity, and stewardship.

All five procedural values apply: reasonable, open and transparent, inclusive, responsive, and accountable.

Recommendations

1. Governments and the health care sector should publicize a clear rationale for giving priority access to health care services, including antivirals and vaccines, to particular groups, such as front line health workers and those in emergency services. The decision makers should initiate and facilitate constructive public discussion about these choices.

2. Governments and the health care sector should engage stakeholders (including staff, the public, and other partners) in determining what criteria should be used to make resource allocation decisions (e.g., access to ventilators during the crisis, and access to health services for other illnesses), should ensure that clear rationales for allocation decisions are publicly accessible and should provide a justification for any deviation from the pre-determined criteria.

3. Governments and the health care sector should ensure that there are formal mechanisms in place for stakeholders to bring forward new information, to appeal or raise concerns about particular allocation decisions, and to resolve disputes.

C4. Global governance implications, such as travel advisories

In rural China, a farmer developed a chest infection, and then family travels began a chain of events that would take the SARS virus to the other side of the world. In Geneva, officials of the World Health Organization (WHO) weighed the risk of the spread of SARS, and issued travel warnings that would affect a number of countries, sometimes causing severe economic impacts.

The current avian flu virus is moving across vast distances, carried by wild birds.

If this virus mutates to become transmissible among humans, the WHO has warned that it could reach all continents in less than three months. The WHO will have to carefully consider when it will institute travel measures to protect the global community from spread of the disease.

Overview

The SARS outbreak showed our global interdependence, and the increasing risk to global human security from the emergence and rapid spread of communicable diseases. It showed the need for global solidarity, involving highly coordinated public health responses that involve the cooperation of local, regional, national, and supra-national governments.

One way that governments and the WHO seek to control the spread of communicable diseases is through restrictions on travel. Especially during the early stages of what looks like a pandemic, travel advisories can help to slow the spread of the virus. These restrictions can impose severe penalties not only on individuals, but also on entire regions. The ethical challenges of global public health decision-making are well illustrated by the issuance of travel advisories.

During the 2003 SARS crisis, the WHO advised international travelers against all non-essential travel to a number of regions, including parts of China, including Hong Kong, as well as Taiwan and Toronto. There were many side effects of those public health decisions. The reduction in travel and tourism cost Canada, particularly Toronto and the province of Ontario, many millions of dollars in economic losses.

Analysis of the SARS case showed that federal states, where powers are shared among national and provincial or state governments, can face problems in organizing themselves to respond to public health crises. During SARS, the Canadian federal government's ability to obtain data from the Province of Ontario was dependent on voluntary transfer since the management of communicable disease outbreaks falls under provincial jurisdiction. Problems with communication among governments may have led to a delay in providing information on SARS to the WHO. This in turn could have undermined the WHO's confidence in the Canadian response, which perhaps contributed to the imposition of the travel advisory on Toronto.

While it was the duty of the WHO to do everything it could to prevent the spread of SARS to other countries, and in particular developing countries that have limited resources to combat the spread of the disease, it had to do so in a manner that was respectful of national sovereignty. Conversely, nations such as Canada had a responsibility as members of the global community to cooperate fully in the international pandemic response.

The Working Group's examination of global governance has centered on the issue of travel advisories as well as national and international responsibilities related to pandemic response. In particular, any decision by the WHO that can infringe upon the sovereignty of a nation needs to be clearly justified and the process must be transparent. There were concerns about the issuance of travel advisories during SARS. These issues have been addressed in the revised International Health Regulations (IHR), which have formalized the process by which the WHO can take such measures. The WHO must carefully consider how and when it issues travel recommendations. The issuing of recommendations that are perceived by nations to be inappropriate could lead to their lack of confidence in the WHO's leadership, and also undermine their support for the IHR. Conversely, the failure of the WHO to institute travel advisories in a timely manner, perhaps due to political pressure, could lead to the otherwise preventable spread of the pandemic.

Individual countries have a responsibility to the international community to communicate information on the emergency of public health threats. The revised international health regulations have outlined these responsibilities primarily as they relate to surveillance. However, countries with federal systems of government may not be able to comply with these responsibilities due to the allocation of powers within the country. This is potentially true for such countries as Canada, the United States, and Australia. Ultimately, it is the responsibility of these countries to utilize whatever policy instruments the federal governments have available to ensure that they can comply with the requirements of the new IHR.

The surveillance responsibilities of individual countries may be beyond the capacity of many developing countries. These countries are being pressured to improve their existing surveillance infrastructure. However, doing so may divert resources from areas in which needs are much greater in order to achieve goals that are more in the interest of developed countries. Developed countries must be aware of this trade-off and take measures, most suitably in the form of increased investment, to ensure that enhanced surveillance does not occur at the expense of managing the multitude of ongoing public health threats many developing countries face.

To sum up, protecting global health requires governments around the world to show solidarity and to be open and transparent in the way they carry out health protection responsibilities.

Ethical values and processes

Based on our guide of substantive values and process for ethical decision-making, the substantive values most applicable to this issue are: protection of the public from harm, proportionality, trust, and solidarity.

All five procedural values apply: reasonable, open and transparent, inclusive, responsive, and accountable.

Recommendations

1. The World Health Organization should remain aware of the impact of travel recommendations on affected countries, and should make every effort to be as transparent and equitable as possible when issuing such recommendations.

2. Federal countries should utilize whatever mechanisms are available within their system of government to ensure that relationships within the country are adequate to ensure compliance with the new International Health Regulations.

3. The developed world should continue to invest in the surveillance capacity of developing countries, and should also make investments to further improve the overall public health infrastructure of developing countries.

C5. Other ethical issues

In addition to the four key ethical issues explored by the JCB Working Group, there may be other important issues that people feel should be discussed in advance of a pandemic. These might include, for example:

- research ethics during a public health emergency;
- the ethical treatment of animals, such as the culling of poultry flocks, during a public health emergency; and
- compensation for farmers put out of business and loss of food supply and income resulting from mass culls.

This paper should be seen as fostering a public debate and providing guidance on issues that have been carefully studied.

D. NEXT STEPS

The JCB Working Group strongly encourages all governments and health care systems around the world to assess their pandemic plan against the ethical framework and recommendations presented in this discussion paper.

Looking ahead, we can say that if the pandemic strikes it will cause great hardship, but societies will struggle through. They will be better able to do so if they have prepared in all possible ways, including having general agreement on an ethical approach. Afterwards, history will judge today's leaders on how well they prepared for and acted during the crisis and if they treated people in an ethical manner.

The Working Group looks forward to receiving comments on this discussion paper, and encourages an open dialogue on its key points and recommendations.

E. END MATERIALS

Consolidated list of recommendations:

An ethical guide for pandemic planning

1. National, provincial/state/territorial, and municipal governments, as well as the health care sector, should ensure that their pandemic plans include an ethical component.

2. National, provincial/state/territorial, and municipal governments, as well as the health care sector, should consider incorporating both substantive and procedural values in the ethical component of their pandemic plans.

Recommendations from Issue 1

Health workers' duty to provide care during a communicable disease outbreak

1. Professional colleges and associations should provide, by way of their codes of ethics, clear guidance to members in advance of a major communicable disease outbreak, such as pandemic flu. Existing mechanisms should be identified, or means should be developed, to inform college members as to expectations and obligations regarding the duty to provide care during a communicable disease outbreak.

2. Governments and the health care sector should ensure that:

    a. care providers' safety is protected at all times, and providers are able to discharge duties and receive sufficient support throughout a period of extraordinary demands; and

b. disability insurance and death benefits are available to staff and their families adversely affected while performing their duties.

3. Governments, hospitals and health regions should develop human resource strategies for communicable disease outbreaks that cover the diverse occupational roles, that are transparent in how individuals are assigned to roles in the management of an outbreak, and that are equitable with respect to the distribution of risk among individuals and occupational categories.

Recommendations from Issue 2

Restricting liberty in the interest of public health by measures such as quarantine

1. Governments and the health care sector should ensure that pandemic influenza response plans include a comprehensive and transparent protocol for the implementation of restrictive measures. The protocol should be founded upon the principles of proportionality and least restrictive means, should balance individual liberties with protection of public from harm and should build in safeguards such as the right of appeal.

2. Governments and the health care sector should ensure that the public is aware of:

    a. the rationale for restrictive measures;
    b. the benefits of compliance; and
    c. the consequences of non-compliance.

3. Governments and the health care sector should include measures in their pandemic influenza preparedness plans to protect against stigmatization and to safeguard the privacy of individuals and/or communities affected by quarantine or other restrictive measures.

4. Governments and the health care sector should institute measures and processes to guarantee provisions and support services to individuals and/or communities affected by restrictive measures, such as quarantine orders, implemented during a pandemic influenza emergency. Plans should state in advance what backup support will be available to help those who are quarantined (e.g., who will do their shopping, pay the bills and provide financial support in lieu of lost income). Governments should have public discussions of appropriate levels of compensation in advance, including who is responsible for compensation.

Recommendations from Issue 3

Priority setting, including the allocation of scarce resources, such as vaccines and antiviral medicines

1. Governments and the health care sector should publicize a clear rationale for giving priority access to health care services, including antivirals and vaccines, to particular groups, such as front line health workers and those in emergency services. The decision makers should initiate and facilitate constructive public discussion about these choices.

2. Governments and the health care sector should engage stakeholders (including staff, the public and partners) in determining what criteria should be used to make resource allocation decisions (e.g., access to ventilators during the crisis, and access to health services for other illnesses), should ensure that clear rationales for allocation decisions are publicly accessible and should provide a justification for any deviation from the pre-determined criteria.

3. Governments and the health care sector should ensure that there are formal mechanisms in place for stakeholders to bring forward new information, to appeal or raise concerns about particular allocation decisions and to resolve disputes.

Recommendations from Issue 4

Global governance implications, such as travel advisories

1. The World Health Organization should remain aware of the impact of travel recommendations on affected countries, and should make every effort to be as transparent and equitable as possible when issuing such recommendations.

2. Federal countries should utilize whatever mechanisms are available within their system of government to ensure that relationships within the country are adequate to ensure compliance with the new International Health Regulations.

3. The developed world should continue to invest in the surveillance capacity of developing countries, and should also make investments to further improve the overall public health infrastructure of developing countries.

Acknowledgements

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Other:

The authors would also like to acknowledge Terry Collins of Collins Associates, Toronto Public Health, York Region Public Health, and members of the SARS Ethics study team.

Editorial support:

The Working Group acknowledges the editorial assistance of Michael Keating who drafted this report. The authors participated at every stage of the study, and are solely responsible for its content.

Funding support:

Peter Singer is a Canadian Institutes of Health Research Distinguished Investigator.
Ross Upshur holds the Canada Research Chair in Primary Care Research.
Kumanan Wilson is a Canadian Institutes of Health Research New Investigator.

This discussion paper draws greatly upon the findings of the research project "Ethical Challenges in the Preparedness and Response for SARS: An Interdisciplinary Research Study," which was funded by the Canadian Institutes

of Health Research (Grant # SAR-67798). The co-principal investigators of the study are Ross Upshur and Abdallah Daar.

The “Ethical Challenges in the Preparedness and Response for SARS” study received additional financial support from Toronto Public Health.

Authors' contributions:

All authors contributed substantially to the drafting and editing of the paper and all have read and approved the final version to be published. Ross Upshur and Peter Singer will serve as guarantors.

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-END-

CANADA

CONSOLIDATION

CODIFICATION

Genetic Non-Discrimination Act

Loi sur la non-discrimination génétique

S.C. 2017, c. 3

L.C. 2017, ch. 3

Current to June 3, 2021

À jour au 3 juin 2021

Published by the Minister of Justice at the following address:
http://laws-lois.justice.gc.ca

Publié par le ministre de la Justice à l'adresse suivante :
http://lois-laws.justice.gc.ca

OFFICIAL STATUS OF CONSOLIDATIONS

Subsections 31(1) and (2) of the *Legislation Revision and Consolidation Act*, in force on June 1, 2009, provide as follows:

Published consolidation is evidence

31 (1) Every copy of a consolidated statute or consolidated regulation published by the Minister under this Act in either print or electronic form is evidence of that statute or regulation and of its contents and every copy purporting to be published by the Minister is deemed to be so published, unless the contrary is shown.

Inconsistencies in Acts

(2) In the event of an inconsistency between a consolidated statute published by the Minister under this Act and the original statute or a subsequent amendment as certified by the Clerk of the Parliaments under the *Publication of Statutes Act*, the original statute or amendment prevails to the extent of the inconsistency.

CARACTÈRE OFFICIEL DES CODIFICATIONS

Les paragraphes 31(1) et (2) de la *Loi sur la révision et la codification des textes législatifs*, en vigueur le 1er juin 2009, prévoient ce qui suit :

Codifications comme élément de preuve

31 (1) Tout exemplaire d'une loi codifiée ou d'un règlement codifié, publié par le ministre en vertu de la présente loi sur support papier ou sur support électronique, fait foi de cette loi ou de ce règlement et de son contenu. Tout exemplaire donné comme publié par le ministre est réputé avoir été ainsi publié, sauf preuve contraire.

Incompatibilité — lois

(2) Les dispositions de la loi d'origine avec ses modifications subséquentes par le greffier des Parlements en vertu de la *Loi sur la publication des lois* l'emportent sur les dispositions incompatibles de la loi codifiée publiée par le ministre en vertu de la présente loi.

LAYOUT

The notes that appeared in the left or right margins are now in boldface text directly above the provisions to which they relate. They form no part of the enactment, but are inserted for convenience of reference only.

MISE EN PAGE

Les notes apparaissant auparavant dans les marges de droite ou de gauche se retrouvent maintenant en caractères gras juste au-dessus de la disposition à laquelle elles se rattachent. Elles ne font pas partie du texte, n'y figurant qu'à titre de repère ou d'information.

NOTE

This consolidation is current to June 3, 2021. Any amendments that were not in force as of June 3, 2021 are set out at the end of this document under the heading "Amendments Not in Force".

NOTE

Cette codification est à jour au 3 juin 2021. Toutes modifications qui n'étaient pas en vigueur au 3 juin 2021 sont énoncées à la fin de ce document sous le titre « Modifications non en vigueur ».

TABLE OF PROVISIONS

An Act to prohibit and prevent genetic discrimination

TABLE ANALYTIQUE

Loi visant à interdire et à prévenir la discrimination génétique

S.C. 2017, c. 3

An Act to prohibit and prevent genetic discrimination

[*Assented to 4th May 2017*]

Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

Short Title

Short title

1 This Act may be cited as the *Genetic Non-Discrimination Act*.

Interpretation

Definitions

2 The following definitions apply in this Act.

disclose includes to authorize disclosure. (*communiquer*)

genetic test means a test that analyzes DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (*test génétique*)

health care practitioner means a person lawfully entitled under the law of a province to provide health services in the place in which the services are provided by that person. (*professionnel de la santé*)

L.C. 2017, ch. 3

Loi visant à interdire et à prévenir la discrimination génétique

[*Sanctionnée le 4 mai 2017*]

Sa Majesté, sur l'avis et avec le consentement du Sénat et de la Chambre des communes du Canada, édicte :

Titre abrégé

Titre abrégé

1 *Loi sur la non-discrimination génétique*.

Définitions

Définitions

2 Les définitions qui suivent s'appliquent à la présente loi.

communiquer Est assimilé à l'acte de communiquer le fait d'autoriser la communication. (*disclose*)

professionnel de la santé Personne légalement autorisée en vertu de la loi d'une province à fournir des services de santé au lieu où elle les fournit. (*health care practitioner*)

test génétique Test visant l'analyse de l'ADN, de l'ARN ou des chromosomes à des fins telles la prédiction de maladies ou de risques de transmission verticale, ou la surveillance, le diagnostic ou le pronostic. (*genetic test*)

Prohibitions

Genetic test

3 (1) It is prohibited for any person to require an individual to undergo a genetic test as a condition of

(a) providing goods or services to that individual;

(b) entering into or continuing a contract or agreement with that individual; or

(c) offering or continuing specific terms or conditions in a contract or agreement with that individual.

Refusal to undergo genetic test

(2) It is prohibited for any person to refuse to engage in an activity described in any of paragraphs (1)(a) to (c) in respect of an individual on the grounds that the individual has refused to undergo a genetic test.

Disclosure of results

4 (1) It is prohibited for any person to require an individual to disclose the results of a genetic test as a condition of engaging in an activity described in any of paragraphs 3(1)(a) to (c).

Refusal to disclose results

(2) It is prohibited for any person to refuse to engage in an activity described in any of paragraphs 3(1)(a) to (c) in respect of an individual on the grounds that the individual has refused to disclose the results of a genetic test.

Written consent

5 It is prohibited for any person who is engaged in an activity described in any of paragraphs 3(1)(a) to (c) in respect of an individual to collect, use or disclose the results of a genetic test of the individual without the individual's written consent.

Exceptions: health care practitioners and researchers

6 Sections 3 to 5 do not apply to

(a) a physician, a pharmacist or any other health care practitioner in respect of an individual to whom they are providing health services; or

(b) a person who is conducting medical, pharmaceutical or scientific research in respect of an individual who is a participant in the research.

Interdictions

Test génétique

3 (1) Nul ne peut obliger une personne à subir un test génétique comme condition préalable à l'exercice de l'une ou l'autre des activités suivantes :

a) pour lui fournir des biens ou des services;

b) pour conclure ou maintenir un contrat ou une entente avec elle;

c) pour offrir ou maintenir des modalités particulières dans le cadre d'un contrat ou d'une entente avec elle.

Refus de subir un test génétique

(2) Nul ne peut refuser d'exercer une activité visée à l'un des alinéas (1)a) à c) à l'égard d'une personne au motif qu'elle a refusé de subir un test génétique.

Communication des résultats

4 (1) Nul ne peut obliger une personne à communiquer les résultats d'un test génétique comme condition préalable à l'exercice d'une activité visée à l'un des alinéas 3(1)a) à c).

Refus de communiquer les résultats

(2) Nul ne peut refuser d'exercer une activité visée à l'un des alinéas 3(1)a) à c) à l'égard d'une personne au motif qu'elle a refusé de communiquer les résultats d'un test génétique.

Consentement écrit

5 Il est interdit à quiconque exerce une activité visée aux alinéas 3(1)a) à c) à l'égard d'une personne de recueillir, d'utiliser ou de communiquer les résultats d'un test génétique de celle-ci sans son consentement écrit.

Exceptions : professionnels de la santé et chercheurs

6 Les articles 3 à 5 ne s'appliquent pas :

a) au médecin, au pharmacien et à tout autre professionnel de la santé qui fournissent des services de santé à une personne;

b) au chercheur qui mène des recherches médicales, pharmaceutiques ou scientifiques à l'égard d'un participant à ces recherches.

Offences and Punishment

Contravention of sections 3 to 5

7 Every person who contravenes any of sections 3 to 5 is guilty of an offence and is liable

(a) on conviction on indictment, to a fine not exceeding $1,000,000 or to imprisonment for a term not exceeding five years, or to both; or

(b) on summary conviction, to a fine not exceeding $300,000 or to imprisonment for a term not exceeding twelve months, or to both.

Canada Labour Code

8 [Amendment]

Canadian Human Rights Act

9 [Amendment]

10 [Amendments]

Coordinating Amendments

11 [Amendments]

Infractions et peines

Contravention aux articles 3 à 5

7 Quiconque contrevient à l'un des articles 3 à 5 commet une infraction et encourt, sur déclaration de culpabilité :

a) par mise en accusation, une amende maximale de un million de dollars et un emprisonnement maximal de cinq ans, ou l'une de ces peines;

b) par procédure sommaire, une amende maximale de trois cent mille dollars et un emprisonnement maximal de douze mois, ou l'une de ces peines.

Code canadien du travail

8 [Modification]

Loi canadienne sur les droits de la personne

9 [Modification]

10 [Modifications]

Dispositions de coordination

11 [Modifications]

TORYS LLP

Genetic discrimination: it's criminal!

July 14, 2020

Yael Bienenstock | Andrew Bernstein | Christopher Richter

The Supreme Court of Canada has upheld sections 1 to 7 of the *Genetic Non-Discrimination Act* (the Act) as a valid exercise of the federal criminal law power[1]. Among other things, the Act prohibits individuals and corporations from forcing individuals to disclose the results of genetic tests as a condition of obtaining access to goods, services or contracts. On a reference by the government of Québec, the Québec Court of Appeal held that sections 1 to 7 of the Act were *ultra vires* Parliament's criminal law power because they lacked any real criminal law purpose. In a 5-4 decision, the Supreme Court of Canada reversed the Québec ruling (Torys acted for the Canadian Life and Health Insurance Association, who intervened in the case).

What you need to know

- The *Genetic Non-Discrimination Act* is a valid exercise of Parliament's criminal law power under section 91(27) of the *Constitution Act, 1867*.
- Sections 1 to 7 of the Act establish various prohibitions in respect of genetic testing. Among other things, they prohibit:
  - individuals and corporations from refusing an individual access to goods, services and contracts because the individual refused to take a genetic test, or refused to disclose the results of a genetic test; and
  - using individuals' genetic test results without their written consent in the areas of contracting and the provision of goods and services.
- The Supreme Court's three sets of reasons in this decision demonstrate that the case turned almost entirely on how the law was characterized and whether it had a valid criminal law purpose:
  - The two sets of majority decisions held that the law was about providing individuals control over their personal information. Both emphasized privacy concerns, autonomy and the idea that fears over how genetic testing information would be used could lead to health-related harms.
  - The dissent held that the true aim of the provisions is to regulate contracts, particularly contracts of insurance and employment. The dissenting judges found that the provisions were intended to remove a "stumbling block"—fear of how genetic testing information would be used—so that Canadians would take advantage of genetic tests. They concluded that the provisions were aimed at promoting health benefits, not targeted at any "public health evil," and were outside the jurisdiction of criminal law power.

- Employers and businesses will need to ensure that they adapt their procedures to prevent violations. As this is criminal law, sanctions include fines of up to $1,000,000 and imprisonment of up to five (5) years.

The *Genetic Non-Discrimination Act*

The *Genetic Non-Discrimination Act* arose from a private member's bill introduced in the Senate in December 2015. While most private members' bills languish on the order paper, the Senate passed the bill by unanimous vote. The government opposed the bill, taking the position that it lacked the constitutional authority to enact it. However, it did not require party backbenchers to vote against it, and it passed through the House of Commons with a strong majority.

The Act defines—and makes it a criminal offence to engage in various conduct in respect of—genetic testing:

- Section 2 of the Act defines a genetic test as "a test that analyzes DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis."
- Sections 3, 4 and 5 establish prohibitions relating to genetic tests. Individuals and corporations cannot:
  - force individuals to take genetic tests or disclose genetic test results as a condition of obtaining access to goods, services and contracts;
  - refuse an individual access to goods, services and contracts because they have refused to take a genetic test or refused to disclose the results of a genetic test; or
  - use individuals' genetic test results without their written consent in the areas of contracting and the provision of goods and services.

The term "genetic discrimination" in the title of the Act refers to the possibility that people will be treated differently according to their genetic profile. For example, someone with genetic markers for certain diseases may be assessed higher premiums for life, health or disability insurance.

The regulation of contracts is generally a matter of property and civil rights and within exclusive provincial jurisdiction under section 92(13) of the *Constitution Act, 1867*. However, Parliament invoked its section 91(27) criminal law power to pass the Act, as was clear from the form of the legislation.

Shortly after it was enacted, the Government of Québec referred to the Québec Court of Appeal the question of whether Parliament has the constitutional authority to enact sections 1-7 of the Act. In an interesting twist, the Attorney General of Canada's position was that these provisions are outside Parliament's jurisdiction over criminal law. A unanimous Québec Court of Appeal agreed in a 5-0 ruling, concluding that the provisions could not be upheld under the criminal law power because they lacked any valid criminal law purpose. However, the Supreme Court of Canada reversed this ruling in a 5-4 split decision.

The SCC's decision: protecting autonomy, privacy and health—or regulation of contracts?

Section 91(27) of the *Constitution Act, 1867* gives Parliament the exclusive authority to make laws in relation to criminal law. Courts have held that the criminal law power is "broad and plenary." It has been used to uphold legislation regulating tobacco advertising, the environment, and excessively high rates of interest for borrowing and lending. It is well-accepted that a law is a valid exercise of the criminal law power if, in pith and substance, it: (1) consists of a prohibition; (2) is accompanied by a penalty; and (3) is backed by a criminal law purpose. There was no dispute that the *Genetic Non-Discrimination Act* met the first two criteria. The split in the Court turned entirely on the judges' characterizations of the legislation, and in particular, whether the impugned provisions were directed to a valid criminal law purpose.

Majority reasons

The Act is about protecting personal information and preventing discrimination. Emphasizing the title and text of the Act, as well as its legislative history and parliamentary debates, Justices Abella, Karakatsanis and Martin held that in enacting the *Genetic Non-Discrimination Act*, Parliament sought to both prohibit genetic discrimination and alleviate Canadians' fear of suffering genetic discrimination. They emphasized the deeply personal nature of decisions about genetic testing, and concluded that Parliament saw genetic test results relating to health as "particularly vulnerable to abuse and discrimination." As a result, Parliament sought to fill a gap in Canada's laws that made individuals vulnerable to genetic discrimination in contracting and the provision of goods and services. They concluded that "in pith and substance, ss. 1 to 7 of the Act protect individuals' control over their detailed personal information disclosed by genetic tests in the areas of contracting and the provision of goods and services in order to address fears that individuals' genetic test results will be used against them and to prevent discrimination based on that information."

The Act responds to threats to privacy, autonomy, equality, public health. In upholding the legislation, Justices Abella, Karakatsanis and Martin rejected the idea that valid criminal law must be directed to an "evil." Instead, they held that a law will have a criminal law purpose if it represents Parliament's response to a threat of harm to public order, safety, health or morality or fundamental social values, or to a similar public interest. No particular degree of harm must be established. Parliament must simply have acted in response to a reasoned apprehension of harm to one or more of these public interests. They concluded that this law represents Parliament's response to emerging threats to autonomy, personal privacy, equality and public health and is therefore valid criminal law.

The Act is about protecting health by removing barriers to genetic testing. In a concurring opinion, Justices Moldaver and Côté agreed that sections 1 to 7 of the Act are valid, but disagreed on the underlying analysis. They held that the pith and substance of the provisions is to "protect health by prohibiting conduct that undermines individuals' control over the intimate information revealed by genetic testing." In other words, Parliament sought to remove barriers to genetic testing so that

individuals would be free to have tests without fear of how the results would be used. On this theory, sections 1 to 7 are directed to the valid criminal law purpose of targeting detrimental health effects, and are therefore a valid exercise of the criminal law power. Justices Moldaver and Côté did not comment on the requisite degree of harm that is required for valid criminal law. In their view, the legislation was valid on any standard of harm because there was evidence of people refraining from genetic testing out of fear as to how the results would be used, thereby suffering significant harm or putting themselves at risk.

Dissent

The Act is about regulating contracts for goods and services. Chief Justice Wagner and Justices Brown, Rowe and Kasirer dissented. Emphasizing the actual text of the legislation, they held that the pith and substance of sections 1 to 7 of the Act was "to regulate contracts and the provision of goods and services, in particular contracts of insurance and employment, by prohibiting some perceived misuses of one category of genetic tests, the whole with a view to promoting the health of Canadians." Because promotion of beneficial health practices is not a valid criminal purpose, the provisions were not valid criminal law. The dissenting judges also disagreed with the majority as to the level of harm required. Relying on the 1951 *Margarine Reference*, the dissenters held that in order to be valid criminal law, legislation must be directed at an "evil or injurious or undesirable effect upon the public." The threat must be well defined, and real in the sense that Parliament must have a concrete basis and a reasoned apprehension of harm. Here, there was "nothing on the record suggesting that the prohibited conduct is a threat to Canadians."

Immediate and long-term implications

The Act applies generally to the provision of goods and services. Employers and businesses will need to ensure that they adapt their procedures to prevent violations. As this is criminal law, sanctions include fines of up to $1,000,000 and imprisonment of up to five (5) years. The implications of this decision have already been felt in the insurance industry, which has been complying with the Act and will now have to make those practices permanent. Legislation in every province requires prospective insureds to disclose any information that is material to the insurance[2]. This is referred to as the principle of equal information. Failing to disclose or misrepresenting this information renders the contract voidable by the insurer. The courts will have to work out how the Act affects this fundamental principle of insurance law.

The long-term implications of this decision, however, may be more troubling. The majority's expansive interpretation of the Criminal Law power means that Parliament may be able to regulate a whole variety of matters previously considered to be within provincial authority under "property and civil rights." So long as the form of the regulation is amendments to the *Criminal Code*, and there is some ostensible relationship with health and/or privacy (or perhaps autonomy or equality), it appears that at least some judges of the Supreme Court will uphold the provision. How and when Parliament chooses to use this power in the future remains to be seen. Predicting the outcome of future decisions regarding the scope of the criminal law power will be difficult in light of the divided Court in this case.

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[1] S.C. 2017 c. 3

[2] See for example, section 183(1) of Ontario's Insurance Act and art. 2408 of the Civil Code of Quebec

To discuss these issues, please contact the author(s).

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Catalogue no. 45-28-0001

StatCan COVID-19:
Data to Insights for a Better Canada

Impacts of the COVID-19 pandemic in nursing and residential care facilities in Canada

by Janine Clarke

Release date: June 10, 2021

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StatCan COVID-19:
Data to Insights for a Better Canada

Impacts of the COVID-19 pandemic in nursing and residential care facilities in Canada

by **Janine Clarke**

Introduction

In the last 10 years, there has been very little information collected nationally on residential care facilities despite about 500,000 Canadians living in these settings (Statistics Canada, 2016). Significant data gaps exist concerning these facilities and their residents, which has been further highlighted by the COVID-19 pandemic.

Of the 500,000 Canadians living in residential care facilities, the vast majority (425,000) live in either nursing homes (also known as long-term care homes) or seniors' homes (also known as retirement homes or assisted living facilities) (Statistics Canada, 2016). These facilities in particular have been among the hardest hit by the COVID-19 pandemic in Canada. During the first wave of the pandemic (March through August 2020), residents of nursing and seniors' homes accounted for more than 80% of all reported COVID-19 deaths (Canadian Institute for Health Information, 2020). Furthermore, infections among staff at these facilities represented more than 10% of the country's total cases (9,500 cases, including 9 deaths) (Canadian Institute for Health Information, 2020). By mid-December (partway through the second wave that lasted from September 2020 through February 2021), there were about 44,000 cases and 9,200 deaths in nursing and seniors' homes (Public Health Agency of Canada, 2020). As of early March 2021, reports indicated that nursing and seniors' homes continued to account for the greatest proportion of outbreak-related cases and deaths, representing about 7% of all cases and more than 50% of all deaths (Public Health Agency of Canada, 2021a, 2021b). Many residents of nursing and seniors' homes are at increased risk for negative outcomes of the virus (such as hospitalization or death) as they are older and more likely to have complex chronic conditions (Industry Canada, 2020). Residential care facilities in general are potentially at higher risk for the spread of infection given the unavoidable close contact between staff and residents (Industry Canada, 2020).

This article presents preliminary results on the impact of the COVID-19 pandemic in nursing homes and seniors' homes as well as mental health facilities and other residential care facilities (such as group homes for persons with disabilities or addictions, homes for women, etc.) in Canada during the period up to and including December 31, 2020. Results presented are from 4,217 of the 5,260 residential care facilities that responded[1] to the recently completed 2020 Nursing and Residential Care Facility Survey.

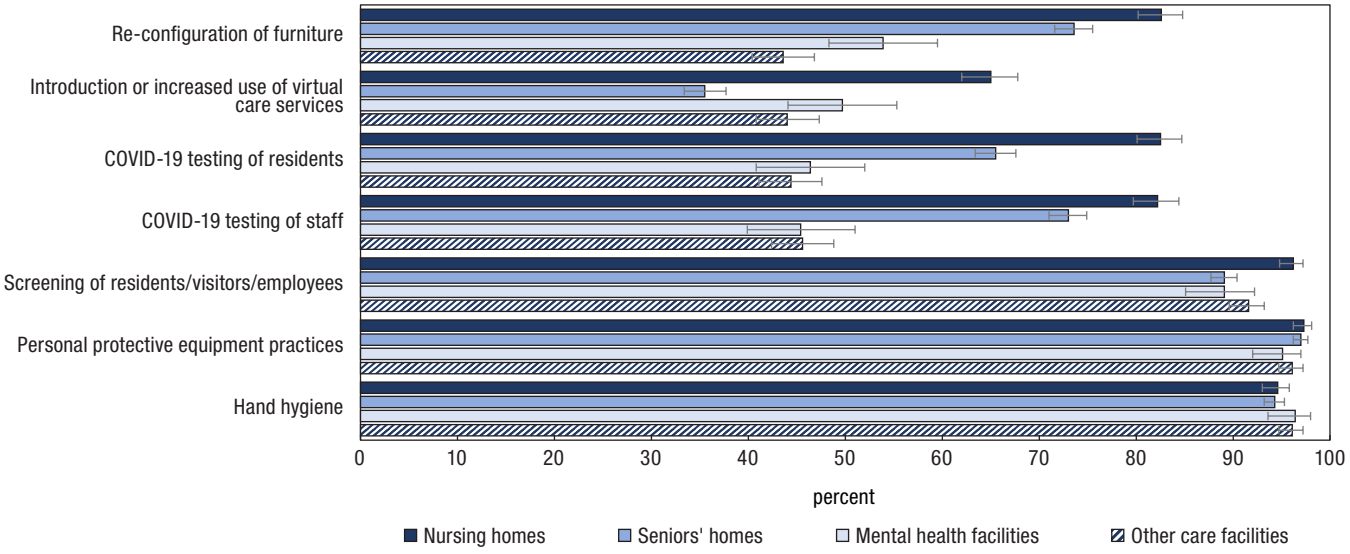
Nearly all facilities reported implementing new or increased Infection Prevention and Control procedures in response to the pandemic

Regular hand washing and environmental cleaning and disinfection are among the many daily practices recommended for preventing the spread of infection in settings such as residential care facilities. With the emergence of the COVID-19 pandemic, public health authorities recommended additional infection prevention and control (IPC) measures such as the regular use of personal protective equipment (PPE) such as masks, gloves or gowns (Government of Canada, 2020). Results of the survey suggest that nearly all responding facilities implemented one

1. At this time, the NRCFS data file and these results are considered preliminary. As such, the results presented in this article are subject to change; an updated and more comprehensive analysis of the data is planned for a later date.

or more new or increased IPC measures in response to the pandemic (data not shown). About 9 out of 10 facilities also introduced other public-health recommended changes, such as the reconfiguration of furniture, the regular testing for COVID-19 among residents and staff or the increased use of virtual care services. Some of the most commonly reported changes are presented in Chart 1, by facility type.

Chart 1
Percent of responding facilities reporting selected new or increased protocols in response to the COVID-19 pandemic, by type of facility, Canada, 2020



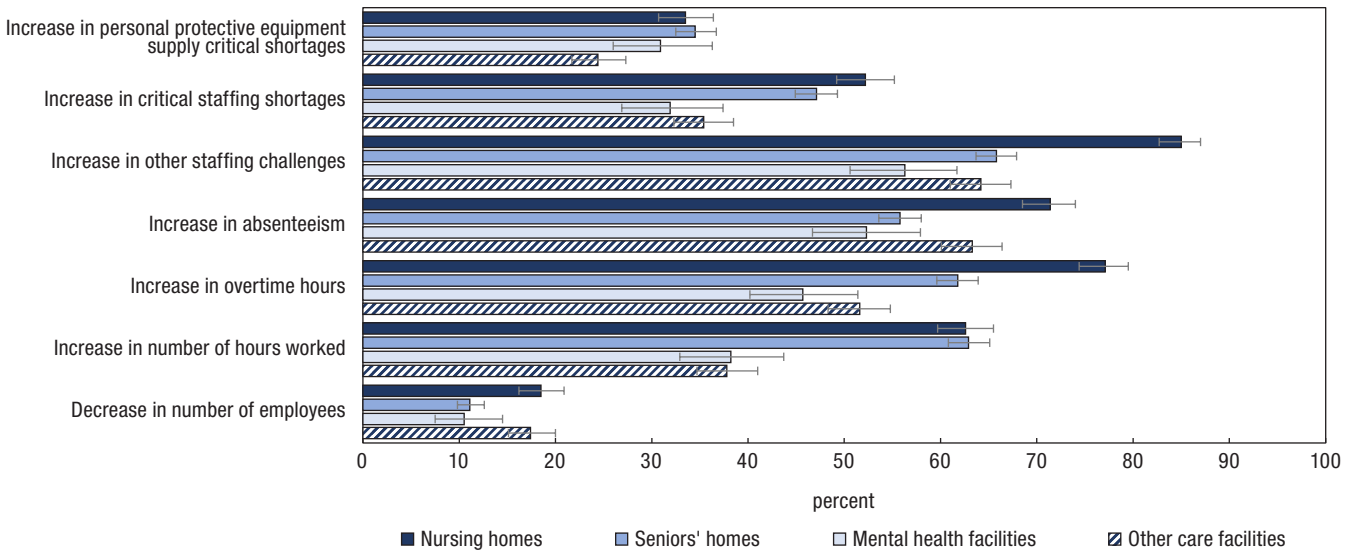
Note: At this time, these results are considered preliminary and are subject to change. Results refer to protocols newly introduced or increased at any point up to and including December 31, 2020.
Source: Nursing and Residential Care Facility Survey 2020.

Nursing homes were more likely to experience staffing-related challenges

Despite all of the public-health measures taken by facilities, many facilities still reported facing many important challenges at some point in 2020 as a result of the pandemic (Chart 2). For example, about 86% of facilities reported experiencing at least one staffing-related challenge in 2020 (data not shown); however, nursing homes were much more affected by certain staffing challenges compared to other types of facilities (Chart 2).

Among nursing homes, 77% reported an increase in the number of overtime hours, 71% reported an increase in absenteeism and 85% reported other staffing challenges among direct-care employees such as nurses or other health care workers (Chart 2). More than half of nursing homes also reported critical staffing shortages, which was defined as a shortage of staff, particularly in key roles (such as directors of care, nurses or personal support workers) that had an impact on the quality of resident care and employee safety. Furthermore, about one-third of nursing homes reported experiencing critical shortages in PPE in 2020. Some studies have indicated that health care workers may be at increased risk of mental health impacts due to increased risk of exposure and demanding working conditions. A recent crowdsource survey of health care workers in Canada reported that 70% of health care workers indicated their mental health was somewhat or much worse now compared to before the pandemic, and more than half (56%) reported that most days were quite a bit or extremely stressful (Statistics Canada, 2021).

Chart 2
Challenges faced by responding facilities during the COVID-19 pandemic, by type of facility, 2020



Note: At this time, these results are considered preliminary and are subject to change. Results refer to challanges faced at any point up to and including December 31, 2020. Employee- and staffing-related challenges refer to direct-care, for example nurses or other health care workers.
Source: Nursing and Residential Care Facility Survey 2020.

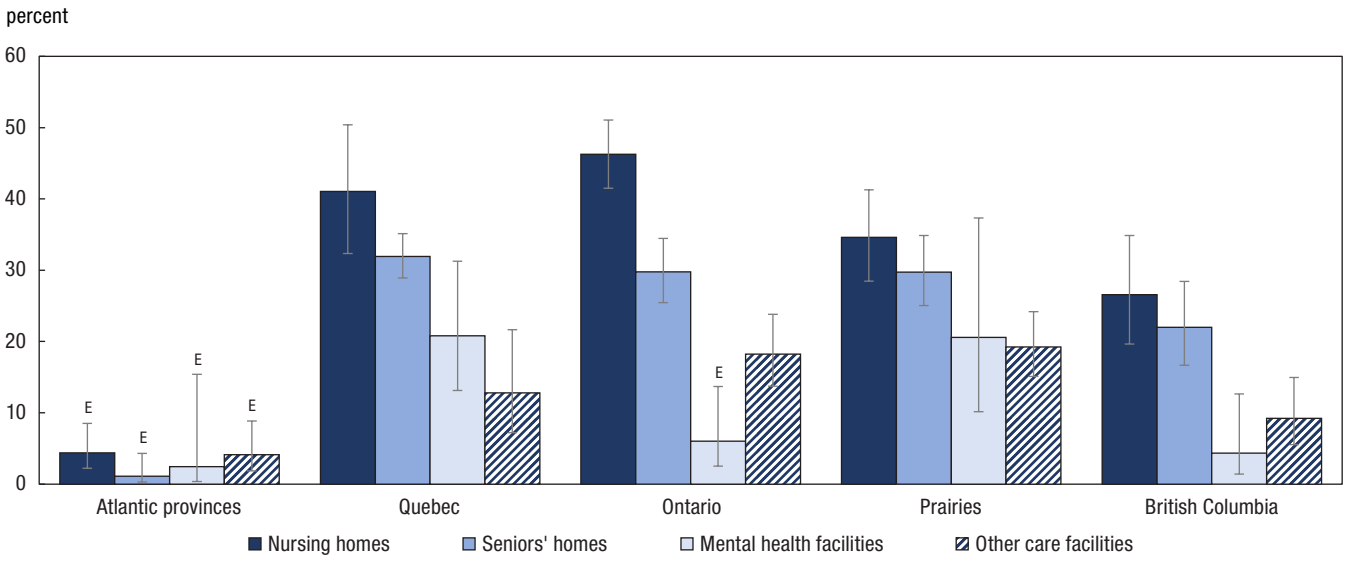
Nursing homes and seniors' homes were more likely to report at least one COVID-19 case among residents compared to other types of facilities

Chart 3 shows that the percent of responding residential care facilities that reported a COVID-19 outbreak (defined as at least one case among residents (Canadian Institute for Health Information, 2020)) at any point in 2020 was highest in Ontario (32% of facilities), followed by Quebec[2] (31% of facilities), the Prairies (27% of facilities), British Columbia (17% of facilities), and the Atlantic provinces (3% of facilities) (data not shown). Outbreaks were generally higher in nursing homes and seniors' homes compared to other facilities, though the differences were not always statistically significant (Chart 3).

The impact of COVID-19 in nursing and seniors' homes has been widely covered in the media and several reports and inquiries have taken place in an effort to reduce the risk of infection, outbreaks and associated deaths in the future (Canadian Institute for Health Information, 2021b; Government of Nova Scotia, 2020; Ontario Long-Term Care Commission, 2021; Office of the Auditor General of Ontario, 2021; Revera, 2020). As was the case for these reports, an important goal of the recent NRCFS was to contribute to the better understanding of the factors associated with increased rates of COVID-19 infection.

2. The response rate for public facilities in Quebec was less than 10%.

Chart 3
Percent of responding facilities reporting at least one COVID-19 case among residents, by region and type of facility, 2020



[E] use with caution
Note: At this time, these results are considered preliminary and are subject to change. Results refer to cases reported up to and including December 31, 2020.
Source: Nursing and Residential Care Facility Survey 2020.

Logistic regression analysis of a subset of facilities[3] suggests that among responding nursing homes, facilities were at greater risk of an outbreak if they reported: having at least one case among employees, being a larger facility (more than 50 residents), and having experienced an increase in critical staffing shortages (Table 1). Among responding seniors' homes, facilities were at greater risk for an outbreak if they reported: at least one case among employees and being a larger facility (more than 25 residents). COVID-19 cases among staff was the most significant predictor of outbreaks: facilities that reported at least one case among employees were about 4 times more likely to have experienced an outbreak, and among seniors' homes, those facilities were nearly 7 times more likely. For seniors' homes, having only private rooms at the facility was also associated with a decreased risk of outbreaks.

These results are in line with previously published research in Canada which have shown that larger facilities (National Collaborating Centre for Methods And Tools 2020; Canadian Institute for Health Information 2021b), facilities having shared rooms (Brown et al. 2020), and facilities reporting cases among employees (Fisman et al. 2020) were more likely to have experienced outbreaks or to have more severe outbreaks.

3. Due to an insufficient number of responding facilities, data from Yukon, Northwest Territories and Nunavut are excluded from the regression analysis.

Table 1
Adjusted risk ratios for reporting at least one COVID-19 case among residents in nursing homes and seniors' homes, by selected facility characteristics, 2020

	Nursing homes			Seniors' homes		
		95% Confidence interval			95% Confidence interval	
Characteristic	Adjusted risk ratio[1]	from	to	Adjusted risk ratio[1]	from	to
For profit status						
For profit	1.04	0.90	1.20	1.11	0.96	1.27
Not for profit†	...	...	...	...	...	...
Types of rooms						
Private rooms only	0.94	0.79	1.11	0.86*	0.76	0.97
Shared rooms†	...	...	...	...	...	...
Size of facility (number of residents)						
25 or fewer residents†	...	...	...	...	...	...
26 to 50 residents	1.80	0.92	3.51	1.56*	1.22	2.00
51 to 100 residents	2.48*	1.31	4.66	1.67*	1.29	2.16
101 or more residents	3.52*	1.87	6.63	2.17*	1.69	2.79
Registered nurses on staff						
Yes	0.85	0.68	1.07	0.93	0.82	1.06
No†	...	...	...	...	...	...
At least one employee case reported						
Yes	4.16*	2.91	5.93	6.57*	5.26	8.22
No†	...	...	...	...	...	...
Critical staffing shortages[2]						
Increased	1.22*	1.04	1.43	1.08	0.96	1.22
Decreased or no change†	...	...	...	...	...	...
Personal protective equipment shortages[3]						
Increased	1.02	0.87	1.20	1.00	0.88	1.14
Decreased or no change†	...	...	...	...	...	...

... not applicable
* significantly different from reference category ($p < 0.05$)
† reference category
1. A risk ratio greater than 1 indicates an increased risk and a risk ratio less than 1 indicates a decreased risk. All variables presented are included in the same model, and are also adjusted for region: Atlantic, Quebec, Ontario, Prairies and British Columbia. The territories are excluded due to insufficient sample size.
2. A critical staffing shortage was defined as a shortage in direct-care staff (e.g. nurses) that impact the quality of resident care and employee safety.
3. A personal protective equipment shortage was defined as having less than a two-day supply available.
Note: At this time, these results are considered preliminary and are subject to change. Results refer to cases reported up to and including December 31, 2020.
Source: Nursing and Residential Care Facility Survey 2020.

Other research has shown many other factors to be associated with outbreaks in nursing or seniors' homes such as a lack of availability of registered nurses (National Collaborating Centre for Methods And Tools 2020) or personal support workers (Canadian Institute for Health Information 2021b). However, these factors were not significant when included in the present analysis. For-profit status has also been suggested to be associated with outbreaks during this pandemic (NCCMT 2020; Stall et al. 2020). For-profit status was not found to be significant in the present analysis either, which is similar to more recent findings in an Ontario report which found that for-profit status was not significantly associated with either the severity of outbreaks or the resident mortality rate after controlling for other factors (Canadian Institute for Health Information 2021b).

Other factors that have been shown or suggested to be significantly related to COVID-19 cases or deaths in nursing and seniors' homes include: being part of a large chain of facilities (Canadian Institute for Health Information 2021b), having a smaller ratio of nursing staff to residents (Canadian Institute for Health Information 2021b), having a greater proportion of older residents (National Collaborating Centre for Methods And Tools 2020), having a greater proportion of male residents (National Collaborating Centre for Methods And Tools 2020), as well as

the number of cases in the surrounding community (National Collaborating Centre for Methods And Tools 2020; Canadian Institute for Health Information 2021b). These factors were not considered in the current analysis due to a lack of availability or the need for additional data review and validation, but may be evaluated in future analyses.

Conclusion

Preliminary data from the 2020 Nursing and Residential Care Facility Survey show that, among responding facilities, the majority of responding residential care facilities in Canada reported, at some point up to and including December 31, 2020, making changes to IPC practices, such as introducing or increasing practices such as hand washing and use of PPE or making other changes to the facility such as the installation of partitions or the regular testing of residents or staff. However, the majority of responding facilities also reported facing important challenges such as an increase in absenteeism among staff. Several responding facilities even reported significant staffing shortages or shortages in PPE supplies during this reference period. The preliminary data also suggest that after controlling for region, among responding facilities, large facilities, cases among employees and staffing shortages were associated with an outbreak in nursing homes, while shared rooms, large facilities and cases among employees were associated with outbreaks in seniors' homes. However, more research is needed to better understand the impact of the pandemic on nursing and residential care facilities in Canada.

Data source & methods

Data for this analysis are from the 2020 Nursing and Residential Care Facility Survey (NRCFS), a national survey targeting public and private sector establishments classified to code 623 "Nursing and residential care facilities" of the North American Industry Classification System (NAICS) 2017. This includes nursing homes, seniors' homes, mental health facilities and other care facilities (such as homes for women, or substance use facilities). Data were collected directly from respondents using an electronic questionnaire. Collection took place from January 5 to March 31, 2021. At the time of analysis, the overall response rate for the survey was 66% (n = 5,260 facilities). Response rates were generally higher in the private sector (71%) than in the public sector (55%)[2] and varied by province (as high as 79% in Nova Scotia and as low as 54% in Newfoundland and Labrador). The overall response rate in the territories was less than 25%. Included in this article are responding facilities that reported having at least one bed, at least one resident and at least one employee (n = 4,217). Excluded were those that did not meet the listed criteria, had missing or invalid data, or were considered to be out of scope for the survey.

The survey collected basic information on facility characteristics, such as employee and resident counts for the 2019/2020 fiscal year, as well as information related to the COVID-19 pandemic up to and including December 31, 2020. Basic descriptive statistics are used to describe the many changes and challenges faced by each type of facility during the pandemic. In nursing and seniors' homes, logistic regression was used to assess the relationship between certain facility characteristics (including: region, for-profit status, private or shared rooms, number of residents, registered nurses on staff, cases among employees, critical staffing shortages and personal protective equipment shortages) and the risk of an outbreak, defined as one or more COVID-19 cases among residents. Results are presented as risk ratios, which compares the risk of an outbreak for one group (e.g. Ontario) versus another group (e.g. Quebec), adjusted for all other listed variables. A risk ratio greater than 1 indicates an increased risk and a risk ratio less than 1 indicates a decreased risk.

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3350-Op LASER 20-01 (COS)

14 May 20

Distribution List

OP LASER – JTFC OBSERVATIONS IN
LONG TERM CARE FACILITIES IN ONTARIO

References: A. Letter: Ontario Request for Assistance in Provincial Long Term Care Facilities, Fed Min PS Blair to Ont SOLGEN Jones, 24 Apr 20; and
B. 3350-1 (J33) JTF-LR Task Order 003 - JTFC Op LASER 20-01, 26 Apr 20.

1. Sir, as auth at Ref A and directed at Ref B, JTFC has employed Augmented Civilian Care (ACC) teams, since 28 Apr 20, in five Province of Ontario-prioritized Long Term Care Facilities (LTCF) that were in urgent and immediate need of personnel to provide humanitarian relief and medical support.

2. Since arrival, and with the benefit of two weeks of observation, CAF ACC have identified a number of medical professional and technical issues present at the five LTCF. From a command and medical perspective, challenges were expected at these facilities given the severe deficiencies and shortfalls that existed/exist at the provincially-prioritized assignments; the CAF was meant to go to locations with the greatest need of our support. This is a reflection of the conditions at those distressed locations. Consequently, issues and challenges have been collated and consolidated in medical reporting in the key areas of Standards and Quality of Medical Care. Annexes A-E provide detail by individual LTCF. The purpose of this letter is to ensure that these observations do not go unnoticed by our chain of command, the Province of Ontario, and most importantly at the individual LTCF where efforts are currently underway in an open, transparent and collaborative manner at the local level between each LTCF and ACC to aid in recovery by addressing the specific areas of observation.

3. Nothing in this letter is meant to encroach upon the purview of the CAF Surgeon General, the established relationship between that office and the Chief Medical Officer of Health for Ontario, or the formal and informal connections by the CFHS and its offices, with those medical and professional Colleges and Associations that represent the medical professionals and health care capabilities within the Ontario health care system. Rather, this is meant to compliment that discussion by ensuring a command awareness on these issues so as to support the Surgeon General, the CFHS and our CAF medical and non-medical general duty personnel as they execute daily tasks as an ACC team in this unexpected and difficult operating environment.

4. The Province of Ontario, and its Incident Management System (IMS) responsible to the Command Table and is responsible for dealing with the COVID crisis, co-chaired by the Provincial Deputy Ministers (DM) for both Health and for Long-Term Care, respectively, are aware that CAF ACC teams have made observations with Standards and Quality of Medical Care. Informally, key figures in the IMS understand the general themes of our observations but have not been privileged with specifics or detail. We have sought to make observations that are strictly factual in nature and are not meant to assess or pass judgment on LTCF leadership or staffs. From the perspective of our medical and non-medical personnel in-situ, however, the observations are sufficiently serious in nature to warrant them also being shared with the Province of Ontario, given that the CAF is responding to their RFA and LTCF fall under the Province's authority. I believe that this is best done under the Surgeon General's purview, and JTFC can enable that via our Regional Surgeon who has established links with the Provincial IMS Lead and Operations Head. Additionally, I will make myself available, should it be directed or desired, to address these issues at my level, with my Provincial counterparts: DM for Health, DM for Long-Term Care, or with the Deputy Solicitor General for Ontario (Dep SOLGEN) who is responsible for RFA within the Province.

5. Far more importantly for the health of the residents who are the focus of all concerned, is our transparency and collaborative work with each LTCF to improve the situation so as to have an immediate effect on both daily operations and incremental facility recovery. To that end, I can assure that each ACC team has addressed their own observations with the LTCF management and the competent medical authority available at each site. Every engagement to date has been positive with an acknowledgement by the LTCF that they need to improve, with the improvement on these observed issues being as equal in importance to: overall recovery as proper staffing, sufficient medical resources and supplies, coherent management return on site and establish a working connection to respective health networks.

6. I believe care and attention by our ACC personnel remains our strongest tool in this domain. Notwithstanding the observed deviations in care and accepted practices, our CAF medical professionals lead by example in these LTCF and are ably supported by their non-medical general duty personnel and the structure of the Task Force that enables each ACC team. The content of the annexes was the result of the ACC Nursing Officer team leads, the work of the ACC Senior Nursing Officer, Capt K. Martin and the Regional Surgeon, LCol C. Mercer. Any specific interest with the Annex content is best directed via the Regional Surgeon as JTFC technical authority for the medical content.

7. Sir, I remain available at your convenience for direction or discussion.

Respectfully,

C.J.J. Mialkowski
Brigadier General
Commander

Annexes / Distribution List (next page)

Annexes

Annex A – Observation Report on LTCF Eatonville Care Centre
Annex B – Observation Report on LTCF Hawthorne Place Care Centre
Annex C – Observation Report on LTCF Orchard Villa
Annex D – Observation Report on LTCF Altamont
Annex E – Observation Report on LTCF Holland Christian – Grace Manor

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Annex A to Observation Report on LTCF
Eatonville Care Centre
3350-Op LASER 20-01
14 May 20

EATONVILLE CARE CENTRE
420 THE EAST MALL, ETOBICOKE, ON M9B 3Z9

1. Infection control:
   a. Isolation: COVID-19 positive residents allowed to wander. This means anyone in the facility (staff, residents, and visitors) is at risk of being exposed and passing it throughout the home; as the resident's location is not predictable, full appropriate PPE is not possible;
   b. PPE practices – resident rooms: facility staff are under the impression that if the infection between 2 residents is the same, there's no need to change their gown; and
   c. PPE practices – outside rooms: facility staff often wear PPE outside of rooms and at the nurses station.

2. Standards of practice/quality of care concerns:
   a. Reusing hypodermoclysis supplies even after sterility has been obviously compromised (e.g. catheter pulled out and on the floor for an undetermined amount of time);
   b. Poor palliative care standards – inadequate dosing intervals for some medications, some options limited based on level of staff administering medication (ex: hydromorphone injection won't be given if RN unavailable);
   c. There are no mouth or eye care orders or supplies for palliative residents;
   d. Poor Foley catheter care. CAF SNO (Senior Nursing Officer) reports poor adherence to orders, no consistent safety checks. Significant incidents of excessive sediment or abnormal discharge and bleeding with no follow on action; and
   e. Generally very poor peri-catheterization care reported. Example: Retracting penis foreskin to clean isn't happening on a widespread level. CAF have found nearly a dozen incidents of bleeding fungal infections.

3. Supplies:
   a. General culture of fear to use supplies because they cost money (fluid bags, dressings, gowns, gloves etc);
   b. Key supplies are often under lock and key, not accessible by those who need them for work (e.g. wipes for PSWs); and
   c. Expired medication. Much of the ward stock was months out of date (inference: residents have likely been getting expired medication for quite some time).

4. Ambiguity on local practices:
   a. Extra soaker pad: residents who routinely soil their bed despite incontinence products are not permitted to have an extra soaker pad or towel in bed to help protect sheets and blankets from soiling. (PSWs are afraid for their jobs on this issue) rationalization used is that an extra pad is undignified;
   b. Cohorting residents. Ministry requirement cited as reason they still have negative residents rooming with positive residents; and
   c. Unable to post information that would greatly increase patient safety and appropriate care. Example: an inconspicuous card above bed that stated code status, diet texture/fluid consistency, transfer status etc. was deemed to be "undignified". This

presents a safety risk to residents who may get improper care and liability risk to the care providers.

5. Communication:
   a. PSWs can be task focused and do not always report discovered abnormalities to registered staff;
   b. Policies and facility-specific procedures aren't communicated to staff (example: how to sign for a narcotics shipment, what to do in the event of a call bell failure);
   c. Information about residents is difficult to access and hard to communicate (example: a neurologic exam after a fall is hard to interpret when it's unclear what the resident's baseline neurologic status is);
   d. Information on LTCF COVID status (residents and staff) is not available or updated; and
   e. Management is unable to effectively enforce restrictions on use of CAF PPE.

6. Staffing:
   a. New staff that have been brought to LTCF haven't been trained or oriented;
   b. LTFC is severely understaffed during day due to resident comorbidities and needs (need more PSWs, RPN and RNs);
   c. MDs not present and have to be accessed by phone (not always within reach);
   d. Morale and well-being of staff at risk. Many are overworked, seem burned out and have no time off (some have not seen their families for weeks);
   e. The staffing is such that it is impossible to provide care at a pace that is appropriate to each resident or allow them any kind of independence. (example: a resident states he would like to ambulate to the toilet, a PSWs says, "no I just changed him." Or people are often sedated with narcotics when they are likely just sad or depressed in a context where there isn't the staffing to support the level of care and companionship they need;
   f. ACC staff report not having witnessed any psychosocial support for these residents who have all of a sudden had their families taken away (Reported as "It's heartbreaking to get a report about someone who is "agitated and difficult" and has been getting PRN narcotics or benzodiazepines to sedate them but when you talk to them they just say they're "scared and feel alone like they're in jail" – no agitation or sedation required; and
   g. Gross in-adherence to some recurring orders (example: regular vital signs or patient turning); in some cases PSWs are reported to asking ACC team members not to do these since they "wake up the resident".

7. Inappropriate Behaviour:
   a. CAF member have witnessed aggressive behaviour which ACC staff assessed as abusive/inappropriate. Incidents have been reported to management on numerous occasions. Witness reports have been completed and LTC has commenced investigation to the knowledge of ACC staff. Examples include aggressiveness when changing incontinence product, not stopping or slowing when resident complained of pain, pulling residents, aggressive transfers impacting resident ability to participate in care as able (roll self in bed), degrading or inappropriate comments directed at residents etc;

b. Reports of inaccurate charting or documentation being amended by agency staff following submission regarding patient's pain levels, nutrition, eating status etc; and

c. ACC staff report inaccurate reporting regarding resident's status to family (feeding, pain levels, general condition etc).

8. ACC engagement with facility staff:

a. Concerns were initially raised by the on-site SNO to local leadership. On 4 May 20, a teleconf was conducted between CO TBG1, OC ACC, and leadership from Eatonville Care Centre, as well as corporate management. Major concerns were raised, in particular standards of care issues, poor IPAC, poor charting, narcotic misuse, and wound care. Concerns were raised in a collegial manner and facility staff advised they will address the deficiencies.

Annex B to Observation Report on LTCF
Hawthorne Place Care Centre
3350-Op LASER 20-01
14 May 20

HAWTHORNE PLACE CARE CENTRE
2045 FINCH AVE WEST, NORTH YORK, ON M3N 1M9

1. Infection control:
   a. Numerous fans blowing in hallways (increased spread of COVID-19);
   b. Poor training and adherence to IPAC protocols noted;
   c. Significant deterioration of cleanliness standards throughout LTC;
   d. Adherence to IPAC BPG is severely impacted. All ACC and GD pers report numerous incidents of PPE breakdown by LTC staff. Protocols in place have a near 100% contamination rate for equipment, patients and overall facility. Nurses/PSWs are often observed not changing PPE for several hours while moving between numerous patient rooms. Equipment is seldom/ever observed to be disinfected but is used between +ve/-ve patients. Med cart, BP cuffs, thermometers etc. not disinfected between uses;
   e. Little to no disinfection had been conducted at the facilities prior to CAF operations. Significant gross fecal contamination was noted in numerous patient rooms;
   f. Insect infestation noted within LTC - ants and cockroaches plus unknown observed;
   g. Delayed changing soiled residents leading to skin breakdown; and
   h. N95s provided to staff without fit-test.

2. Standards of Practice/Quality of Care Concerns:
   a. Forceful and aggressive transfers, little/no regular turning of patients leading to increased number and complexity of pressure ulcers;
   b. Forceful feeding observed by staff causing audible choking/aspiration, forceful hydration causing audible choking/aspiration;
   c. Patients observed crying for help with staff not responding for (30 min to over 2 hours);
   d. Narcotics are not considered a high alert medication therefore this is no mandatory independent verification required within the LTC. High risk of dosing error;
   e. Activities of Daily Living – staff report residents having not been bathed for several weeks (noted at commencement of task);
   f. DNR status not posted causing staff to race to EMR during code to determine DNR status. CPR has been initiated in absence of ability to verify DNR status (likely futile, and also putting staff at risk as CPR is aerosol generating);
   g. Feeding status not posted/readily available. Given the lack of permanent staff or oversight, patient meals are often mixed up, with incidents of inappropriate meals being fed to residents with swallowing difficulties (increases likelihood of choking or aspiration);
   i. Access to PCC (electronic health record) inconsistent and numerous reports of a lack of charting/documentation by staff causing significant gaps in information;
   j. Reports by SNO of little to no documentation on resident's status within EMR for up to 6 months. Unclear regarding reasons for lack of charting but resident's status indicated a requirement for additional information and documentation;

k. Regular wellness checks suboptimal or inconsistent with staff resulting in many hours between wellness checks day/night shift;
l. SNO reported incident of patient's enteral feed bottle not being changed for so long the contents had become foul and coagulated; date and expiration of contents not noted on bottle;
m. SNO reported incident of permanent catheter being in situ 3 weeks beyond scheduled change date. Catheter was changed by SNO but stated documentation and adherence to timelines was problematic;
n. Topical prescription medicine shared between residents; and
o. Staff report significant lack of appropriate wound care to advanced (stage 4/unstageable) wounds due to significant shortage of supplies, lack of documentation, non-sterile technique, no packing or improper packing of wounds.

3. Supplies:
   a. Wound care supplies insufficient or locked away – high turnover of staff and lack of familiarity with LTC led to poor practices due to supply shortage;
   b. No crash cart available for use in the event of a cardiac arrest;
   c. Linen shortage noted. Either more linens need to be purchased or laundry staff required for night shift. Shortage led to residents sleeping on beds with no linen leading to increased skin breakdown; and
   d. Availability of iPads and time constraints led to significant lack of documentation within EMR. Significant gaps in information exist especially WRT pressure ulcer progression, swallowing status or patient mental status.

4. Ambiguity on local practices:
   a. Palliative care orders not charted/unknown to agency staff thus often not observed;
   b. Resident census and documentation outdated; and
   c. Resident assignment is not clear for PSWs leading to residents being uncared for.

5. Communication:

   a. Poor communication between shifts or lack of handover at shift change led to resident care aspects being missed.

6. Staffing:
   a. No (civilian) RN in the building other than SNO during weekends. SNO and Executive Director (also an RN) only RNs on site on numerous occasions during the week. Significant resultant safety concerns regarding patient ratios (1 RN for up to 200 patients);
   b. Little or no orientation for new staff resulting in low adherence to protocols or a significant awareness of policy;
   c. Contact information and on call schedule not provided to unit staff creates significant delays for referral and direction during emergencies;
   d. Nursing and PSW shift schedule poorly managed. Break time is not planned. Staff disappear and leave the floor unattended;

e. SNO reports that agency pulled back/rerouted RNs when they found out CAF members present resulting in regular degradation of patient ratios and instability of planning;
f. No shift handovers witnessed since arriving on site;
g. PSW often rushed and leave food on table but patients often cannot reach or cannot feed themselves (therefore they miss meals or do not receive meal for hours);
h. Public inter-professional disputes amongst agency/permanent staff; and
i. ACC personnel are heavily relied upon to train and mentor new staff;

7. ACC engagement with facility staff:
   a. Concerns were initially addressed by the on-site SNO to local leadership, including charge nurses. On 4 May 20, a teleconf was conducted between CO TBG1, OC ACC, and leadership from Hawthorne Place, as well as corporate management. Major concerns were raised, in particular standards of care issues, poor IPAC, poor charting, and narcotics misuse. Concerns were raised in a collegial manner and facility staff advised they will address the deficiencies, however, given lack of resources available, they may have difficulty in affecting a plan.

Annex C to Observation Report on LTCF
Orchard Villa
3350-Op LASER 20-01
14 May 20

ORCHARD VILLA
1955 VALLEY FARM RD, PICKERING, ON L1V 3R6

1. Infection control:
   a. Lack of cleanliness noted:
      1) Cockroaches and flies present; and
      2) Rotten food smell noted from the hallway outside a patient's room. CAF member found multiple old food trays stacked inside a bedside table.
   b. Inappropriate PPE use noted throughout all staffing levels (doctors included); and
   c. Poor IPAC/PPE practices (double/triple gowning and masking, surgical mask under N95, scarves under masks, etc).

2. Standards of Practice/Quality of Care Concerns:
   a. Patient's being left in beds soiled in diapers, rather than being ambulated to toilets;
   b. Mouth care and hydration schedule not being adhered to;
   c. Lack of proper positioning (head of the bed raised) for meals/fluids;
   d. PSW and Nurses aren't always sitting up residents before feeding/hydrating/giving meds; choking/aspiration risk is therefore high; includes observation of incident that appeared to have contributed in patient death (code blue due choking during feeding while supine – staff unable to dislodge food or revive resident);
   e. Respecting dignity of patients not always a priority. Caregiver burnout noted among staff;
   f. Unsafe nursing medication administration errors;
   g. Staff putting food and important belongings outside of residents reach;
   h. Nurses appear to document assessments without actually having assessed the resident;
   i. Incident of likely fractured hip not addressed by staff; Med Tech and SNO addressed and transferred resident to hospital;
   j. Multiple falls, without required assessments following the fall;
   k. Inconsistent and suboptimal assessment and treatment of pain; and
   l. Lack of knowledge evident regarding what qualifies as a restraint. Multiple scenarios of walking aids being removed, or mattresses set on floor as patients were unable to stand from that low position (to prevent them from wandering the facility).

3. Supplies:
   a. Liquid oxygen generators not filled therefore not usable;
   b. Limited and inaccessible wound care supplies;
   c. Found 1 working suction locked in basement storage room; remainder of suction units not functional, last battery check was in 2014;
   d. Oxygen concentrators not easily accessible.
   e. Patients were sleeping on bare mattresses because of lack of access to laundry/linens; and
   f. Poor access to linens, soaker pads, etc.

4. Ambiguity on local practices:
   a. Unable to access LTFC policies easily; cannot access facility's policies without having a login;
   b. Incident reporting channels are "locked", staff unable to report anything other than med errors;
   c. No accessible incident reporting policy in place;
   d. Poor identification of Code status in documentation;
   e. Swallowing assessments not up to date (safety issue);
   f. Minimal familiarity on process to document new orders – orders missed; and
   g. Challenges in contacting on call medical staff leading to confusion and concerns when an emergency in progress.

5. Communication:
   a. Communication inconsistencies between expectations from LTCF leadership and the floor staff regarding facility's policies;
   b. No communication between PSWs and RPN/RNs that patients are choking with meals, or unable to chew/swallow etc.; and
   c. Poor communication between facility management and housekeeping. Patients being moved into rooms that have not been cleaned due to miscommunications.

6. Staffing:
   a. Lack of training for new/agency staff. Nursing staff unsure where or how to document status changes, how to change medications, where order sets are located, where supplies are located etc; lack of knowledge IRT suction equipment, code procedures;
   b. No accountability for staff in regards to upholding basic care needs or best practices;
   c. Poor or no handover between shifts; lack of teamwork or collaboration, blame previous shift for poor care; and
   d. Initially some registered staff did not have access to electronic charting system.

7. ACC engagement with facility staff:
   a. Concerns were initially raised by on-site SNOs to facility leadership, such as charge nurses. On 11 May 20, a teleconf was conducted between CO TBG1, OC ACC, and leadership from Orchard Villa. Concerns were raised regarding these issues, particularly staffing levels, internal communications, standards of practice, and poor IPAC. Concerns were raised in a collegial manner and facility staff advised they will address the deficiencies.

Annex C to Observation Report on LTCF
Altamont Care Community
3350-Op LASER 20-01
14 May 20

ALTAMONT CARE COMMUNITY
92 ISLAND RD. SCARBOROUGH. ON M1C 2P5

1. Standards of Practice/Quality of Care Concerns:
   a. Inadequate nutrition – due to significant staffing issues, most residents were reported to not having received 3 meals per day and there was significant delay in meals. Poor nutritional status due to underfeeding was reported by ACC personnel;
   b. Significant number of residents have pressure ulcers, stage 2, 3 and 4 and unstageable as a result of prolonged bed rest. ACC have identified 15 residents having wounds that require significant care plan; Wound dressing orders have not been updated nor adhered to by agency staff causing further degradation of wound; wound care nurse scheduled to visit LTC every Wednesday to do dressing changes, however she was not able to come in the 2 weeks preceding this report, resulting in a significant deterioration of the wound care management and dressing changes;
   c. At time of arrival many of the residents had been bed bound for several weeks; No evidence of residents being moved to wheelchair for parts of day, repositioned in bed, or washed properly;
   d. A non-verbal resident wrote disturbing letter alleging neglect and abuse by a PSW. Letter was handed to Med Tech by resident and was immediately brought to the attention of management. Note: this was handled immediately by the LTFC management team; and
   e. SNO reported significant concerns regarding agency staff clinical skills. Some of the personnel such as RPNs require clinical updates in order to continue practicing safely. The following are reported examples:
      1) A resident's blood sugar was assessed as 5.7mmol/L, the RPN was about to give Humalog, when SNO realized it, it was identified to the RPN that Humalog is a rapid acting insulin thus an inappropriate medication. The RPN states it is a long action and that there is no problem to administer it. After SNO insist on confirmation of protocol, it is identified that the Humalog protocol indicate to not administer if Blood sugar is lower than 10mmol/L;
      2) RPN states she is not able to dilute and administer Ceftriaxone IM. SNO had to show to RPN how to reconstitute and administer the medication;
      3) The RPN are using the wrong bandages and non-sterile dressings for packing. Wound care and packing were inappropriately completed by RPN requiring SNO to redo the packing;
      4) Resident was complaining of chest pain. RPN and SNO conducted assessment of resident and advised on call physician. Physician ordered Nitroglycerin. Patient's BP was 95/62 thus contraindication was communicated to physician who insisted on the treatment using Nitroglycerin. SNO and RPN withheld drug related to safety reasons; and
      5) When initiating and installing a subcutaneous butterfly, nurses are priming the line with NS and not the proper medication – not best practice.

2. Supplies:
   a. The facility has insufficient wound care material and supplies; and
   b. Residents have no way to receive additional personal supplies since the lockdown. They are unable to receive personalized shampoo, snacks, magazines, newspapers etc.

3. Ambiguity on local practices:
   a. LTCF had no accurate nominal roll as to resident room and bed locations. This came to ACC attention during an emergency when our facility experienced a flooding issue in one of the wards; and
   b. ACC staff reported that medications are being reported/documented as being given but in fact they are not. Some agency staff have only been providing regular PO meds and not giving elixirs, drops nor PRN medication.

4. Staffing:
   a. Scheduling is a significant concern at this facility:
      1) Evening shift is unstable, often no PSWs are present after 1430. PSW ratio often 1 per wing (30-40+ patients/PSW);
      2) The current staff to patient ratio at the facility do not allow for more care than the most basic daily requirements. Residents are changed and fed, however no ability to provide nail care, skin care, repositioning, nor adequate wound care;
      3) Night shift also understaffed and often requires significant movement of personnel within facility to stabilize number of personnel between wings; and
      4) Unverified reports of only 2 x PSW within facility during ACC rest day.
   b. Staff members (especially the nurses) avoid shrouding/post-mortem care of the deceased patients; very few PSW's assist with the post-mortem care and often times (when CAF present) they leave the military staff to do the post-mortem care;
   c. Regular arguments between staff observed (with derogatory language);
   d. There is no administrator present for evening/night shifts and no systems are being utilized to ensure follow up on incident reports;
   e. ACC on wing 4 have identified that since the regular staff have returned, they are rushing patients, not respecting their pace and have been observed making degrading or inappropriate comments directed at residents; and
   f. Kitchen staff do not attend to the snack cart during night shift and nursing staff are forbidden from entering the kitchen. Residents often get hungry around 3-4AM and are told they can have a cookie, some cold coffee, or wait until morning. ACC staff have been supplementing where necessary with personal food supplies to ensure that residents don't go hungry.

5. ACC engagement with facility staff:
   a. Concerns were initially raised by on-site SNOs to facility leadership, such as charge nurses. On 8 May 20, a teleconf was conducted between CO TBG1, OC

ACC, and leadership from Altamont. Concerns were raised regarding these issues, particularly standards of practice issues and poor IPAC. Concerns were raised in a collegial manner and facility staff advised they will address the deficiencies. In fact, staff advised that infection curve was flattening and that staffing levels were increasing.

Annex E to Observation Report on LTCF
Holland Christian Homes (Grace Manor)
3350-Op LASER 20-01
14 May 20

HOLLAND CHRISTIAN HOMES (GRACE MANOR)
7900 MCLAUGHLIN RD. BRAMPTON. ON L6Y 5A7

1. Infection control:
   a. Staff moving from COVID+ unit to other units without changing contaminated PPE;
   b. Some staff not following IPAC policies (i.e. not hand washing between patient interactions);
   c. Wearing same pair of gloves for several tasks from one patient to another;
   d. Cleaning gloves between patients with hand sanitizer; and
   e. No staff break room on COVID+ floor where PPE can be removed in order to eat.

2. Standards of Practice/Quality of Care Concerns:
   a. Improper sterile technique with dressing changes (i.e. wound packing);
   b. PRN medication administration not always documented;
   c. Improper documentation regarding patient DNR status; and
   d. Concerns about agency staff:
      1. Leaving food in a resident's mouth while they are sleeping;
      2. Aggressively repositioning a resident;
      3. Improper use of lifts; and
      4. Not assisting residents during meals (staff would rather write the resident refused to eat, rather than helping them.

4. ACC engagement with facility staff:
   a. On 7 May 20, a teleconf was conducted between CO TBG1, OC ACC, and leadership from Holland Christian Homes. Minor concerns were raised in a collegial manner and facility staff advised they will address the deficiencies.

Government of Canada Gouvernement du Canada

Operation LASER

From: National Defence

Operation LASER 20-01 - COVID-19

For up-to-date Department of National Defence information related to COVID-19, please visit: https://www.canada.ca/en/department-national-defence/campaigns/covid-19-military-response.html

On this page

Operation LASER is the Canadian Armed Forces' (CAF) response to a worldwide pandemic situation.

Canadian Joint Operations Command (CJOC) leads this operation, and is the command authority for the six standing regional Joint Task Forces, through which CAF support is delivered. They are situated in key locations across the country and provide operational command and control for task forces in and/or deployed to their respective regions.

Employment of CAF resources

The Canadian Armed Forces has recognized the need for greater flexibility when offering assistance to remote communities struggling with COVID-19. Therefore, the commander of CJOC has empowered the Regional Task Force Commanders to task Canadian Ranger (CR) patrols at their discretion. The goal is to leverage local resources for assessment purposes without the need for formal activation, as they are pre-positioned to identify emerging needs in their respective communities. These tasks differ from formal activations and deployments in both scale and process.

While a rapid CR activation can provide emergency relief and help identify emerging needs in remote communities, it does not offer the same scale of resources as an official RFA deployment. The traditional Request for Assistance (RFA) process is an official communication between the provincial/territorial governments, other relevant stakeholders, and the federal government. By assigning the authority to task Canadian Rangers to the regional level, the CAF aims to help improve the federal response to emergencies in remote communities.

Canadian Armed Forces assistance

▼ October 2020 to April 2021

- ▶ Public Health Agency of Canada
- ▶ Neskantaga First Nation
- ▶ Opaskwayak Cree Nation
- ▶ Hatchet Lake Denesuline First Nation
- ▶ Shamattawa First Nation

- ▶ Red Sucker Lake First Nation
- ▶ Ekuanitshit First Nation
- ▶ Fond-du-Lac Denesuline First Nation
- ▶ Attawapiskat First Nation
- ▶ Garden Hill First Nation
- ▶ Ginoogaming First Nation
- ▶ Fort Nelson First Nation
- ▶ Pauingassi Anishnaabe First Nation
- ▶ Muskrat Dam First Nation
- ▶ Cross Lake Cree Nation
- ▶ Mathias Colomb Cree Nation
- ▶ Tahltan Nation Dease Lake
- ▶ Support to COVID-19 testing in Nova Scotia
- ▶ Support to the Province of Ontario
- ▶ Fort Albany First Nation
- ▶ Kashechewan First Nation
- ▶ Lac Seul First Nation
- ▶ Moose Cree First Nation
- ▶ Long Lake 58 First Nation

▼ January to July 2020

- ▶ Support to long-term care facilities
- ▶ Support to Public Health Ontario
- ▶ Canadian Ranger support to Quebec
- ▶ Northern Saskatchewan
- ▶ Northern Ontario
- ▶ British Columbia
- ▶ Yukon, Northwest Territories and Nunavut

Land Port of Entry

Following a request for assistance, from 19 February to 28 March 2021, Canadian Armed Forces (CAF) personnel provided Government of Canada departments with planning and logistics support to establish testing sites at 16 land ports of entry (LPOE) across Canada. The task fell under Operation LASER, the CAF response to the global COVID-19 pandemic. In support of Public Health Agency of Canada (PHAC), the CAF provided preliminary logistics support to the establishment of these sites at the border. At all times, CAF personnel took precautions to help minimize the spread of COVID-19, protecting our personnel and those with whom we interacted and assisted. CAF support to LPOE testing was limited to four main tasks:

- At the federal level, assisted the PHAC with the planning for, and establishment of, LPOE testing sites;
- Provided planning support – such as advice on site layout, operations and sustainment – to PHAC at the regional level;

- Assisted PHAC personnel with contracting for the initial establishment of the these sites; and
- Provided general duty support in the establishment of the LPOE testing sites.

The CAF did not engage in any activities related to testing, quarantine, or law enforcement at the border.

The strategic objectives for Operation LASER

1. Save lives
2. Assist federal, provincial, territorial and regional partners
3. Maintain CAF readiness, effectiveness, and resilience

Phases of the operation

Operation LASER is the activation of Contingency Plan (CONPLAN) LASER for the response to a pandemic of an influenza-like disease. The plan consists of 4 phases. The Chief of the Defence Staff activated phase 2 of Operation LASER on March 2, 2020. On March 13, 2020, he activated phase 3.

Phase 1: Pandemic preparedness

- Mitigation planning and normal monitoring of worldwide pandemic threats
- This phase is permanently activated unless a higher Phase is active

Phase 2: Pandemic alert

- Active monitoring of the evolving pandemic threat, with some protective measures adopted

- This phase is activated by the Chief of the Defence Staff (CDS)

Phase 3: Pandemic response

- Activated on order of the CDS, this phase is characterized by widespread and continuous transmission of the virus in the general population and the imminent risk or existence of significant absentee rates
- The CAF response will be dependent on the disease's impact in and around the location of CAF elements and requests for assistance to civil authorities

Phase 4: Post pandemic restoration

- This phase starts when the CDS declares that the pandemic situation has concluded
- This phase involves the resumption and re-establishment of all DND/CAF services and operations to normal levels
- This phase transitions back to Phase 1 and coincides with Public Health Agency of Canada (PHAC) declaring a post-pandemic phase

Image gallery

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Canadian Armed Forces Operations Retweeted

COM SNMG1
@COM_SNMG1

#SNMG1 bids fair winds & following seas to HDMS Absalon, FS Commandant Blaison, HNoMS Storm, HNoMS Gnist, HMS Albion, RFA Mounts Bay & USS Thomas Hudner for joining us during Ex #BALTOPS50 in the Baltic Sea from June 6-18 ⚓ #WeAreNATO #StrongerTogether

from June 6-18 #WeAreNATO #StrongerTogether

9h

Canadian Armed Forces Operations
@CFOperations

Today, Vice-Admiral Bob Auchterlonie became the new Commander of CJOC, taking over from Major-General Bill Seymour. CJOC is responsible for Canadian military operations at home and abroad.

10h

Canadian Armed Forces Operations
@CFOperations

CAF members make a difference wherever they go!

Date modified:

2021-06-11

COVID-19 Scientific Advisory Group Rapid Response Report

Key Research Question: What is the effectiveness of wearing medical masks, including home-made masks, to reduce the spread of COVID-19 in the community? [Updated June 19, 2020]

Context

- On June 5th, 2020, the WHO, despite a limited evidence base, provided guidance on the continuous use of medical masks by health workers and caregivers in areas of known or suspected community transmission regardless of whether direct care to COVID-19 patients is being provided. In addition they provided guidance to decision makers using a risk based approach for the use of masks in areas with community transmission of COVID-19 when physical distancing is difficult (ie. public transit, shops, or other confined or crowded spaces).
- On May 20, 2020, the Public Health Agency of Canada recommended that non-medical masks be used in settings where it is not possible to maintain a 2-metre physical distance. The federal transportation minister then mandated mask use on planes, rail transport, and ships.
- The government of Alberta has initiated distribution of 20 million, single-use non-medical masks to the community which appear to be of high grade (with a 3 layer design, purporting a 96% filtration rate for particles up to 3 um and Delta-R 1.7 which would meet FFP2 requirements).
- Community mask use is now either encouraged or mandatory in over 80 countries, with many jurisdictions encouraging but not mandating the use of cloth masks; however, some countries such as Australia and New Zealand continue to not recommend community masking and have achieved low rates of COVID activity despite the lack of this particular intervention.
- Shortages of medical (procedure, surgical masks) masks and N95 masks for health care workers persist globally and nationally.
- With a focus on recovery and relaxation of social distancing in the context of the stabilization of the initial wave of the pandemic, the general population is returning to community and workplace settings where social distancing will not always be possible, which is driving interest in, and controversies around the use of cloth and home-made masks.

Key Messages from the Evidence Summary

- As medical masks are often bundled with other IPC interventions and have variable compliance, clinical trials on the effectiveness of medical masks have been challenging. Systematic reviews of randomized controlled trials in health care settings have not demonstrated a significant reduction in acute respiratory infections, (ARIs), ILIs or laboratory confirmed viral infections with medical mask use although it is acknowledged there were methodological flaws and smaller underpowered studies in the data analyzed.
- There is a paucity of clinical evidence in favor of using medical masks in the community, with multiple randomized trials demonstrating mixed results which when pooled demonstrate no significant reduction in acute respiratory infections (ARIs), ILIs or laboratory confirmed viral infections. There are some lower quality studies showing a reduction in viral infection rates in households, in transmission of viral respiratory infections in the context of mass gatherings, and in university residences when combined with hand hygiene interventions.
- However, while systematic reviews of randomized clinical trials fail to show significant benefit with medical mask use in community settings, more observational and case-control studies

(both at higher risk of bias), have suggested that masks are protective.

- The reasons for the lack of significant reduction for ARIs in the randomized trials is complex and may include: study design, setting, and human factors associated with wearing masks including low compliance with mask wearing, lack of concomitant hand hygiene, inoculation via the conjunctiva, frequent facial touching and mask adjustment leading to inoculation events, risk compensation behaviours, and self-contamination with inappropriate mask doffing. These possibilities have not been rigorously assessed.
- Laboratory studies investigating the efficacy of masks in filtering viral particles as well as studies in medical settings with laboratory based endpoints for bacterial respiratory pathogens (*Pseudomonas aeruginosa and Mycobacterium tuberculosis*) point to a theoretical benefit to medical mask use as a form of source control (protecting others from the wearer). There are no laboratory studies with SARS-CoV-2 and only one looking at other human coronaviruses.
- There are modelling studies and ecological data suggesting a benefit to medical mask use in the community via a reduction in viral transmission rates (R0) across wide ranges of community transmission levels. While these models are suggestive, they have significant inherent bias based on multiple assumptions including assumptions around mask efficacy in preventing transmission, and bundled interventions.
- Based on lab-based bioaerosol and NaCl aerosol studies, medical masks are superior to homemade cloth masks, but non-medical masks and optimally constructed home-made masks may offer some protection in reducing dispersion of droplets. Laboratory-based studies are of highly variable quality, with only a few studies using industry approved filtration efficiency testing methods.
- The newly released guidance from the World Health Organization suggests decision makers advising on non-medical mask use should take into consideration features of filtration efficiency (FE), breathability, number (and combination) of materials used, shape, coating and maintenance of cloth masks. The WHO suggests minimum Q (filter quality factor) score of the material chosen of 3 (three) based on expert consensus and engineering science and industry standards. They further suggest an optimal combination of material for non-medical masks should include three layers:

    1) an innermost layer of a hydrophilic material (e.g. cotton or cotton blends);

    2), an outermost layer made of hydrophobic material (e.g., polypropylene, polyester, or their blends) and

    3) a middle hydrophobic layer of synthetic non-woven material such as polypropylene, or a cotton layer which may enhance filtration or retain droplets

- There is limited evidence of harms related to community mask wearing with no studies identified that have systematically looked at potential harms. Such harms could include behavioral modifications such as risk compensation/non-adherence to social distancing or optimal hand hygiene practices, self-contamination, induction of facial rashes, and increasing real or perceived breathing difficulties. There are also concerns about poor compliance or tolerance of masks in children or those with cognitive challenges and communication difficulties.
- The only clinical study to examine cloth mask efficacy in preventing repiratory virus transmission was in a healthcare setting, comparing continuous cloth or medical masks use to usual practice. Among the comparator (usual practice) group, a large percentage of individuals used medical masks for part of the time. The study had significant methodological issues but did demonstrate

a significantly higher respiratory viral infection event rate of HCW using a 2-ply cotton cloth masks when compared with the use of standard practice. (Macintyre et al, 2015)

- Pre-symptomatic transmission and asymptomatic transmission of SARS-CoV-2 have been described but the degree to which they contribute to community spread is unclear, At this point, there is no direct evidence that the use of a medical or homemade cloth mask or the wider use of masks in the community significantly reduces this risk. For more information, refer to the Asymptomatic Transmission of SARS-CoV-2 rapid review.

Committee Discussion

There was agreement that although the evidence base is poor, the use of masks in the community is likely to be useful in reducing transmission from community based infected persons, particularly those with symptomatic illness. One member was very concerned, and there was some agreement, that a focus on mask-use could lead to a reduced sense of personal risk, i.e. risk compensation. There is some evidence demonstrating less attention to social distancing and hand hygiene as the mainstays of prevention in a community setting. It was noted that while there is evidence from observational studies that medical masks may reduce ARIs and ILIs in health care settings, that there is no clinical trial evidence that use of non-medical or medical masks in the community reduces viral transmission.

There was agreement that there is insufficient information to make a firm recommendation for the use of home-made (non-medical) masks in the community. In the face of difficulties in quantifying risk of asymptomatic transmission and potential benefit outweighing the harms of wider use of home-made masks in the community, several committee members felt strongly that we should carefully balance the recommendation for community use to reflect the precautionary principle as well as evidence gaps. One member felt that to achieve the maximum population benefit, the majority of people should be wearing masks in settings where physical distancing cannot be maintained. To account for these controversies, which were mostly based on uncertainties in the evidence, a Research Gaps section has been added.

There was concern that we may be over-emphasizing the potential harm associated with the use of non-medical masks in the community, and there was general but not unanimous agreement to reduce this emphasis and focus on the need for systematic research looking at benefits and harms with clinical outcomes.

This update was predominantly based on the WHO revised advice, but it was noted that there is little new evidence aside from information on filtration efficiency of different home-made masks since our last update. There remains a lack of data demonstrating benefit of cloth masks as currently used in the community, beyond lab based filtration studies. There remains a significant disconnect between RCTs and observational study results of community mask use, and significant confounding and bias in ecologic trials. Since the last version of this review, there is very little new data except new syntheses of previous studies, new modeling studies, and some new collations of cloth filtration characteristics. One reviewer commented on the system level issues with supporting medical and non-medical mask use in the community as important elements in addition to the patient level harms.

One reviewer highlighted the importance of identifying specific level of guidance and evidence provided by the updated advice from the WHO. As little additional evidence was highlighted in this review, the emphasis of the WHO report was discussed: “the process of interim guidance development during emergencies consists of a transparent and robust process of evaluation of the available evidence on benefits and harms, synthesized through expedited systematic reviews and expert consensus-building facilitated by methodologists. This process also considers, as much as possible, potential resource implications, values and preferences, feasibility, equity, ethics and research gaps” (WHO, June 5,

2020). Therefore more specific description of the document, recommendations and the risk-based approach to community mask use with consideration of local epidemiology has been incorporated. (https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak)

Lastly, committee members felt that the research gaps section should better highlight the remaining uncertainties regarding mask use in the community, and how they might be addressed. This would include better information about optimal mask construction, as well as more robust evidence about their impact on clinically relevant measures of benefit and harm. Finally, additional details about compliance with medical and non-medical mask use in the community would be helpful.

Recommendations

1. In light of concerns around PPE shortages, medical masks should continue to be prioritized for HCWs in direct patient care roles. HCWs should continue to wear medical masks whenever providing direct patient care and whenever social distancing is not possible in health care settings.
2. In the community, medical mask use should be prioritized for those with any symptoms suggestive of COVID-19, as a form of source control. Community caregivers of potentially infectious COVID-19 patients and care providers for those who are more vulnerable to severe infection in the household setting should also wear medical or well-constructed non-medical masks as a form of protection.
3. In settings where social distancing cannot be maintained, medical masks or high-quality non-medical masks should be encouraged as a form of protection for those vulnerable to severe COVID-19 infection outcomes. Vulnerable populations include those over 60 and those with comorbidities or immunosuppression.
4. Evaluation of the extent of community transmission of SARS-CoV-2 is required to continually assess the risks and benefits of community mask use in various situations, although there is insufficient evidence to recommend specific epidemiologic thresholds for this purpose. This is consistent with WHO guidance which advises decision makers to apply a risk-based approach focusing on specific criteria when considering or encouraging the use of masks for the general public that incorporates consideration of local epidemiology. The WHO encourages use of a well-constructed non-medical mask, designed according to the available evidence from materials engineering science, as a possible method of reducing risk of transmission of COVID-19 when social distancing is not possible. Situations where this may be particularly relevant include: on public transportation, workplaces necessitating close proximity to other workers or the public, or when entering and exiting public buildings.
5. In light of widespread interest in masks and anecdotal evidence of potentially harmful, inappropriate use by the public, health officials should widely communicate the need for both optimal mask construction and mask “etiquette”. It is important to strengthen the messaging that their use not replace the need for maintaining social distancing and hand hygiene as more important strategies to prevent transmission of COVID-19; and the need to not touch the mask, to replace when soiled or wet and ensure appropriate laundering. Current advice on when and how to wear home-made or non-medical masks is available at: https://www.albertahealthservices.ca/topics/Page16997.aspx#prev

Research Gaps

1. While there is some additional evidence, there is a need for further research into the optimal construction and fabric composition of home-made or non-medical masks and their efficacy in protection against transmission or acquisition of SARS-CoV-2.
2. Currently, we only have theoretical benefit demonstrated in laboratory studies of the filtration capabilities of cloth masks. Further studies assessing population benefits and harms of home-made (non-medical) masks are urgently required. These studies should include RCTs that assess clinical outcomes.
3. Studies evaluating the frequency and compliance of mask use by individuals in clinical and community settings, potentially using longitudinal surveys and/or contact tracing data would be of benefit while awaiting more rigorous trial results.

Summary of Evidence

Since the last update on April 21, 2020, the World Health Organization has provided new guidance on the use of masks in the community. There has also been a significant number of new studies examining their use. However, there is only one new clinical study. The remainder of the studies have been multiple new systematic reviews and meta-analyses of previously published clinical studies, modelling studies, and laboratory-based studies of various homemade materials.

International guidelines and practices for use of masks in the community setting:

World Health Organization guidance on the use of masks in the community

On June 5th, the WHO provided an update to prior guidance from April 6th. 2020.
The process of interim guidance development during emergencies consists of a transparent and robust process of evaluation of the available evidence on benefits and harms, synthetized through expedited systematic reviews and expert consensus-building facilitated by methodologists. This process also considers, as much as possible, potential resource implications, values and preferences, feasibility, equity, ethics and research gaps (https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak).

The primary differences with this update included:
Updated information on transmission from symptomatic, pre-symptomatic and asymptomatic people infected with COVID-19, as well as an update of the evidence of all sections of this document;
• New guidance on the targeted continuous use of medical masks by health workers working in clinical areas in health facilities in geographical areas with community transmission1 of COVID-19;
• Updated guidance and practical advice for decision-makers on the use of medical and non-medical masks by the general public using a risk-based approach;
• New guidance on non-medical mask features and characteristics, including choice of fabric, number and combination of layers, shape, coating and maintenance. (**WHO, June 2020)**
(see Table 1 in the Appendix).

As it relates to the: Targeted continuous medical mask use by health workers in areas of known or suspected COVID-19 community transmission, the updated WHO guidance document suggests the following guidance: (WHO, June 5, 2020)

In the context of locations/areas with known or suspected community transmission or intense outbreaks

of COVID-19, WHO provides the following guidance:
• Health workers, including community health workers and caregivers, who work in clinical areas should continuously wear a medical mask during their routine activities throughout the entire shift; apart from when eating and drinking and changing their medical mask after caring for a patient who requires droplet/contact precautions for other reasons;
• According to expert opinion, it is particularly important to adopt the continuous use of masks in potential higher transmission risk areas including triage, family physician/GP practices, outpatient departments, emergency rooms, COVID-19 specified units, haematological, cancer, transplant units, long-term health and residential facilities;
• When using medical masks throughout the entire shift, health workers should make sure that:
    - the medical mask is changed when wet, soiled, or damaged;
    - the medical mask is not touched to adjust it or displaced from the face for any reason; if this happens, the mask should be safely removed and replaced; and hand hygiene performed;
    - the medical mask (as well as other personal protective equipment) is discarded and changed after caring for any patient on contact/droplet precautions for other pathogens;
• Staff who do not work in clinical areas do not need to use a medical mask during routine activities (e.g., administrative staff);
• Masks should not be shared between health workers and should be appropriately disposed of whenever removed and not reused;
• A particulate respirator at least as protective as a US National Institute for Occupational Safety and Health-certified N95, N99, US FDA surgical N95, European Union standard FFP2 or FFP3, or equivalent, should be worn in settings for COVID-19 patients where AGPs are performed (see WHO recommendations above). In these settings, this includes its continuous use by health workers throughout the entire shift, when this policy is implemented.

To be fully effective, continuous wearing of a medical mask by health workers, throughout their entire shift, should be implemented along with other measures to reinforce frequent hand hygiene and physical distancing among health workers in shared and crowded places where mask use may be unfeasible such as cafeterias, dressing rooms, etc.

The following potential harms and risks should be carefully taken into account when adopting this approach of targeted continuous medical mask use, including:
• self-contamination due to the manipulation of the mask by contaminated hands;
• potential self-contamination that can occur if medical masks are not changed when wet, soiled or damaged;
• possible development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours
• masks may be uncomfortable to wear;
• false sense of security, leading to potentially less adherence to well recognized preventive measures such as physical distancing and hand hygiene;
• risk of droplet transmission and of splashes to the eyes, if mask wearing is not combined with eye protection;
• disadvantages for or difficulty wearing them by specific vulnerable populations such as those with mental health disorders, developmental disabilities, the deaf and hard of hearing community, and children;
• difficulty wearing them in hot and humid environments.(**WHO, June 5, 2020)**

As it relates to the WHO updated Advice to decision makers on the use of masks for the general public

WHO advises decision makers to apply a risk-based approach focusing on the following criteria when considering or encouraging the use of masks for the general public:

Taking into account the available studies evaluating pre- and asymptomatic transmission, a growing compendium of observational evidence on the use of masks by the general public in several countries, individual values and preferences, as well as the difficulty of physical distancing in many contexts, WHO has updated its guidance to advise that to prevent COVID-19 transmission effectively in areas of community transmission, governments should encourage the general public to wear masks in specific situations and settings as part of a comprehensive approach to suppress SARS-CoV-2 transmission . WHO advises decision makers to apply a risk-based approach focusing on the following criteria when considering or encouraging the use of masks for the general public:

1. Purpose of mask use: if the intention is preventing the infected wearer transmitting the virus to others (that is, source control) and/or to offer protection to the healthy wearer against infection (that is, prevention).
2. Risk of exposure to the COVID-19 virus:
- due to epidemiology and intensity of transmission in the population: if there is community transmission and there is limited or no capacity to implement other containment measures such as contact tracing, ability to carry out testing and isolate and care for suspected and confirmed cases.
- depending on occupation: e.g., individuals working in close contact with the public (e.g., social workers, personal support workers, cashiers).
3. Vulnerability of the mask wearer/population: for example, medical masks could be used by older people, immunocompromised patients and people with comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer and cerebrovascular disease.
4. Setting in which the population lives: settings with high population density (e.g. refugee camps, camp-like settings, those living in cramped conditions) and settings where individuals are unable to keep a physical distance of at least 1 metre (3.3 feet) (e.g. public transportation).
5. Feasibility: availability and costs of masks, access to clean water to wash non-medical masks, and ability of mask wearers to tolerate adverse effects of wearing a mask.
6. Type of mask: medical mask versus non-medical mask

Based on these criteria, (Table 1 in appendix) provides practical examples of situations where the general public should be encouraged to wear a mask and it indicates specific target populations and the type of mask to be used according to its purpose. The decision of governments and local jurisdictions whether to recommend or make mandatory the use of masks should be based on the above criteria, and on the local context, culture, availability of masks, resources required, and preferences of the population.

Masking recommendations
The following link provides a list of countries recommending or requiring community use of masks:
https://masks4all.co/what-countries-require-masks-in-public/
It is updated daily.

Mask provision
Foreseeing impending medical mask shortages, Taiwan enlisted multiple interventions to try to prevent them. These included: state-controlled production and distribution of medical masks with daily, individual, name-based rations of masks (at modest cost) distributed at local drugstore and free provision of masks for school-aged children. South Korea also implemented state control over manufacturing and now provides a weekly ration of two masks (https://www.nytimes.com/2020/04/01/opinion/covid-face-mask-shortage.html).

In Japan (https://english.kyodonews.net/news/2020/04/67ad0dfcd954-delivery-of-cloth-masks-from-govt-starts.html), Hong Kong (https://www.gmask.gov.hk/about/), and Singapore (https://www.gov.sg/article/when-should-i-wear-a-mask) mass-manufactured, re-usable, cloth masks are being provided to citizens. In Hong Kong, pre-registered, low-income families may also receive 5 disposable medical masks per week for 10 weeks at vending machine dispensers (https://finance.yahoo.com/news/world-development-mask-dispensers-live-133000505.html).

The city of Los Angeles is providing garment manufacturers with crude guidelines on sewing non-medical masks (https://www.dropbox.com/s/x9myr2t9mhxd4zo/COVID_Mask-Manufacturer-Packet.pdf?dl=0) that can then be sold to the public.

Current evidence on COVID-19 Transmission:
It is accepted that SARS-CoV-2 is transmitted via droplets (<5 μm) expelled when a patient sneezes or coughs. However, the exact distance droplets can travel has been called into question **(Bourouiba, 2020)**. Others have also posited the possibility of SARS-CoV-2 transmission through ordinary speech (**Asadi S et al, 2020)**. There is also increasing concern regarding pre-symptomatic, pauci-symptomatic, or rarely, asymptomatic transmission of COVID-19, wherein individuals have RT-PCR detectable SARS-CoV-2 from nasal or throat swabs prior to or without development of symptoms **(Bai et al. 2020, Chan et al. 2020, Pan et al. 2020, Kimball et al. 2020, Wei et al. 2020,** and **Li et al. 2020)**. It also appears that viral loads are highest during the early symptomatic phase **(To et al. 2002, Wolfel et al. 2020,** and **Bai et al. 2020**) or even the pre-symptomatic stage. Indeed, **He et al. 2020** infer that infectiousness may peak on or before symptom onset and through modelling, estimate that up to 44% of secondary cases were infected during the index cases' pre-symptomatic stage. Therefore, the main theoretical benefit of masks during the COVID-19 pandemic would be as a form of source control to minimize dispersion of the expelled viral particles from individuals unknowingly transmitting disease.

For more information, refer to the Asymptomatic Transmission of SARS-CoV-2 Rapid Review.

Clinical studies and systematic reviews examining use of medical masks to prevent transmission of COVID-19:
One new clinical study has examined masks for prevention of COVID-19 transmission in the community, specifically, in the household setting. **Wang Y et al, 2020** undertook a retrospective study of 335 people (124 families) to determine characteristics and practices of both the source case and their contacts that were predictors of secondary transmission. They determined that if one or more members of the household (either the primary case or their contacts) wore a mask *before* development of symptoms, there was a 79% reduction in transmission (OR=0.21, 95% CI: 0.06 to 0.79). In another study of 105 cases (imported from Wuhan to other centres) and 392 household contacts, the overall attack rate in households was 16.9%, but was 0% in households of 14 index patients who reportedly self isolated (used masks, dining separately, and residing alone within the home) upon (not before) symptom development (Wei Li et al, 2020).

Clinical evidence for the use of medical masks in mixed settings (clinical and community) prior to COVID-19 has been well summarized in three separate systematic reviews and meta-analyses (**Jefferson et al. 2011, Offeddu et al. 2017, Saunders-Hastings et al, 2017)**. Offeddu et al. focused only on health-care settings, Jefferson et al. 2011 and Saunders-Hasting et al. 2017 looked at mixed settings. All three reviews reported methodologic concerns related to the randomized trials that were often under-powered and prone to reporting biases. Offeddu et al, did a meta-analysis of RCTs comparing any mask (medical or N95) to no masks. They found that masks conferred significant protection against self-reported clinical respiratory illness (RR = 0.59; 95% CI: 0.46–0.77) and influenza-like illness (RR = 0.34; 95% CI: 0.14–0.82) but only a non-statistically significant effect against laboratory-confirmed viral infections. A meta-analysis of observational studies noted a protective effect of medical masks vs. no mask (OR = 0.13; 95% CI: 0.03–0.62) against SARS. Jefferson et al, 2011 undertook a meta-analysis of seven case-control studies (~50% of participants were not health care workers) with 3216 participants and found fewer acute respiratory infections with medical mask use, OR 0.32, 95% CI 0.26 to 0.39. Of all physical interventions (including hand hygiene, gowns and gloves), masks were the most effective. In a meta-analysis of three case-control studies (19% of the participants being in a household setting), Saunders-Hastings et al. found that medical masks provided a non-significant protective effect against pandemic influenza (OR = 0.53; 95% CI 0.16–1.71; I 2 = 48%).

Clinical evidence for the use of masks in the community setting (only) has also been examined, with three systematic reviews by **Brainard et al, 2020 (preprint), MacIntyre et al, 2015, and Barasheed et al, 2016.** Brainard et al, 2020 identified 31 different studies (including pre-post, cross-sectional, case-control, observational, and randomized controlled trials). 12 studies were RCTs. These authors found the evidence to be of low to very low certainty and concluded that “the evidence is not sufficiently strong to support widespread use of facemasks as a protective measure against COVID-19. However, there is enough evidence to support the use of facemasks for short periods of time by particularly vulnerable individuals when in transient higher risk situations.**”** MacIntyre et al. 2015, identified 9 RCTs of facemasks in diverse settings (households and community), and with varied designs and interventions (ie. combination hand washing and facemasks). Due to the heterogeneity, no meta-analysis was undertaken. The results were inconclusive. A copy of the table summarizing these 9 articles is provided in **Table 2** of the **Appendix**. In general, the RCTs included use of a surgical grade facemask but the observational studies did not provide adequate description of the types of masks used.
Barasheed et al. 2016**,** pooled the results of 13 heterogeneously designed studies examining the effectiveness of medical masks at preventing variably defined acute respiratory infection endpoints arising during the Hajj pilgrimage. Based on studies which the authors deemed to be of “average” quality, they found a small, statistically significant benefit (RR 0.89, 95% CI 0.84-0.94). However, pooling of studies of vastly different design may be considered inappropriate from an analytic perspective and it is possible this small difference disappears when a more appropriate pooling is done.

Since the completion of the last review, multiple new systematic reviews, with or without meta-analyses, have been completed. They almost exclusively re-examined the studies already included in the reviews mentioned above.

Any setting:

- **Chu et al, 2020** did a systematic review and meta-analysis **of observational studies** (using frequentist, Bayesian meta-analysis, and random effects meta-regressions) to look at the impact of physical distancing, masks, and eye protection. Their analysis was limited to studies of coronaviruses (SARS-CoV-2, SARS-CoV, and MERS-CoV). They did not identify any

randomized controlled trials. They found any masks (N95, medical mask, or 12-16 layer cotton) reduced risk of infection (unadjusted n=10,170, RR 0.34, 95% CI 0.26-0.45; adjusted studied n=2647, aOR 0.15, 95% CI 0.07-0.34) when compared to no mask. When only medical *or* 12-16 layer cotton masks were compared with no mask, the protective effect was diminished but persisted (aOR 0·33, 95% CI 0·17–0·61). There was no comparison of medical masks to cotton masks. When only the 3 community-based studies were included, masks remained protective (RR 0.56, 95% CI 0.40-0.79). Using the GRADE category of evidence, the findings were deemed to be of low certainty. This study was limited by the observational nature of the studies included which are subject to significant bias.

- **Jefferson et al, 2020** (pre-print) updated their previous review looking at physical interventions to stop the spread of respiratory viruses, this time focusing only on **randomized and cluster randomized trials**. 14 trials assessed the impact of mask wearing. Looking at general population, there was no reduction in ILI cases (RR 0.93, 9% CI 0.83 to 1.05) nor in laboratory-confirmed influenza (RR 0.84, 95% CI 0.61-1.17). No benefit was identified in health care workers either.
- **Liang et al. (pre-print)** examined use of any type of mask in any setting in preventing respiratory virus transmission. In the subgroup of non-HCW, a protective effect was found with a pooled OR of 0.53 (95% CI=0.36 - 0.79), this effect persisted in both household (OR=0.60, 95% CI=0.37-0.97) and the non-household settings (OR=0.44, 95% CI=0.33-0.59). The RCTs included in this study scored 3 or 4/5 on the Jadad scale, but it should be noted that this a quality assessment tool whose use is discouraged by the Cochrane Collaboration with concerns of its ability to detect bias.
- **MacIntyre R and Chughtai AA, 2020** looked only at randomized controlled trials. Including eight trials in community settings, and concluded that when masks were used by ill individuals, their well contacts were protected. Of note, these findings were dissimilar from many others in that among health care workers in clinical settings, they found that only continual use of respirators was beneficial, with medical masks found to be less effective and cloth masks were even less effective than medical masks.

Community settings only:

- **Wei et al. (pre-print)** did a systematic review and meta-analysis of 8 RCTs examining any type of mask in the community setting. Masks lowered the risk of developing ILI (pooled RR=0.81, 95% CI: 0.70-0.95).
- In a pre-registered, rapid review using Bayseian analysis, **Pereski et al. (pre-print)** identified 21 studies examining incidence of ILI (variably reported) in the community. All masks types were considered. 1/11 RCTs and 6/10 observational studies found that masks reduced incidence of ILI. They found that while RCTs showed a moderate likelihood of a *small* effect of wearing medical masks in the community to reduce self-reported ILI, the risk of reporting bias was high. The evidence for reduction of clinically or lab-confirmed infection was equivocal. By contrast, observational studies showed that masks reduced incidence of ILI but there was a high risk of confounding and reporting bias. The difference in the findings between RCTs and observational studies was also noted previously by **Brainard et al.**

Cloth masks only:

- **Mondal et al. (pre-print)** looked at the utility of cloth masks in any setting. They included both clinical and non-clinical studies, in what can be more accurately described as a scoping review. They found two clinical studies, only one of which assessed the clinical effectiveness of cloth masks. This was the study by **MacIntyre et al, 2015** which is discussed later in this review. In the laboratory studies, cloth mask filtration efficiency was highly variable, between 3-95%, likely reflecting the highly variable materials and measurement techniques.

Laboratory based studies examining use of medical masks to prevent transmission of COVID-19:
Given the challenges of clinical studies, another approach has been to directly measure the efficacy of medical masks in both filtering exhaled respiratory viruses and in providing a barrier to entrance of pathogens.

In the only laboratory study to look at coronaviruses, **Leung et al, April 2020** found that coronaviruses could be detected in respiratory droplets (>5um) and aerosols (<5 uM) in 3/10 (30%) and 4/10 (40%) of samples collected without medical masks, respectively. They did not detect any virus in respiratory droplets or aerosols collected from participants wearing medical masks.

Multiple other studies have examined the use of masks for preventing spread of other respiratory pathogens. **Milton et al, 2013** found that medical masks reduced influenza viral copy numbers in exhaled samples by ~3-25 fold (depending on the size of the particle). **Johnson et al, 2009** could detect influenza in all samples of exhaled breath where a mask was not worn but detected no influenza virus by RT-PCR with medical masks. In two separate studies medical masks reduced the release of *Pseudomonas aeruginosa* in patients with cystic fibrosis both when worn for short **(Stockwell et al, 2018)** and longer durations **(Stockwell et al, 2018). Dharmadhikari et al, 2012**, examined the benefit of medical masks as a form of source control on a multi-drug resistant tuberculosis ward where exhaust air from patients is delivered to guinea pig exposure chambers. Compared to patients who did not wear a masks, patients who did wear a mask infected 56% fewer guinea-pigs (36/90 vs 69/90 infected guinea pigs).

Two studies have examined the effectiveness of medical masks to protect the wearer, as a barrier against viral bioaerosols. Ma et al, 2020 found that compared with one-layer of polyester, medical masks blocked 97.15% of avian influenza viral bioaerosols while a 4-layer homemade mask blocked 95.15%. The high efficacy rates of the masks may have been related to the unrealistically tight seals in the model used. **Makison-Booth et al, 2013** realistically adhered masks to the face of a mannequin and then measured the amount of viable live influenza virus from the air in front and behind of five different types of surgical masks. They found that medical masks reduced exposure to aerosolized influenza virus by approximately 6-fold.
Thus, the preponderance of lab-based studies (Milton et al 2013, Johnson et al, 2009, Stockwell et al. 2018, Stockwell et al. 2018, Dharmadhikari et al, 2012, and Leung et al, 2020) suggest the benefit of a mask is as a method of source control with reduction of the amount of respiratory virus released by exhaled particles. That is, the public would be protected from respiratory spread of infection from the mask wearer.

Other studies (modelling, ecological, anecdotal, etc) examining use of medical masks to prevent transmission of COVID-19:

Influenza transmission models:
Brienen et al, 2010 developed a population transmission model to explore the impact of population-wide mask use on an influenza pandemic. They assumed that the reduction in infection risk would be proportional to the reduction in exposure to the virus based on particle retention by the mask and mask coverage (number of people appropriately wearing masks). It is unknown if this assumption is valid. They concluded that masks could lower the basic reproduction number, at least delaying, if not containing, an influenza outbreak. A detailed transmission model by **Trachet et al, 2009;** however was less optimistic, concluding that while 10% of the population using N95 masks could result in a 20% reduction in H1N1, even 50% of the population wearing medical masks would only results in a 6%

reduction in number of cumulative cases. In their model, **Yan et al, 2019,** found that at a population-level compliance of 50%, all types of masks—except low-filtration surgical mask—could reduce prevalence of influenza outbreak to <5%. At a compliance rate of 80%, low-filtration surgical masks (not otherwise defined) could reduce prevalence by 50%.

COVID-19 models: In a model assessing various local interventions, **Tian et al, 2020 (preprint)** estimated reductions in the basic reproduction number $R0$ of SARS-CoV-2 with different interventions. Assuming masks reduce $R0$ by a factor $(1 - epm)^2$, where e is the efficacy of trapping viral particles inside the mask, and pm is the percentage of the population that wears masks – for example, if 50% of the population wears a mask and the mask has a 50% efficacy at trapping particles, $R0$ could drop to 1.35 (down from ~2.4). It is unknown if this assumption is valid.

Eikenberry et al. 2020 developed a mathematical model that adapted the SEIR model of Breinen et al. and Trachet et al. to the COVID19 pandemic epidemiologic parameters and then looked at the impact of varying mask efficacy and compliance rates on transmissions and epidemiologic outcomes (death, hospitalizations). They found that 80% coverage of masks that are only 20% effective could still reduce the effective transmission rate by 1/3. Applied to a case study of Washington state, this could translate into a reduction in mortality of 24-65%. **Javid et al, 2020 (pre-print)** created a simple, proof of principle, SIR model, assuming that masks reduced transmission by 8-16%. Like Eikenberry et al. where there was more mortality benefit seen in areas of lower transmission, Javid et al. noted a more substantial reduction on deaths when the effective R approached 1. Finally, **Worby et al, 2020 (pre-print)** created a SEIRD model to test various strategies for mask allocation (ie. different percentage of allocation to symptomatic vs asymptomatic individuals; or to the elderly population). First, they found that the more effective the mask, the lower the population uptake required. That is, deaths could be reduced by 65% with 15% coverage of a highly effective mask (75%) whereas they would be reduced by only 10% with 30% coverage with a low effectiveness mask (25% containment). In terms of mask allocation, they identified that prioritizing the elderly and maintaining a supply for identified infectious cases is a superior strategy to random distribution.

It should be noted that all the modelling studies listed vary the effectiveness of masks in the model; however, they do not assume that masks can carry harms that could outweigh benefits.

In an ecologic study, **Lo JY et al, 2005** found that in the setting of “community hygienic measures” promotion during the SARS 2003 epidemic in Hong Kong, where ~76% of individuals were wearing masks, the proportion of positive specimens of other respiratory viruses dropped significantly in 2003. A similar finding has been noted in Hong Kong since February 2020, where again mask use has increased with the COVID19 outbreak **(Leung et al, 2020). Kenyon et al. (pre-print)** compared countries who had implemented mask use vs no-mask use (as a binary outcome). At the time of the analysis, 8/49 countries promoted universal mask use. After adjusting for date of the first COVID-19 diagnosis in the country and testing intensity, they found that masking resulted in an average decrease of 326 cases per 1,000,000 inhabitants (linear coefficient -326, -601 to -51, p=0.021). These studies do not allow the effect of masks to be separated from other community measures, including social distancing with school closure, public space closures, hand hygiene, and household hygiene campaigns. When undertaking ecological comparisons, it should be noted that countries such as New Zealand, Australia, Denmark, and Switzerland have had success at containment of their epidemics without the use of universal masking.

There are also two case cluster reports outlining the benefits of community mask use. It is unclear if medical or non-medical masks were used. **Zhang et al, 2013** assessed transmission of influenza A virus on two flights from the United States to China. None of the 9 influenza-infected passengers, compared with 47% (15/32) of control-passengers wore a face mask. Unfortunately, this report does not include any information regarding the location of the other passenger relative to the index case. **Liu et al, 2020** report a case of a SARS-CoV-2 infected male who took two separate buses to return to his hometown. On the first 2-hour bus ride, he did not wear a mask and 5/39 passengers were infected. By contrast, on his second ride, a 50-minute ride, he wore a mask and 0/14 passengers were infected. While **Schwartz et al. 2020** do not focus on the use of a mask by the source case, the source case was masked during a flight from China to Toronto where no SARS-CoV-2 transmissions were identified.

Studies of cloth masks:

Clinical studies

The only clinical study of cloth masks is a cluster randomized trial of cloth masks at all times vs medical masks at all times (2 masks/8h) vs a standard practice arm in hospitals in Vietnam **(Macintyre et al, 2015)**. In this study, cloth mask users had higher rates of ILI compared with the control arm, RR=6.64, 95% CI 1.45 to 28.65 and more laboratory-confirmed virus, RR=1.72, 95% CI 1.01 to 2.94. Compared to medical masks, the RR for ILI was 13.25 in the cloth mask arm and 3.8 in the control (mixed) arm. A possible hypothesis for the worse outcome with cloth masks is that when they become wet, they are more likely to trap viral particles. Alternatively, there may be inadequate washing of the masks.

However, a methodologic concern was that the control arm consisted of high rates of mask wear. Specifically, in the control arm, (170/458) 37% used medical masks and (245/458) 53% used a combination of medical masks and cloth masks, with 24% of control arm participants wearing masks for more than 70% of working hours (versus 57% of participants in the other 2 arms adherent to masks for >70% of working hours). This renders the comparison to have been consistent cloth mask use, to consistent medical mask use, to inconsistent use of any mask type. Therefore, while the study may have conclusively shown the superiority of medical masks to cloth masks in preventing infection acquisition in a health-care setting, it cannot be used to reliably evaluate cloth masks to no masks in a community setting. Given the sudden interest in cloth-mask use, the authors published a response to their own article on March 30, 2020 **(MacIntyre et al. 2020)** wherein they state that HCW should not work without adequate PPE but if they choose to work with a cloth masks, thorough and daily disinfection is required to prevent potential harms. In another commentary, the same author (**MacIntyre CR and Hasanain SJ, 2020)** supports universal masking, stating "There is more evidence supporting face mask use in the community than hand hygiene including in RCTs which compare both interventions directly, so it is inconsistent to advocate hand hygiene as a sound principle but not masks."

Laboratory based studies

Several contemporary and historical studies have looked at whether homemade masks are able to reduce the physical spread of droplets by the mask wearer. In a laser-light scattering experiment, **Anfinrud et al. 2020**, qualitatively showed that while regular speech resulted in droplets ranging in size from 20 to 500 μm, a slightly damp washcloth over the mouth could decrease these forward moving particles. After assessing the filtration performance of a variety of household fabrics (using NaCl aerosols of smaller size than droplets), **Rangesamy et al, 2010** concluded that while markedly inferior to N95 respirators, the filtration rate of some household materials was comparable to surgical masks. **Davies et al, 2013** found that masks made from cotton t-shirt fabric had a filtration

efficiency of viral particles of ~50% as compared to ~90% for medical masks and that medical masks were 3 times more effective in blocking transmission than homemade masks. **Dato et al. 2006,** also found some protection against an aerosol challenge with the use of a homemade cotton mask.

We identified two studies examining the theoretical benefit of homemade masks in reducing personal risk of exposure to particles. As previously noted**, Ma et al. 2020,** found a homemade mask of one polyester cloth layer and 4 layers of kitchen paper to be as effective as medical masks in providing protection against avian influenza virus bioaerosols. However, an artificially tight seal may have been present in this model. **van der Sande et al, 2008** found that medical masks provided about twice as much protection as homemade masks against the entrance of particles. Notably and unlike other groups, they did not find that masks significantly prevented outward dispersal.

Since the last update, we identified multiple other laboratory-based studies investigating filtration efficiency, 3 of which were completed since the last update.

Historical studies

- **Greene et al, 1961** had volunteers wear muslin and flannel masks (the standard for medical masks at the time) in a contained chamber. Bacterial recovery on agar sedimentation plates was dramatically reduced (by 88% to >99% depending on the particle size).
- **Quesnel et al, 1975** used a similar chamber to Green et al. and volunteers were asked to try 4 disposable medical masks and one cotton mask. The filtration efficiency of the cotton mask (after 30 minutes of wear) for larger droplets (>3 μm) >99%.

***Air pollution and fine particulate matter (aerosol) studies* (<2.5 μm)**

- A study by **Shakya et al. 2017**, that was assessing filtration potential of cloth masks for fine particulate matter (air pollution related study) noted that the filtration efficiency of three particle sizes (30, 100, and 500 nm) ranged from 15% to 57%, thus they felt that cloth masks would be of limited utility for particles<2.5 μm.
- **Jung et al, 2014**, also assessed a variety of masks for protection against aerosols. Their testing adhered to the Korean Food and Drug Administration (KFDA) [similar to the European Union (EU) protocol] and the National Institute for Occupational Safety and Health (NIOSH) protocols. 44 different types of masks were tested. On average, the aerosols used for testing were less than 2.5 **μm.** The filtration efficiency of medical masks was only about 60% and only in the 2-12% range for cloth handkerchiefs. Pressure drop was also measured. They found that “general masks” and handkerchiefs provided little protection against aerosols.
- **Jang et al, 2015 [only available in Korean; abstract was reviewed],** using polydisperse NaCl aerosols (0.3~10 μm), compared five commercial cloth masks vs. a respirator. The filtration efficiencies varied from 9.5-28.5% as compared with 91% by the respirator but increased by 1.7-6.8 times after folding to create multiple layers. Washing once reduced filtration efficiency. The authors warned that cloth masks were inadequate in protecting against particulate matter.

Bioaerosol and polydisperse NaCl aerosol studies

- **Rodriguez-Palacios et al, 2020 (pre-print)** used household spray bottles filled with a bacterial suspension to see whether various textiles could prevent dispersion of the bacterial solution (which they said mimicked a sneeze) onto agar containing Petri dishes. All the fabrics used, even in one layer, reduced droplet dispersion to <30cm. As a double layer, they were as effective as medical masks and reduced droplet dispersion to <10cm. The relevance of this model is questionable.

- **Wang et al, 2020 (pre-print)** used industry approved standardized tests to compare 17 different fabrics against approved medical masks. Testing pressure difference (breathability), particle filtration efficiency, bacterial filtration efficiency, and resistance to surface wetting, they found that only 3 materials would pass industry standards. The results showed that three double-layer materials including double-layer medical non-woven fabric (example, polypropylene) medical non-woven fabric plus non-woven shopping bag, and medical non-woven fabric plus granular tea towel could meet all the standards of breathability, particle filtration efficiency (>30%), and resistance to surface wetting, and were close to the standard of the bacterial filtration efficiency (>95%).
- **Aydin et al, 2020 (preprint)** compared one brand of medical mask to a variety of homemade fabrics to assess for: efficiency of blocking droplets, breathability, weight, hydrophilicity, and texture. To measure droplet blockage (or filtration) efficiency, they used a metered-dose inhaler (MDI) loaded with fluorescent beads, of similar size to SARS-CoV-2 virus (70-100nm). A petri dish covered with the various materials was then held 36mm and 300mm away from the MDI and the number of fluorescent beads penetrating through to the petri dish were measured. In this study, even one layer of a 100% cotton t-shirt had 91% efficiency. And while a blend of cotton and polyester had only 40% efficiency, this increased to 99.98% with 3 layers. They concluded that multiple fabrics were comparable to a medical mask in terms of filtration and breathability. However, a 2-3 layer cotton/polyester blend was the closest; despite being far less hydrophobic. Of note, the materials appear to have been tightly adhered to the petri dish.
- **Konda et al, 2020** also tested a variety of household materials. They introduced a polydisperse NaCl aerosol into a mixing chamber, where it passed through the material being tested (held down tightly by a clamp). They analyzed particle size with two different particle analyzers and followed the protocol used for testing face respirators in compliance with the NIOSH 42 CFR Part 84 test protocol. For droplets >300nm, several materials had filtration efficiency equivalent to a medical mask (>95% efficiency), including even one layer of a high thread count cotton. However, the authors recommended a hybrid fabric (cotton + silk) that could leverage both mechanical and electrostatic properties. Furthermore, the authors found that even small gaps (hole of 1% surface area) could reduce filtration efficiency by 60%, highlighting the importance of a tight fit
- **Zhao et al, 2020** evaluated common materials using a modified version of the NIOSH standard test procedure for N95 respirator approval. They used NaCl aerosols (0.075 ± 0.02 μm), without taking real-world leakage from around the mask into account, to identify the material with the highest filtration quality factor (Q) – a metric that results from a high filtration efficiency (low penetration) with low pressure drop. They identified that polypropylene spunbound, a material commonly found in reusable bags, had the optimal Q. While the filtration efficiency was ~6-10% (which was similar to the other fabrics tested), if it were triboelectrically charged or multiple layers were added, its filtration efficiency improved without a concomitant increase in pressure. In fact, as compared with the medical masks they tested (~19-33% filtration efficiency), the five-layer polypropylene had a filtration efficiency of ~50% with a lower pressure drop.

Though there are now many different laboratory studies to draw from, the variability of the methodology of the studies and the variability in their findings make their interpretation challenging. Taken together, these studies suggest that non-medical masks can act as a barrier to outward dispersion of droplets (but not particles <2.5 μm). For that reason, WHO states that non-medical masks “should only be considered for source control (used by infected persons) in community settings and not for prevention”.

Despite the challenges of interpreting non-medical mask studies, a non-medical mask standard has been developed by the French Standardization Association (AFNOR Group) (https://www.afnor.org/en/faq-barrier-masks/). AFNOR Group defines minimum performance in terms of filtration (minimum 70% solid particle filtration or droplet filtration) and breathability (maximum pressure difference of 0.6 mbar/cm2 or maximum inhalation resistance of 2.4 mbar and maximum exhalation resistance of 3 mbar).

In addition, in its latest interim guidance report (https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak), WHO has now provided guidance on the optimal composition and construction of non-medical masks. They advise that when decision-makers are providing recommendations on masks, they should take filtration efficiency, breathability, number and combination of materials used, shape, coating and maintenance into account. Using the filter quality factor "Q" metric, which is a function of filtration efficiency and breathability (with higher values being better), they advise the following mask composition:

a) Inner layer of a hydrophilic material (cotton or cotton blend)
b) Outer layer of a hydrophilic material (ie. polypropylene, polyester or blend)
c) Middle hydrophobic layer of a synthetic non-material such as polypropylene or a cotton layer

Table 3 in the **Appendix** provides a list of different materials with their corresponding filter quality factor as well as filtration efficiency and breathability.

In terms of fit, they also recommend a tightly-fitted flat-fold or duckbill shape.
(WHO, June 5, 2020)

Theoretical sociological benefits and harms of mask use in COVID-19:

From a sociologic perspective, some have noted that if mask wearing were widespread and not just limited to those who are feeling ill, it would reduce the stigma associated with their use and increase the likelihood of their use in ill individuals. Similarly, mask use may act as a visual cue reminding individuals to maintain physical distance and act as visible signal of social solidarity (preprint, **Howard et al. 2020**). In terms of acting as a visual cue, **Seres et al, 2020** undertook a field experiment where they randomized 300 individuals to "exposure" to an individual wearing a mask vs no-mask. Specifically, the *experimenter* was randomly assigned to wear a mask or not. Then, they took the last position in line-ups (ie. a supermarket, store) and noted the distance with which the subsequent customer would stand. Individuals kept a statistically significantly further distance when someone was wearing a mask. Subsequent survey data suggested this was because it was perceived that a masked person preferred more distance.

Finally, it is becoming increasingly clear that racial minorities are disproportionately impacted by COVID-19 (**Hooper et al, 2020)**. In addition to underlying co-morbidities and structural inequalities (ie. lack of access to healthcare), this discrepancy may be attributed to living conditions and employment. As **Yang, 2020** stated "social distancing is a privilege". For instance, outside of LTC outbreaks, most outbreaks in Calgary, Alberta are occurring at warehouses and workplaces (https://www.alberta.ca/covid-19-alberta-data.aspx#toc-1) where social distancing either cannot be or is not being enforced. Mandatory masking, with provision of masks and targeted education about mask hygiene, may be particularly helpful in such settings.

There are also several possible harms associated with widespread mask use. There is concern that moisture retention could increase the risk of infection which is one possible interpretation of the McIntyre study. Masks may also increase the frequency with which individuals touch their face. There is also concern regarding self-contamination of the hands or face with improper donning and doffing technique. In an observational study of ~10,000 pedestrians in Hong Kong in February 2020, 94% of individuals wore masks (84% of which were medical masks). However, 13% of individuals wore them incorrectly, with 5% wearing them inside out or upside-own and 5% wearing them too low **(Tam et al, 2020).**

The importance of risk-compensation in population-level health interventions has been called into question **(B Pless, 2016).** However, the potential harms of masks in creating a false sense of security and consequent neglect of physical distancing or hand hygiene is raised by the World Health Organization **(WHO, 2020).** A recent study by **Yan et al, 2020 (pre-print)** used smart device location data to determine the time spent at home and at various public locations before and after mask mandates were implemented in 36 different states. They accounted for weather patterns, re-openings orders, and time since stay-at-home orders were implemented. They found that masks mandates were associated with an increase of 4% (20-30 minutes) of time outside the home per day and they specifically noted more trips to restaurants. This suggests that for mask to be beneficial, their efficacy in reducing transmission needs to exceed the increased risk associated with a 4% increase in time away from home.

Another concern is related to the environmental impact of mass use of medical masks. For instance, the sheer numbers of disposable masks that would be required in China would be around 900 million daily and would pose significant disposal challenges **(Wang MW et al, 2020).** Safe disposal concern are already arising throughout Asia (https://www.bangkokpost.com/opinion/opinion/1924908/face-mask-crisis-of-another-design)

Another major concern is the risk of PPE shortages for HCW who are more frequently exposed to SARS-CoV-2 than the general public. Indeed, there have been shortages globally, with some countries banning or threatening to ban export of medical masks (https://www.cnbc.com/2020/04/03/coronavirus-trump-to-ban-export-of-protective-gear-after-slamming-3m.html), and with reports of hoarding and price gouging.

Date question received by advisory group: March 31, 2020
Date report submitted to committee: April 2, 2020
Date of first assessment: April 3, 2020
(If applicable) Date of re-assessment: June 19, 2020

Authorship and Committee Members

This report was written and updated by Leyla Asadi and scientifically reviewed by Elizabeth Mackay (primary reviewer), Lynora Saxinger (co-chair), and Nelson Lee. The full Scientific Advisory Group was involved in discussion and revision of the document: Braden Manns (co-chair), John Conly, Alexander Doroshenko, Shelley Duggan, Andrew McRae, Jeremy Slobodan, James Talbot, Brandie Walker, and Nathan Zelyas.

COVID-19 Scientific Advisory Group Rapid Response Report

Appendix

The literature search was conducted by Lauren Seal from the AHS Knowledge Resource Service. The literature search was last updated on May 14, 2020.

Medline/PubMed

1 exp Coronavirus/ or exp Coronavirus Infections/ or coronaviru*.mp. or "corona virus*".mp. or ncov*.mp. or n-cov*.mp. or COVID-19.mp. or COVID19.mp. or COVID-2019.mp. or COVID2019.mp. or SARS-COV-2.mp. or SARSCOV-2.mp. or SARSCOV2.mp. or SARSCOV19.mp. or Sars-Cov-19.mp. or SarsCov-19.mp. or SARSCOV2019.mp. or Sars-Cov-2019.mp. or SarsCov-2019.mp. or "severe acute respiratory syndrome cov 2".mp. or "2019 ncov".mp. or "2019ncov".mp. (18987)

2 Masks/ (4203)

3 mask.mp. (28586)

4 masks.mp. (15768)

5 facemask.mp. (1101)

6 "face-mask".mp. (2557)

7 (face adj2 mask*).mp. (3254)

8 2 or 3 or 4 or 5 or 6 or 7 (37583)

9 homemade.mp. (2899)

10 home-made.mp. (2094)

11 "home made".mp. (2094)

12 handmade.mp. (505)

13 "hand made".mp. (346)

14 hand-made.mp. (346)

15 handcraft*.mp. (335)

16 hand-craft*.mp. (321)

17 "hand craft*".mp. (321)

18 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 (6424)

19 8 and 18 (32)

20 8 or 19 (37583)

21 1 and 20 (140)

22 limit 21 to last year (19)

CINAHL

S1	(MH "Coronavirus+")	
S2	(MH "Coronavirus Infections+")	
S3	coronaviru*	
S4	"corona virus"	
S5	ncov*	
S6	n-cov*	
S7	COVID-19 OR COVID19 OR COVID-2019 OR COVID2019	
S8	SARS-COV-2 OR SARSCOV-2 OR SARSCOV2 OR SARSCOV19 OR SARS-COV-19 OR SARSCOV-19 OR SARSCOV2019 OR SARS-COV-2019 OR SARSCOV-2019	
S9	"severe acute respiratory syndrome cov 2" OR "severe acute respiratory syndrome coronavirus*"	
S10	"2019 ncov" OR 2019ncov OR Hcov*	
S11	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10	
S12	(MH "Masks")	2,140
S13	mask OR masks OR facemask OR face-mask OR face N2 mask OR medical N2 mask OR face N2 cover*	10,693
S14	S12 OR S13	10,693
S15	homemade OR home-made OR "home made" OR handmade OR hand-made OR "hand made" OR handcraft* OR hand-craft* OR "hand craft*"	2,013
S16	S14 AND S15	10
S17	S14 OR S16	10,693
S18	S11 AND S17	87
S19	S11 AND S17	Limiters - Published Date: 20190101-20201231

12

TRIP Pro/Google Scholar/Google/ LitCovid/CEBM/ /Twitter/WHO/Stanford Medicine/REACTing/Nebraska Medicine COVID-19 resources/CAIC-RT – COVID-19 Capacity Tool/NEJM/ The Oakes Academy Coronavirus Clinical Collaboration/CochraneLibrary

("covid-19" OR coronavirus OR COVID19 OR “corona virus” OR ncov OR “n-cov” OR “covid-2019” OR covid2019 OR “SARS-COV-2” OR “sarscov-2” OR sarscov2 OR sarscov19 OR “sars-cov-19” or “sarscov-19” OR sarscov2019 OR “sars-cov-2019” OR “severe acute respiratory syndrome”) AND (mask OR facemask OR “face-mask” OR “face mask” OR “face cover” OR “face covering” OR “homemade mask” OR “home-made mask” OR “handmade mask” OR “hand-made mask” OR “handcrafted mask” OR “hand-crafted mask”)

(mask OR facemask OR “face-mask” OR “face mask” OR “face cover” OR “face covering” OR “homemade mask” OR “home-made mask” OR “handmade mask” OR “hand-made mask” OR “handcrafted mask” OR “hand-crafted mask”)

mask

facemask

face covering

Critical Appraisal

Table 2. Summary of quality assessment results for articles included in this review

				Mixed Methods Appraisal Tool Criteria:	
	Reference	Peer reviewed?	Type of evidence	Are there clear research questions or a clearly identified issue?	Is the collected data or presented evidence appropriate to address the research questions or issue?
1.	Jefferson T, Del Mar CB, Dooley L, Ferroni E, Al-Ansary LA, Bawazeer GA, van Driel ML, Nair S, Jones MA, Thorning S, et al. 2011. Physical interventions to interrupt or reduce the spread of respiratory viruses. The Cochrane Database of Systematic Reviews. 2011(7):CD006207.	☒ Yes	Systematic review and meta-analysis	☒ Yes	☒ Yes

2.	Offeddu V, Yung CF, Low MSF, Tam CC. 2017. Effectiveness of masks and respirators against respiratory infections in healthcare workers: A systematic review and meta-analysis. Clinical Infectious Diseases : An Official Publication of the Infectious Diseases Society of America. 65(11):1934-42.	☒ Yes	Systematic review and meta-analysis	☒ Yes	☒ Yes
3	Saunders-Hastings P, Crispo JAG, Sikora L, Krewski D. 2017. Effectiveness of personal protective measures in reducing pandemic influenza transmission: A systematic review and meta-analysis. Epidemics. 20(C):1-20.	☒ Yes	Systematic review and meta-analysis	☒ Yes	☒ Yes
4	Brainard J ea. 2020. Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review.	☐ No (pre-print)	Systematic review and meta-analysis	☒ Yes	☒ Yes
5	WHO. Advice on the use of masks in the context of COVID19. Available at: https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak .		WHO guidelines		
6	MacIntyre CR, Chughtai AA. 2015. Facemasks for the prevention of infection in healthcare and community settings. BMJ : British Medical Journal. 350(apr09 1):h694.	☒ Yes	Review article	☒ Yes	☒ Yes
7	MacIntyre CR, Seale H, Dung TC, Hien NT, Nga PT, Chughtai AA, Rahman B, Dwyer DE, Wang Q. 2015. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. BMJ Open. 5(4):e006577.	☒ Yes	Cluster randomzied trial	☒ Yes	☒ Yes
8	Leung, N.H.L., Chu, D.K.W., Shiu, E.Y.C. *et al.* Respiratory virus shedding in exhaled breath and efficacy of face masks. *Nat Med* (2020). https://doi.org/10.1038/s41591-020-0843-2	☒ Yes	Randomzied lab-based trial	☒ Yes	☒ Yes
9	Davies A, Thompson K, Giri K, Kafatos G, Walker J, Bennett A. 2013. Testing the efficacy of homemade masks: Would they protect in an influenza pandemic? Disaster Medicine and Public Health Preparedness. 7(4):413-8.	☒ Yes	Laboratory	☒ Yes	☒ Yes
10	Makison Booth C, Clayton M, Crook B, Gawn JM. 2013. Effectiveness of surgical masks against influenza bioaerosols. Journal of Hospital Infection. 84(1):22-6.	☒ Yes	Laboratory	☒ Yes	☒ Yes

APPENDIX

Table 1: Situations and types of masks recommended for use in the community (from the World Health Organization, June 2020 interim guidance "Advise on the use of masks in the context of COVID-19")

https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak

Situations/settings	Population	Purpose of mask use	Type of mask to consider wearing if recommended locally
Areas with known or suspected widespread transmission and limited or no capacity to implement other containment measures such as physical distancing, contact tracing, appropriate testing, isolation and care for suspected and confirmed cases.	General population in public settings, such as grocery stores, at work, social gatherings, mass gatherings, closed settings, including schools, churches, mosques, etc.	Potential benefit for source control	Non-medical mask
Settings with high population density where physical distancing cannot be achieved; surveillance and testing capacity, and isolation and quarantine facilities are limited	People living in cramped conditions, and specific settings such as refugee camps, camp-like settings, slums	Potential benefit for source control	Non-medical mask
Settings where a physical distancing cannot be achieved (close contact)	General public on transportation (e.g., on a bus, plane, trains) Specific working conditions which places the employee in close contact or potential close contact with others e.g., social workers, cashiers, servers	Potential benefit for source control	Non-medical mask
Settings where physical distancing cannot be achieved and increased risk of infection and/or negative outcomes	Vulnerable populations: • People aged ≥60 years • People with underlying comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease, immunosuppression	Protection	Medical mask
Any setting in the community*	Persons with any symptoms suggestive of COVID-19	Source control	Medical mask

*This applies to any transmission scenario

Table 2. Summary of high level evidence (GRADE guidelines) on facemasks in the household setting (from: Raina MacIntyre, and Abrar Ahmad Chughtai BMJ 2015;350:bmj.h694)

Study, year of publication	Design, participants	Mask type, intervention	Outcome	Results	Comments, limitations, biases
Cowling[11] 2008	• Cluster RCT • 198 index cases and household contacts • Hong Kong	• Medical masks • Hand hygiene • Control	• Self reported influenza symptoms • Laboratory confirmed influenza (by culture or RT-PCR) in household	• No significant difference in rates of laboratory confirmed influenza (OR 1.16, 95% CI 0.31 to 4.34) and ILI (0.88, 0.34 to 2.27) in the medical masks arm versus control arm	• Both index cases and household contacts used medical masks • This pilot study was small and underpowered • Compliance 45% in index cases and 21% in household contacts • Compliance data showed that some index cases in the control and hand hygiene arms used medical masks
Cowling[12] 2009	• Cluster RCT • 407 index cases and 794 household contacts • Hong Kong	• Hand hygiene • Masks + hand hygiene • Control (education)	• Self reported influenza symptoms • Laboratory confirmed influenza (by RT-PCR) in household	• No significant difference in rate of laboratory confirmed influenza in three arms • Significant difference if masks + hand hygiene together applied within 36 hours of illness (OR 0.33, 0.13 to 0.87) • Hand hygiene alone was not significant	• No separate medical mask arm, making it difficult to evaluate the efficacy of masks • Both index cases and household contacts used masks • Compliance 49% in index cases and 26% in household contacts using masks • Compliance data showed that some index cases in the control and hand hygiene arms used medical masks
MacIntyre[13] 2009	• Cluster RCT • 145 child index cases and well adult household contacts • Australia	• Medical masks for contacts • P2 respirators (equivalent to N95) for contacts • Control	• Self reported ILI • Laboratory confirmed respiratory infection	• No significant difference in ILI and laboratory confirmed respiratory infections in all three arms • Adherent use of P2 or medical masks significantly reduced the risk of ILI (HR 0.26, 0.09 to 0.77)	• Only household contacts used medical masks • Low compliance: 21% of household contacts wore masks often/always
Aiello[14] 2010	• Cluster RCT • 1437 well university residents • Michigan, USA	• Medical masks • Medical masks + hand hygiene • Control	• Self reported ILI • Laboratory confirmed influenza (by culture or RT-PCR)	• No significant difference in ILI in three arms • Significant reduction in ILI in the medical masks + hand hygiene arm over 4-6 weeks (P<0.05)	• Self reported ILI • Not all ILI cases (n=368) were laboratory tested (n=94) • No data on compliance
Larson[15] 2010	• Block RCT • 617 households • Manhattan, USA	• HE • HE + hand sanitiser • HE + hand sanitiser + medical masks	• Self reported ILI • Self reported URI • Laboratory confirmed influenza through culture	• No significant difference in rates of URI, ILI, or laboratory confirmed influenza between the three arms • Significantly lower secondary attack rates of URI/ILI/influenza in the HE	• No separate medical masks group • Household contacts used medical masks • Low compliance and around half of household in the masks arm used
Canini[16] 2010	• Cluster RCT • 105 index cases and 306 households • France	• Medical mask (as source control to be used by index case) • Control	• Self reported ILI in household	• No significant difference in the rates of ILI between the two arms (OR 0.95, 0.44 to 2.05)	• Trial stopped early owing to low recruitment and influenza A/H1N1-pdm09 in subsequent year
Simmerman[17] 2011	• Cluster RCT • 465 index patients and their families • Thailand	• Hand hygiene • Hand hygiene + medical masks • Control	• Self reported ILI • Laboratory confirmed influenza by PCR and serology in family members	• No significant difference in secondary influenza infection rates between hand hygiene arm (OR 1.20, 0.76 to 1.88) and hand hygiene plus medial masks arm (1.16, 0.74 to 1.82)	• No separate medical mask group • Owing to H1N1 pandemic, hand and respiratory hygiene campaigns and mask use substantially increased among the index cases (from 4% to 52%) and families (from 17.6% to 67.7%) in control arm
Aiello[18] 2012	• Cluster RCT • 1178 university residents • Michigan, USA	• Medical masks • Medical masks + hand hygiene • Control	• Clinically diagnosed and laboratory confirmed influenza (by RT-PCR)	• No overall difference in ILI and laboratory confirmed influenza in three arms • Significant reduction in ILI in the medical masks + hand hygiene arm over 3-6 weeks (P<0.05)	• Good compliance: medical mask + hand hygiene group used masks for 5.08 h/day (SD 2.23) and medical mask group used masks for 5.04 h/day (SD 2.20) • Self reported ILI • Effect may have been due to hand hygiene because medical masks alone not significant
Suess[19] 2012	• Cluster RCT • 84 index cases and 218 household contacts • Berlin, Germany	• Masks • Masks + hand hygiene • Control	• Laboratory confirmed influenza infection and ILI	• No significant difference in rates of laboratory confirmed influenza and ILI in all arms by intention to treat analysis • The risk of influenza was significantly lower if data from two intervention arms (masks and masks + hand hygiene) were pooled and intervention was applied within 36 hours of the onset of symptoms (OR 0.16, 0.03 to 0.92)	• Around 50% participants wore masks "mostly" or "always" • Participants paid to provide respiratory samples

CI=confidence interval; CRI=clinical respiratory infection; HCW=healthcare worker; HE=health education; HR=hazard ratio; ILI=influenza-like illness; OR=odds ratio; PCR=polymerase chain reaction; RCT=randomised controlled trial; RR=relative risk. RT=reverse transcriptase; SD=standard deviation; URI=upper respiratory tract infection.

Table 3. Non-medical mask filtration efficiency, pressure drop and filter quality factor* (from the World Health Organization, June 2020 interim guidance "Advise on the use of masks in the context of COVID-19" Adapted from Jung et al, 2014 and Zhao et al, 2020)

https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak

Table 3. Non-medical mask filtration efficiency, pressure drop and filter quality factor*

Material	Source	Structure	Initial Filtration Efficiency (%)	Initial Pressure drop (Pa)	Filter quality factor, Q ** (kPa^{-1})
Polypropylene	Interfacing material, purchased as-is	Spunbond (Nonwoven)	6	1.6	16.9
Cotton 1	Clothing (T-shirt)	Woven	5	4.5	5.4
Cotton 2	Clothing (T-shirt)	Knit	21	14.5	7.4
Cotton 3	Clothing (Sweater)	Knit	26	17	7.6
Polyester	Clothing (Toddler wrap)	Knit	17	12.3	6.8
Cellulose	Tissue paper	Bonded	20	19	5.1
Cellulose	Paper towel	Bonded	10	11	4.3
Silk	Napkin	Woven	4	7.3	2.8
Cotton, gauze	N/A	Woven	0.7	6.5	0.47
Cotton, handkerchief	N/A	Woven	1.1	9.8	0.48
Nylon	Clothing (Exercise pants)	Woven	23	244	0.4

* This table refers only to materials reported in experimental peer-reviewed studies. The filtration efficiency, pressure drop and Q factor are dependent on flow rate. ** According to expert consensus, three (3) is the minimum Q factor recommended.

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COVID-19 Scientific Advisory Group Evidence Summary and Recommendations

Likelihood of Transmission of COVID-19 infection after COVID-19 Vaccination

March 23, 2021

The AHS Scientific Advisory Group is a contributing member of COVID-END, the COVID-19 Evidence Network to support Decision-making.

This document summarizes the COVID-END report on the likelihood of transmission of COVID-19 infection after COVID-19 vaccination, prepared by member group University of Calgary HTA on March 2, 2021 adds some additional information, and develops key messages and recommendations grounded in the Alberta healthcare system context.

Lay Summary

- This document summarizes the COVID-19 Evidence Network to support Decision-making report on the likelihood of transmission of COVID-19 infection after COVID-19 vaccination, and adds some relevant information for decision makers in Alberta.
- The original question arose from healthcare leaders but has become a focus of wide interest: as the numbers of vaccine recipients go up, people wonder if public health measures still apply after vaccination, including using masks in public, and whether quarantine rules are to remain the same after vaccination.
- One issue is that the vaccine studies were designed to measure vaccine protection from COVID-19 illness, with all available vaccines are very effective at decreasing hospitalization and death from COVID-19. However they were not set up to assess the risk of transmission after vaccination. This is important since some vaccines protect against illness and carriage/transmission, while others protect against illness but the vaccinated person can still carry or spread the germ (example, pertussis). If asymptomatic SARS-CoV-2 infection after vaccination is common, and significant transmission after vaccination can occur, then currently recommended precautions would need to be maintained until more people have received vaccine.

Key Messages

- We will continue to see the reported vaccine protection numbers change as trials are done at different times, in different places, and with differing numbers of variants of concern (VOC). All of the vaccines have been highly protective against severe COVID-19.
- Information from limited studies that performed routine viral swabs after vaccination regardless of symptoms show that having a positive test without documented symptoms is less common in vaccinated people, although positive tests can still occur. Some vaccines seems to protect against this asymptomatic test positivity better than others.
- Some studies show that the amount of virus in positive tests collected after vaccination appears to be lower, so people may be less likely to transmit to others.
- Studies in which small numbers of vaccinated monkeys were exposed to the virus showed all COVID-19 vaccines reduce lung infection well but seem to vary in how well they prevent the SARS-CoV-2 virus from infecting/being carried in the nose, so it is possible that some vaccines may be better at preventing onward spread than others.
- None of the vaccine studies to date have directly measured whether people who are vaccinated and end up testing positive for COVID-19 transmit the virus to fewer people than people who test positive for COVID-19 and are not vaccinated

Conclusion: Although so far studies look promising that vaccination will reduce transmission, until more studies are finished it is most safe to maintain current precautions during vaccine rollout and reassess the evidence frequently.

Authorship and Committee Members

Name	Contribution
Jamie Boyd	Extraction of key messages from COVID-END review; content writer, post-meeting revisions
Lynora Saxinger	Primary scientific reviewer - writer and revision
Alexander Doroshenko, Elizabeth MacKay, Robyn Harrison, Uma Chandran, Marcia Johnson	Secondary scientific reviewers- content revision
Braden Manns & Lynora Saxinger	Scientific Advisory Group chairs (oversight and leadership responsibility)
John Conly, Alexander Doroshenko, Shelley Duggan, Marcia Johnson, Nelson Lee, Elizabeth MacKay, Andrew McRae, Melissa Potestio, Jeremy Slobodan, Brandie Walker, Nathan Zelyas	Discussion, revision, and approval of document

The AHS Scientific Advisory Group is a contributing member of COVID-END, the COVID-19 Evidence Network to support Decision-making. This document summarizes the COVID-END report on likelihood of transmission of COVID-19 infection after COVID-19 vaccination, prepared by member group University of Calgary HTA and uses its findings to develop key messages and recommendations grounded in the Alberta healthcare system context.

The original report can be accessed here

Topic: Likelihood of Transmission of COVID-19 Infection after COVID-19 Vaccination

1. **Can people who have started or finished a COVID-19 vaccine series develop asymptomatic COVID-19 infection and transmit the virus to other individuals? If so, how large is the risk, in comparison to unvaccinated people?**
    a. **Should close contacts of confirmed or probable COVID-19 cases who have started, or finished a COVID-19 vaccine series be required to quarantine in a similar fashion to those who are not vaccinated?**
    b. **Should health care workers (HCW) assessed as having an exposure in any setting but who have started, or finished a vaccine series be required to quarantine and be off work in a similar fashion to those HCW who are not vaccinated?**

Context

- It is not yet clear whether the current COVID-19 vaccines are as effective at reducing transmission as they are at reducing disease. There are vaccines that prevent disease but do not completely block transmission (e.g., acellular pertussis vaccine) - this therefore could impact transmission during and after vaccine rollout and is a consideration in public health recommendations for vaccine recipients.
- Theoretically, immunization may reduce COVID-19 transmission through 3 mechanisms: reduction of the number of people with transmissible symptomatic or asymptomatic COVID-19 infection, and potentially by reducing the infectiousness of those who do develop COVID-19 infection at any point after immunization.
- Vaccine trials for currently licensed vaccines have used symptomatic COVID-19 disease as their primary end point to establish vaccine efficacy. There are limited data to evaluate the efficacy (clinical trials settings) or real-world effectiveness (observational studies) of COVID-19 vaccines for secondary end points such as in decreasing viral loads in breakthrough infection, and in reduction of asymptomatic RT-PCR positive states after vaccination.
- There are no presently available epidemiologic studies on evidence of forward transmission after immunization; therefore, there is uncertainty around vaccine

effectiveness against potential transmission of infection from asymptomatic vaccinated people, although transmission from asymptomatic individuals is lower.

- Public health recommendations around personal protective equipment (PPE) and management of exposures and contact have not yet differentiated their recommendations for vaccinated and unvaccinated individuals.
- As the availability of COVID-19 vaccines increases and more population groups can be vaccinated, it will be important to have an evidence-informed approach to public health measures to reduce incidence rates and prevent/control any potential additional waves of SARS-CoV-2 transmission, but also to rationalize measures based on risk of infection and transmission.
- To best inform evolution of PPE use and quarantine policy, a review of current literature was requested by Alberta Health to delineate what is known about the risk of transmission of infection after vaccination and evaluate implications of changes to quarantine restrictions for vaccinated individuals, both within the healthcare system and the community.
- The scope of this review was focused on:

  1) A COVID-END data summary on detection of SARS-CoV-2 positivity in the absence of symptoms in vaccinated individuals from existing vaccine efficacy and effectiveness studies, data around post-infection proxy measures of infectivity such as Ct (cycle threshold) values and viral load in asymptomatic and symptomatic vaccinated people, and a targeted assessment of preclinical vaccine studies with primate challenge studies where virologic data was collected in vaccinated and unvaccinated animals after infection challenge. This review is expected to be updated in an iterative fashion as evidence emerges: the most recent version of this data can be accessed here.

  2) A brief review of select studies addressing the biologic plausibility and pathophysiology of expected transmission during an evolving immune response or with antibody exposure (viral load, Ct values, immune response to vaccination, and COVID-19 transmission papers); as well as an expanded description of HCW vaccine effectiveness studies.

  3) A brief jurisdictional scan of public health guidance for vaccinated people.

- In this review's potential recommendation and guidance, it is recognized that decision-makers must balance vaccination effectiveness considerations with other factors such as economics, ethics, equity, feasibility, and acceptability. The evidence base around these factors was, however, not systematically assessed in this review. It is recognized that policy makers contemplating changes to recommendations for healthcare settings and the community must consider if it is equitable to treat individuals differently based on whether or not they have been vaccinated, given that not all individuals are eligible access to COVID-19 vaccines at this time.

Key Messages for Alberta

Asymptomatic infection and transmission in vaccinated individuals – summary of the COVID-END report (in this version, literature was searched to February 26, 2021 – this is a living review with scheduled updates so please use the link for most current version)

- People who are partially or fully vaccinated (see definitions, Appendix) have been documented to have detectable SARS-CoV-2 by RT-PCR at various time points after their vaccine first dose, although cultivatable virus has not been assessed. There have been no epidemiologic reports of transmission from SAR-CoV-2 positive vaccinated individuals as yet. There is rapidly evolving data in this area, and readers are requested to refer to the most recent posted version of the COVID-END report.
- Using the existing data on the proportion of vaccinated individuals testing COVID-19 positive without documented symptoms with licensed vaccines in randomized controlled trials (RCT) and observational studies, it is possible to illustrate the risk of testing positive after varied exposure risks to help plan management of exposures in vaccinated persons and recommended preventative measures, although presently it is unclear to what degree testing positive post vaccination is a true risk for forward transmission.
- The primary endpoint of the vaccine RCTs has been detection of test positive symptomatic COVID-19. Some RCT and cohort studies of selected COVID-19 vaccines, Pfizer BioNTech (PfBNT), Oxford AstraZeneca (AZ), Moderna and Janssen present data which suggest a reduction in the likelihood of testing positive for SARS-CoV-2 RT-PCR in the absence of documented symptoms after vaccination. The data for AZ vaccine efficacy against asymptomatic positivity is more equivocal, with an analysis of dose timing showing effectiveness against asymptomatic positivity, building later after the initial dose (3-month range 25-60%) although notably the likelihood of any positive tests declines after the first dose. It is not possible to directly compare findings across studies owing to variations in the assessment of symptom status, study design, and setting of the trials particularly with respect to degree of circulation of variants of concern (VOC).
- Separate preclinical primate studies where small numbers of vaccinated animals were challenged with SARS-CoV-2 showed vaccinated animals receiving the Moderna mRNA (8 weeks prior) or Novavax protein vaccine (35 days prior) were much less likely to have SARS-CoV-2 recovered from nasal or lower respiratory samples than unvaccinated animals. The AZ vaccine challenge study suggested it was protective against lower respiratory replication but showed no protection against nasal virus replication.
- Population-based data on SARS-CoV-2 RT-PCR Ct values (a proxy of viral load) of positive tests collected after vaccination in Israel describes significantly higher Ct values (a lower amount of virus) in vaccinated (AZ or Pfizer) than in unvaccinated controls. There was no symptom data available. This suggests that vaccination may reduce the amount of virus present in symptomatic and asymptomatic post vaccine positive cases, and thus may plausibly reduce transmission risk. More evidence is required to provide a

clearer indication of impact on Ct values and correlation with subsequent transmission.

- Existing evidence on vaccine efficacy against VOCs is limited and is the topic of a separate in progress rapid review which will be found at the COVID-END website.
- As most of the current data is around viral detection by RT-PCR rather than evidence of cultivatable virus and epidemiologic evidence of transmission, further research is required to clarify the likelihood of forward transmission from asymptomatic or minimally symptomatic vaccinated people, both for wild type COVID-19 (no major mutations) and VOC. However, extant data does suggest vaccinated individuals are less likely to have asymptomatic detection of SARS-CoV-2 carriage than unvaccinated individuals, although this effect is less pronounced and appears to occur later with AZ vaccine versus mRNA vaccines. Those who do have detectable virus may have lower amounts of virus present, using a proxy of Ct values, which is methodologically less robust that other laboratory methods, but still supportive of potentially lower transmission risk for vaccinated individuals.
- Other data that pertains to the plausibility of vaccine-induced reduction of transmission was reviewed: monoclonal antibody therapeutics trials for COVID-19 infection, a study that included assessment of epidemiologic evidence of transmission from individuals who were persistently RT-PCR positive after natural infection but had evidence of an immunologic response, and two studies looking at viral load or Ct measures and association with transmission. **In total, these studies support that viral load can be reduced by circulating antibody, that a lower viral load or higher Ct on RT-PCR is associated with a reduced risk of transmission, and RT-PCR positivity in the presence of neutralizing antibody and/ or correlates of cell mediated immunity should not be considered to necessarily represent transmissible infection**

Additional Evidence Review
Jurisdictional Scan:
1) Quarantine guidance for community close contacts who are fully vaccinated

- A brief jurisdictional scan revealed that aside from recent CDC (CDC[b], 2021; CDC[c], 2021) guidance there are very few guidance recommendations that have been made publicly available regarding quarantine for fully vaccinated citizens (Appendix I).
- Current recommendations from Alberta, Ontario and British Columbia require all individuals assessed as having an exposure to quarantine, regardless of immunization status.
- The US CDC (CDC[a]) released interim clinical considerations on February 10, 2021 which state that vaccinated individuals with exposure to a confirmed or suspected case of COVID-19 are not required to quarantine if they meet all three of the following criteria: 1) fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of

one dose of a single-dose vaccine); 2) Are within 3 months following receipt of the last dose in the series; and 3) Have remained asymptomatic since the current COVID-19 exposure.

- A few news media articles were identified that outline some countries have modified restrictions for arriving travelers to include a quarantine exemption for travelers meeting certain criteria such as: >14 days since second vaccination was administered and within three months from the date of receiving second vaccine dose.

2) Quarantine guidance for vaccinated HCWs after exposure and data from HCW surveillance and observational studies.

- The Interim Clinical Considerations released by the US CDC (CDC[a]) suggest that quarantine recommendations for vaccinated individuals in community (i.e., no quarantine requirement if the aforementioned criteria are met) should be given consideration with respect to HCW quarantine and recognize staffing considerations (Appendix I). The guidance highlights that fully vaccinated HCWs meeting the listed criteria would need to quarantine from health care settings but would follow the community guidelines above in the community.
- The Minnesota Health Department (2021) released HCW recommendations that suggest HCWs with a high-risk exposure should quarantine from work for 14 days and align with the CDC recommendations in stating that HCWs who are fully vaccinated and meet the CDC criteria described earlier would not be required to quarantine within the community (but should not attend at work).
- No Canadian recommendations regarding quarantine for fully vaccinated HCWs follow an exposure are currently available.

3) HCW specific data on asymptomatic or unknown test positivity post-vaccination was reviewed. An ongoing HCW surveillance cohort suggested a 97% reduction in asymptomatic or undocumented test positive cases from 21 days after dose 1 of the Pfizer vaccine (vaccinated people were 0.23% versus 8.13% positive without documented symptoms) (Hall et al., 2021). In this study HCW vaccinated people were also proportionally less likely to have classic COVID-19 symptoms (40% versus 63%). In a laboratory-based observational efficacy research letter from Israel also involving HCW showing overall vaccine efficacy of 75% after two weeks from vaccination (Pfizer) there was a 29% reduction in positive tests without documented symptoms, although previous RT-PCR positivity was not excluded (Amit et al., 2021). The same group published a community-based analysis showing similar results: dose 1 (2 and 3 week) effectiveness of 29% and 52%, and 90% efficacy 1 week after dose 2 (Dagen et al., 2021).

Summary: Vaccine effectiveness data

- Based on the evolving data including these studies, for overall first dose protection mRNA vaccines are most effective from approximately 3 weeks after the first dose (61%-97% effective against asymptomatic, 94% against

symptomatic) and the effectiveness of dose 1 of nonreplicating adenovirus vaccine against combined asymptomatic and symptomatic SAR-SCoV-2 detection increases from about 46.3% at 3 weeks to 67-80% at 3 months.

- Risk scenarios are presented in Tables 1-3 of this document to illustrate HCW risk of developing asymptomatic (and symptomatic) COVID-19 as well asymptomatic and/ or asymptomatic infection.
  Example: the risk of a vaccinated HCW > 3 weeks after an mRNA vaccine developing COVID-19 following a low-risk exposure ranges from 0.003%-0.02% and from 0.006%-0.04% after a medium risk exposure. The risk of a vaccinated HCW > 3 months after an adenovirus vaccine developing COVID-19 after a low-risk exposure is 0.025%-0.125% and after a medium risk exposure is 0.05-0.45%.

Committee Discussion

The committee initially provided feedback that including the pathophysiologic plausibility data including animal data, and virologic, immunologic and epidemiologic data around the likelihood of RT-PCR positivity and transmission was useful. It was recognized that this is a rapidly evolving area and as such firm recommendations may not be possible versus providing provisional recommendations and guidance in some areas. It was recognized that it is expected that further evidence will support the thesis that test positivity does not necessarily infer transmission risk, and that better data on which to assess transmission risk will allow progressive changes to reduce restrictions required to manage transmission risk from vaccinated people in the short to medium term.

Recommendations for Alberta

Recommendation 1: Isolation and testing for symptoms in partially or fully vaccinated people (see appendix for definitions)

All vaccinated people should be instructed to self-isolate and seek testing with development of COVID-compatible symptoms, with standard isolation and contact tracing procedures as per nonimmunized people in that setting (e.g., by Public Health guidance in the community setting and the Return-to-Work guidelines for HCWs).
Rationale: Vaccine protection against severe, hospitalized and fatal infection is robust in trial data thus far, but mild to moderate COVID-19 infection, including experiencing less severe and less typical symptoms have been described. Testing and contact tracing will allow assessment of transmission from vaccinated individuals in Alberta.

Recommendation 2: Quarantine recommendations for vaccinated people exposed to COVID-19 in identified health care or vulnerable settings

The evidence is presently insufficient to suggest a widespread practice change, but there is a need for appropriate risk management in the setting of uncertainty and rapidly evolving evidence. Therefore, we suggest case by case assessment

in higher risk or vulnerable settings with special considerations around PPE use, service provision, and presence of higher risk individuals. These settings include acute or long-term care (LTC), congregate living settings, shelters, and correctional facilities, where there is support by Public Health, Infection Prevention & Control [IPC], and/ or Workplace Health and Safety [WHS]) in detailed risk assessment. This should consider the nature of the exposure, whether the exposed individual was partially or fully vaccinated, the time elapsed since vaccination/expected degree of protection, and situational knowledge of the likelihood of VOC and degree of exposure risk. This information may assist in counselling, or in determination of the need for quarantine depending on the evolution of present evidence.
It is noted that individuals who develop symptoms, who are more likely to transmit, are to self-isolate and seek testing with symptoms (see Recommendation 1).

Rationale: Vaccination reduces the risk of contracting SARS-CoV-2, and the risk of subsequent forward transmission from asymptomatic or paucisymptomatic viral carriage. Although the risk of forward transmission with SAR-CoV-2 RT-PCR positivity and no or minimal symptoms after vaccination is expected to be significantly reduced, a wide range of vaccine efficacy is currently described and the data are not yet conclusive. Some Alberta HCWs have been observed to have RT-PCR positive infection after three weeks from the first dose (R. Harrison, personal communication). Moreover, increasing VOC transmission mandates additional precautions. Further HCW specific recommendations therefore will await more conclusive data.

Recommendation 3: Quarantine recommendations for vaccinated people exposed to COVID-19 in general community settings

In community settings not identified above, current quarantine guidelines should be followed. Available evidence is insufficient to inform a standard recommendation around public health guidelines for quarantine of partially or fully vaccinated individuals, although it is expected that more conclusive data is forthcoming fairly quickly. It is noted that other Public Health considerations such as community-based transmission patterns, the proportion of individuals who are vaccinated, and the evolving picture of VOC in Alberta would also be assessed with the evolving evidence in determining public quarantine recommendations.

Recommendation 4: Use of preventative measures (including masks, hand hygiene, physical distancing, sanitizing high touch surfaces) by vaccinated persons in the community

All vaccinated persons should continue to use recommended measures when in close contact and shared airspace with unvaccinated persons, as well as in public spaces, under current public health guidance.

Rationale: There is evolving data around the epidemiology of transmission of infection from vaccinated persons and although the risk of transmission is likely reduced, the degree of this reduction is not known. Of importance, as not everyone has had an opportunity to be vaccinated yet, public mask wearing and adherence to other measures should be uniformly continued as a socially supportive and appropriate measure for all until the recommendation is removed by Public Health. It is also recognized that there may be other social factors to consider in public health guidance for vaccinated people in public or private spaces, including incentivizing people to seek immunization.

Recommendation 5: Use of Alberta data sources to delineate post vaccination transmission risk in Alberta
We recommend analysis of existing Population and Public Health data collected on positive SARS-CoV-2 tests occurring after vaccination, identification of variant strain infections, outbreak data, and epidemiologic contact tracing data with laboratory data including Ct values, to prospectively monitor for evidence of forward transmitting infection from vaccinated persons in Alberta, through the COVID Responsive Analytics Collaboration (CRAC).

Practical Considerations for Alberta

- Based on current effectiveness data, people with exposures occurring >3 weeks after an initial mRNA vaccine initial dose and >3 months after a nonreplicating adenovirus vaccine dose would be considered to be significantly protected from asymptomatic, mild and moderate disease. It is noted that protection against hospitalization and death from COVID-19 is extremely high for all available vaccines starting from 2 to 3 weeks after the first dose.

Research gaps

There is a lack of surveillance data on how common truly asymptomatic test positivity is after vaccination. Further evaluation of those who test positive on RTPCR after vaccination should include additional viral studies including but not limited to viral load, cultivatable virus and sub-genomic RNA, correlations with humoral and cell mediated immune responses. Finally, epidemiologic studies to assess evidence of transmission from vaccinated persons is required. Although it is not expected that all of these elements are required to be able to inform risk management in vaccinated persons in the short to medium term, higher quality data in key areas will support initial changes to quarantine and PPE management.

Evidence Summary
The full report can be accessed here.

1. Risk Table Illustrating Potential Likelihood of COVID-19 after vaccination by varied exposure risks
2. Additional Study Descriptions (expanded from COVID-END report)
    a. HCW risk studies
    b. Pathophysiologic Considerations from virologic, immunologic and epidemiologic studies in natural infection

1. Risk Tables – Illustration of estimated risk of vaccinated HCW by varied exposure risk, by time since first dose of vaccine.

The below three tables calculate potential risk reduction for a HCW exposed to COVID-19 after a first dose of COVID-19 vaccine (of two dose regimen) across various scenarios including attack rate, exposure risk (low, medium, high, very high-superspreader event), vaccine type (mRNA and nonreplicating adenovirus).

Vaccine related risk reduction ranges are based on available HCW study data including some additional data extraction and calculation for 3 weeks post dose 1 mRNA; 3 weeks to 12 weeks post dose 1 nonreplicating adenovirus. Vaccination protection following first dose was selected both based on available data and because this is relevant as the dosing schedules are currently based on an extended interval for many vaccinated people.

These data should be considered within the context of current uncertainties including long-term follow up data beyond three months after vaccination. As an example, interpretation from Table 1, the risk of a HCW developing an asymptomatic COVID-19 infection (estimated to be 20% of all infections) following a low-risk exposure (attack rate 0.5%) after receiving first dose of vaccine would be between 1/1,190 (3 weeks post vaccination) and 1/4,000 (12 weeks post vaccination) for nonreplicating adenovirus vaccines and 1/2,564 to 1/33,333 for mRNA vaccines 3 weeks post vaccination.

Table 1. Estimated risk of partially vaccinated HCW developing **asymptomatic** COVID-19 (approximately **20% of all cases**) after varied exposures (current data estimates from wild type SARS-CoV-2 and are evolving – will require frequent updates) compared with no vaccination[1]

Attack Rate based on Exposure Risk[2] *A*	Risk of Developing COVID-19 based on Proportion of Type of COVID-19 Infection x Exposure Risk *B* *(A x 20%)*	Range of expected protection based on current studies (as of March 13, 2021) nonreplicating adenovirus vaccine (nrAD) protection range assessed from 3 weeks and 12 weeks after first dose 16%-75% mRNA vaccine (mRNA) assessed from 3 wks after 1st dose 61%-97%	Estimated Vaccine Risk Reduction Range (based on current data) assumes protection remains the same regardless of exposure risk[3] *C*	Range of Risk of developing COVID-19 following vaccination regimen *D* *(B x C)*
Low risk 0.5%	0.1%	nrAD vaccine protection range: 16%-75%	0.84 - 0.25	**1/1,190 - 1/4,000**
		mRNA vaccine protection range: 61-97%	0.39 – 0.03	**1/2,564 – 1/33,333**
Medium risk 1%	0.2%	nrAD vaccine protection range: 16%-75%	0.84 - 0.25	**1/595 – 1,200**
		mRNA vaccine protection range: 61-97%	0.39 – 0.03	**1/1,282 - 1/16,666**
High risk 5%	1%	nrAD vaccine protection range: 16%-75%	0.84 - 0.25	**1/119 - 1/400**
		mRNA vaccine protection range: 61-97%	0.39 – 0.03	**1/256 - 1/3,333**
Very high-Superspreader event 10%	2%	nrAD vaccine protection range: 16%-75%	0.84 - 0.25	**1/59 - 1/200**
		mRNA vaccine protection range: 61-97%	0.39 – 0.03	**1/128 - 1/1,666**

[1] Estimate of type of COVID-19 cases (symptomatic ~80%) is a conservative estimate derived from a meta-analysis on the proportion of asymptomatic case and potential range for community transmission. Byambasuren O, Cardona M, Bell K, Clark J, McLaws M-L, Glasziou P. Estimating the extent of asymptomatic COVID-19 and its potential for community transmission: systematic review and meta-analysis. Official Journal of the Association of Medical Microbiology and Infectious Disease Canada. 2020;5(4):223-234. https://jammi.utpjournals.press/doi/pdf/10.3138/jammi-2020-0030

[2] Estimates for attack rate derived from study data and stratified to estimate range from low risk to superspreader event risk. from Abbas et al. which identified HCW risk to range from ~2-8%. Abbas, M., Robalo Nunes, T., Martischang, R. et al. Nosocomial transmission and outbreaks of coronavirus disease 2019: the need to protect both patients and healthcare workers. Antimicrob Resist Infect Control 10, 7 (2021). https://doi.org/10.1186/s13756-020-00875-7

[3] Study data applied to all infections and asymptomatic infections: nonreplicating adenovirus vaccines - AZ: 16% after 3 weeks, (25-60% after 12 weeks, NS); Janssen: 75% after 12 weeks (PCR and/or serology without previous symptoms). mRNA vaccines - Moderna: 61% from 3 weeks after dose 1; Pfizer BioNTech (Hall et al., 2021): 97% 21 days after dose 1 in HCW; Pfizer BioNTech (Dagen et a., 2021l): 29% effectiveness 15 days after dose 1 in HCW

Table 2. Estimated risk of partially vaccinated HCW developing **symptomatic** COVID-19 (**80% of all cases**) after varied risk exposures (current data estimates from wild type SARS-CoV-2 and are evolving - will require frequent updates) compared with no vaccination[1]

Attack Rate based on Exposure Risk[2] *A*	Risk of Developing COVID-19 based on Proportion of Type of COVID-19 Infection x Exposure Risk *B* *(A x 80%)*	Range of expected protection based on current studies (as of March 13, 2021) Vaccination Type Nonreplicating adenovirus vaccine effectiveness range across studies (67% 3w post dose 1 to -75% 12 w post dose 1) mRNA vaccine effectiveness range (70% 3 w post dose 1 to 95% 2 wks post dose 1)	Estimated Vaccine Risk Reduction Range (based on current data) assumes protection remains the same regardless of exposure risk[3] *C*	Risk of vaccinated person developing COVID-19 by regimen *D* *(B x C)*
Low risk 0.5%	0.4%	nrAD vaccine protection range: 67% - 75%	0.22 - 0.66	**1/757 – 1/1136**
		mRNA vaccine protection range: 70% - 95%	0.3 - 0.05	**1/833 – 1/5000**
Medium risk 1%	0.8%	nrAD vaccine protection range: 67% - 75%	0.33 – 0.22	**1/378 – 1/568**
		mRNA vaccine protection range: 70% - 95%	0.3 – 0.05	**1/416 – 1/2500**
High risk 5%	4%	nrAD vaccine protection range: 67% - 75%	0.33 – 0.22	**1/75 – 1/113**
		mRNA vaccine protection range: 70% - 95%	0.3 – 0.05	**1/83 – 1/500**
Superspreader event 10%	8%	nrAD vaccine protection range: 67% - 75%	0.33 – 0.22	**1/37 – 1/56**
		mRNA vaccine protection range: 70% - 95%	0.3 – 0.05	**1/41 – 1/250**

[1] Estimate of type of COVID-19 cases (symptomatic ~80%) is a conservative estimate derived from a meta-analysis on the proportion of asymptomatic case and potential range for community transmission. Byambasuren O, Cardona M, Bell K, Clark J, McLaws M-L, Glasziou P. Estimating the extent of asymptomatic COVID-19 and its potential for community transmission: systematic review and meta-analysis. Official Journal of the Association of Medical Microbiology and Infectious Disease Canada. 2020;5(4):223-234. https://jammi.utpjournals.press/doi/pdf/10.3138/jammi-2020-0030

[2] Estimates for attack rate derived from study data and stratified to estimate range from low risk to superspreader event risk. from Abbas et al. which identified HCW risk to range from ~2-8%. Abbas, M., Robalo Nunes, T., Martischang, R. et al. Nosocomial transmission and outbreaks of coronavirus disease 2019: the need to protect both patients and healthcare workers. Antimicrob Resist Infect Control 10, 7 (2021). https://doi.org/10.1186/s13756-020-00875-7

[3] Study data applied to symptomatic infections: nonreplicating adenovirus vaccines – AZ (Voysey et al): 76% after 3 weeks and 78% after 12 weeks; Janssen (Janssen, 2021): 67% after 14 days. mRNA vaccines – Pfizer (registration trial data, BCCDC analysis) 95% after 2 weeks onwards; Pfizer (Amit el al., 2021) 75% after 2 weeks; Pfizer (Hall et al., 2021) 70% after 3 weeks.

Table 3. Estimated risk of partially vaccinated HCW developing **symptomatic or asymptomatic** COVID-19 after varied risk exposures (current data estimates are from wild type SARS-CoV-2 and are evolving - will require frequent updates) compared with no vaccination[1]

Attack Rate based on Exposure Risk[2] *A*	Risk of Developing COVID-19 based on Proportion of Type of COVID-19 Infection x Exposure Risk *B* *(A x 100%)*	Range of expected protection based on current studies (as of March 13, 2021) Vaccination Type Nonreplicating adenovirus vaccine effectiveness range across studies (16% 3w post dose 1 to -75% 12 w post dose 1) mRNA vaccine effectiveness range (61% 3 w post dose 1 to 97% 3 wks post dose 1)	Estimated Vaccine Risk Reduction Range (based on current data) assumes protection remains the same regardless of exposure risk[3] C	Risk of developing COVID-19 following vaccination regimen *D* *(B x C)*
Low risk 0.5%	0.5%	nrAD vaccine protection range: 16% - 75%	0.84 - 0.25	**1/250 – 1/800**
		mRNA vaccine protection range: 61% - 97%	0.39 - 0.03	**1/512 – 1/6666**
Medium risk 1%	1%	nrAD vaccine protection range: 16% - 75%	0.84 - 0.25	**1/119 – 1/400**
		mRNA vaccine protection range: 61% - 97%	0.39 – 0.03	**1/256 – 1/3333**
High risk 5%	5%	nrAD vaccine protection range: 16% - 75%	0.84 – 0.25	**1/23 – 1/80**
		mRNA vaccine protection range: 61% - 97%	0.39 – 0.03	**1/51 – 1/666**
Superspreader event 10%	10%	nrAD vaccine protection range: 16% - 75%	0.84 – 0.25	**1/11 – 1/40**
		mRNA vaccine protection range: 61% - 97%	0.39 – 0.03	**1/25 – 1/333**

[1] Estimate of type of COVID-19 cases (symptomatic ~80%) is a conservative estimate derived from a meta-analysis on the proportion of asymptomatic case and potential range for community transmission. Byambasuren O, Cardona M, Bell K, Clark J, McLaws M-L, Glasziou P. Estimating the extent of asymptomatic COVID-19 and its potential for community transmission: systematic review and meta-analysis. Official Journal of the Association of Medical Microbiology and Infectious Disease Canada. 2020;5(4):223-234. https://jammi.utpjournals.press/doi/pdf/10.3138/jammi-2020-0030

[2] Estimates for attack rate derived from study data and stratified to estimate range from low risk to superspreader event risk. from Abbas et al. which identified HCW risk to range from ~2-8%. Abbas, M., Robalo Nunes, T., Martischang, R. et al. Nosocomial transmission and outbreaks of coronavirus disease 2019: the need to protect both patients and healthcare workers. Antimicrob Resist Infect Control 10, 7 (2021). https://doi.org/10.1186/s13756-020-00875-7

[3] Study data applied to all infections and asymptomatic infections: nonreplicating adenovirus vaccines - AZ: 16% after 3 weeks, (25-60% after 12 weeks, NS); Janssen: 75% after 12 weeks (PCR and/or serology without previous symptoms). mRNA vaccines - Moderna: 61% from 3 weeks after dose 1; Pfizer BioNTech (Hall et al., 2021): 97% 21 days after dose 1; Pfizer BioNTech (Dagen et al., 2021): 29% effectiveness 15 days after dose 1 in HCW

2. **Additional Study Descriptions (not included in COVID-END report)**
    a. **HCW risk studies**

The first study is an ongoing COVID-19 surveillance study of HCWs with q2weekly assessments of risk, vaccine status, symptoms, and nasal or nasal plus oral swabs (Hall et al., 2021). A subset also had twice weekly rapid testing, so case ascertainment was likely very high. The vaccine effectiveness overall was 72% from 21 days after dose one and 86% after two doses (most were adhering to the dosing schedule quite closely). Protection was noted from day 10 post first dose in these data. The study took place over two months and involved 23,320 HCWs in 104 hospitals, of whom 35% were previously documented SARS-CoV-2 positive. The intensity of exposure in this study was quite high, with 977 infections documented in 15,160 previously unvaccinated participants over 2 months which is roughly 6% of the unvaccinated HCW cohort acquiring infection over 2 months.

Also, of practical relevance in those testing positive, the unvaccinated group had a higher proportion with “classic” symptoms at 63%: 14% had other symptoms, 5% were asymptomatic and 17% unknown. In the vaccinated group only 40% had classic symptoms, 13% had other symptoms, 13% were asymptomatic, and 31% had unknown – therefore asymptomatic or non-classic symptoms comprised 26% of the post vaccine test positive. This may have implications for symptom-based screening in vaccinated individuals, suggesting the need to include generalized and milder symptoms as a rationale to seek testing.

Another observational HCW study by Amit et al. (2021) in Israel documented vaccine effectiveness of 75% from 15 to 28 days after dose one of the PfBNT vaccine in HCWs and was higher against symptomatic infection (reaching 90% day 22-28). Asymptomatic test positive data was limited as it was not active surveillance and sampling. However, 10 of 19 infections occurring in vaccines after day 15, and 5 of 7 infections occurring after day 22 were asymptomatic. The reasons they were tested was not given, although one might posit this was part of exposure investigation. Baseline status was not assessed so prolonged RT-PCR positivity post infection was not ruled out. This was a cohort of 9,109 vaccine eligible HCWs with active daily symptom reporting and availability of same-day testing, so the overall rate of asymptomatic swab positivity was 0.2%. The Ct values of these positives were not given. The overall infection rate in the whole cohort for the 2-month study was 1.9%.

2.b) Pathophysiologic Considerations from virologic, immunologic and epidemiologic studies in natural infection

Virologic, immunologic and epidemiologic analysis of individuals who had persistent RT-PCR positivity but developed measurable immune responses suggested that asymptomatic individuals with viral shedding after natural infection are unlikely to be a significant source of transmission (no infections in 757 close contacts of 26 RT-PCR positive individuals) (Vibholm et al., 2021). COVID-19 therapy trials of neutralizing anti-spike monoclonal antibody treatments show rapid clearance of virus from the nasopharynx after administration of these therapies.

As noted, lower viral loads in positive SARS-CoV-2 tests after vaccination were observed in a lab-based population study in Israel. This may be expected to reduce transmission risk, as a recent epidemiologic investigation using quantitative viral loads showed the index case viral load to be is a major driver of transmission, with only 32% of index cases responsible for transmission, and an attack rate of 12% in contacts of index cases with a viral load $<10^6$ and 25% in contacts of index cases with a viral load of 10^{10} (Marks et al., 2021). A preprint (Bjorkman et al., 2021) of university roommate transmission showed that index cases who transmitted infection had an average viral load 6.5 log higher than those who did not. Transmission from asymptomatic students to roommates occurred in 20% of rooms with an infected student, with a lower mean Ct (E gene) of 26.2 in transmission index cases versus 28.9, (median 26.11 in transmission index cases versus 29.32).

In total, these observations suggest that viral carriage is likely reduced by developing immune responses against SARS-CoV-2, and that any residual viral detection may not be associated as strongly with transmission given current observations of lower viral loads/higher Ct values post vaccination and consistent data showing correlation of that with reduced transmission risk in natural infection. There were no studies of cultivatable virus carriage after vaccination identified yet.

Appendix

List of Abbreviations

AZ	Oxford AstraZeneca vaccine
CDC	Centres for Disease Control and Prevention
Ct	Cycle threshold
COVID-19	Coronavirus Disease 2019
mRNA	Messenger ribonucleic acid
PfBNT	Pfizer BioNTech vaccine
PPE	Personal protective equipment
RCT	Randomized controlled trial
RT-PCR	Reverse transcription polymerase chain reaction
SARS-Cov-2	Severe Acute Respiratory Syndrome Coronavirus 2
WHO	World Health Organization

Definitions and Terms

1. **Vaccination refers to administering a vaccine to produce immunity, and immunization is the process by which a person is protected from disease through vaccination. Immunized and vaccinated are considered largely interchangeable terms, with "vaccinated" preferred in this report - but "immunized" may be used especially where study results are quoted.**
2. **Fully vaccinated/vaccinated:**
   Two dose vaccines:
   a. Current mRNA vaccines, Moderna and Pfizer 2 doses required – 2 weeks after last dose
   b. Nonreplicating Adenovirus Vaccine, AstraZeneca/Covishield 2 doses required 2 weeks after last dose
   One dose vaccine:
   c. Nonreplicating Adenovirus Vaccine, Janssen- Johnson & Johnson requires only one dose – 3 weeks after dose
3. **Partially vaccinated/vaccinated:**
   a. Between one dose of 2 two dose series and the post second dose 2- or 3-week period noted above.
   Or
   b. Within 3 weeks of the one dose in a single dose vaccine.

Comments on these definitions:

- Time post-vaccine dose at which protection is assumed will be reassessed with evolving data. It is noted that considerable protection is observed in partially vaccinated persons depending on the time elapsed since the initial dose, from 3 weeks after dose one of mRNA vaccine and from 2-3 months after dose 1 of Astra Zeneca vaccine.
- If the duration of protection is found to be limited then a booster dose may be required to maintain protection. Both the duration of protection and, thus, the recommendation for further doses remain unclear at this time.
- The allowed/optimal interval of time between doses in a two dose schedule is subject to ongoing policy review with some emerging data suggesting the need to modify the interval for specific patient subgroups.

Appendix I. Jurisdictional Review of Quarantine Processes for Vaccinated Persons Exposed to COVID-19

Source (with citation)	Purpose/Summary	Conclusions/Recommendations
Centers for Disease Control and Prevention (CDC)(a). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. **https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html**	• Last updated February 10, 2021 • Updated quarantine recommendations for vaccinated persons. Fully vaccinated persons who meet criteria will no longer be required to quarantine following an exposure to someone with COVID-19. Additional considerations for patients and residents in healthcare settings are provided	• **Vaccinated persons with an exposure** to someone with suspected or confirmed COVID-19 are **not required to quarantine if they meet all of the following criteria**: - Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine); - Are within 3 months following receipt of the last dose in the series; - Have remained asymptomatic since the current COVID-19 exposure ***Persons who do not meet all 3 of the above criteria should continue to follow current quarantine guidance after exposure to someone with suspected or confirmed COVID-19.** • **Fully vaccinated persons who do not quarantine should still watch for symptoms of COVID-19 for 14 days following an exposure**. If they experience symptoms, they should be clinically evaluated for COVID-19, including SARS-CoV-2 testing, if indicated. In addition, vaccinated persons should continue to follow current guidance to protect themselves and others, including all other SARS-CoV-2 testing recommendations and requirements, and state, territorial, tribal, and local travel recommendations or requirements. **Vaccinated healthcare personnel, patients, and residents in healthcare settings:** • These criteria could also be applied when considering **work restrictions for fully vaccinated healthcare personnel with higher-risk exposures, as a strategy to alleviate staffing shortages**. Of note, exposed healthcare personnel would not be required to quarantine outside of work • **Vaccinated inpatients and residents in healthcare settings should continue to quarantine following an exposure to someone with suspected or confirmed COVID-19** - Exception is **due to the unknown vaccine effectiveness in this population, the higher risk of severe disease and death, and challenges with social distancing in healthcare settings**. Although not preferred, healthcare facilities could consider waiving quarantine for vaccinated patients and residents as a strategy to mitigate critical issues (e.g., lack of space, staff, or PPE to safely care for exposed patients or residents) when other options are unsuccessful or unavailable. These decisions could be made in consultation with public health officials and infection control experts.

CDC(c). Science Brief: Background Rationale and Evidence for Public Health Recommendations for Fully Vaccinated People. https://www.cdc.gov/coronavirus/2019-ncov/more/fully-vaccinated-people.html	• Last updated March 8, 2021 • Summarize evidence available through March 3, 2021 for the currently authorized COVID-19 vaccines (administered according to the recommended schedules) and additional considerations used to inform public health recommendations for fully vaccinated people, including: • Vaccine efficacy and effectiveness against SARS-CoV-2 infection • Vaccine performance against emerging SARS-CoV-2 variant strains • Impact of prevention measures in the context of vaccination • Population attitudes and behaviors towards vaccination and prevention measures	• Adherence to prevention measures, such as **wearing masks and physical distancing, will continue to be important in the context of vaccine implementation** • Rapidly increasing vaccination rates **may allow for the phasing out of some prevention measures as coverage increases** • There **may be certain activities that can be performed after vaccination, such as nursing home visitation**, as long as other measures are maintained • **Prevention measures will continue to be important for all people, regardless of vaccination status**, especially during this period of vaccine deployment • As vaccination coverage increases, a **balanced, stepwise approach to phasing out certain prevention measures in fully vaccinated people**, ideally those that are the most disruptive to individuals and society**, can be taken** • Information about activities that fully vaccinated people can safely undertake must be communicated in a clear and unambiguous fashion • Maintaining a requirement to continue all prevention measures after vaccination may disincentivize vaccine uptake
CDC(b). Interim Public Health Recommendations for Fully Vaccinated People. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html	• Last updated March 8, 2021 • First set of public health recommendations for fully vaccinated people. This guidance will be updated and expanded based on the level of community spread of SARS-CoV-2, the proportion of the population that is fully vaccinated, and the rapidly evolving science on COVID-19 vaccines. * People are considered fully vaccinated for COVID-19 ≥2 weeks after they have received the second dose in a 2-dose series (Pfizer-BioNTech or Moderna), or ≥2 weeks after they have received a single-dose vaccine (Johnson and Johnson [J&J]/Janssen). * This guidance applies to COVID-19 vaccines currently authorized for emergency use by the Food and Drug Administration: Pfizer-BioNTech, Moderna, and Johnson and Johnson [J&J]/Janssen COVID-19 vaccines * Recommendations apply to non-healthcare settings	• **Fully vaccinated people can**: - Visit with other fully vaccinated people indoors without wearing masks or physical distancing - Visit with unvaccinated people from a single household who are at low risk for severe COVID-19 disease indoors without wearing masks or physical distancing - Refrain from quarantine and testing following a known exposure if asymptomatic • For now, **fully vaccinated people should continue to**: - Take precautions in public like wearing a well-fitted mask and physical distancing - Wear masks, practice physical distancing, and adhere to other prevention measures when visiting with unvaccinated people who are at increased risk for severe COVID-19 disease or who have an unvaccinated household member who is at increased risk for severe COVID-19 disease - Wear masks, maintain physical distance, and practice other prevention measures when visiting with unvaccinated people from multiple households - Avoid medium- and large-sized in-person gatherings - Get tested if experiencing COVID-19 symptoms - Follow guidance issued by individual employers - Follow CDC and health department travel requirements and recommendations • **Indoor visits between fully vaccinated people who do not wear masks or physically distance from one another are likely low risk** • Indoor visits between **fully vaccinated** people and **unvaccinated people who do not wear masks or physically distance from one another are likely low risk for the vaccinated people**; Therefore, the level of precautions taken should be determined by the **characteristics of the unvaccinated people**, who remain unprotected against COVID-19

		- If the **unvaccinated people are from a single household that does not have individuals at risk** of severe COVID-19, they **can visit with fully vaccinated people indoors, without anyone wearing masks**, with a low risk of SARS-CoV-2 transmission - If any of the **unvaccinated people or their household members are at increased risk of severe COVID-19, all attendees should take precautions** including wearing a well-fitted mask, staying at least 6 feet away from others, and visiting outdoors or in a well-ventilated space - If the **unvaccinated people come from multiple households, there is a higher risk** of SARS-CoV-2 transmission among them. Therefore, **all people involved should take precautions** including wearing a well-fitted mask, staying at least 6 feet away from others, and visiting outdoors or in a well-ventilated space • **All people**, regardless of vaccination status, should **adhere to current guidance to avoid medium- or large-sized in-person gatherings** (e.g., sporting events, concerts, festivals, conferences, parades, or weddings) and to follow any applicable local guidance restricting the size of gatherings • **Fully vaccinated people engaging in social activities in public settings** (e.g., indoor restaurant dining) should **continue to follow all guidance for these settings** including wearing a well-fitted mask, maintaining physical distance (at least 6 feet), avoiding crowds, avoiding poorly ventilated spaces, covering coughs and sneezes, and washing hands frequently • **At this time, CDC is not updating travel recommendations and requirements** • **Recommendations for Isolation, Quarantine and Testing:** - **Any fully vaccinated person who experiences symptoms consistent with COVID-19 should isolate themselves** from others, **be clinically evaluated** for COVID-19, **and tested** for SARS-CoV-2 if indicated - **Fully vaccinated people with no COVID-like symptoms do not need to quarantine or be tested following an exposure** to someone with suspected or confirmed COVID-19, as their risk of infection is low; should still monitor for symptoms for 14-days following an exposure - **Fully vaccinated residents of non-healthcare congregate settings** (e.g., correctional and detention facilities, group homes) **should continue to quarantine for 14 days and be tested for SARS-CoV-2 following an exposure** to someone with suspected or confirmed COVID-19 – because residential congregate settings may face high turnover of residents, a higher risk of transmission, and challenges in maintaining recommended physical distancing - **Fully vaccinated employees of non-healthcare congregate settings and other high-density workplaces** (e.g., meat and poultry processing and manufacturing plants) **with no COVID-like symptoms**

		do not need to quarantine following an exposure; however testing following an exposure and through routine workplace screening programs (if present) is still recommended
World Health Organization (WHO)	• As of March 2, 2021, no publicly-available considerations and/or guidance on the quarantine requirements for vaccinated individuals exposed to COVID-19	
Alberta Health. COVID-19 VACCINE Questions & answers for the public and health-care practitioners. https://www.alberta.ca/assets/documents/covid-19-vaccine-q-and-a-health-care-practitioners.pdf	• Last updated February 2021 • Guidelines on frequently asked questions about the COVID-19 vaccination process for the general public and health care practitioners	Post-Immunization: • All individuals, **including those immunized with COVID-19 vaccine, should continue to follow public health measures for prevention and control of COVID-19 infection and transmission**. This includes masking when in public, maintaining physical distancing, practicing diligent hand hygiene, and staying home when sick. • **Will I have to quarantine if I received the vaccine and then am a close contact of someone who was positive for COVID-19?** - **Yes**, continue to follow all public health measures, including quarantining if you are informed that you are a close contact of a COVID-19 case for the reasons stated above • **Will I have to quarantine if I received the vaccine and am returning to Canada from an international destination?** - **Yes**, continue to follow all public health measures, including all federal and provincial quarantine requirements • **If I am immunized outside of Canada, do I still need a negative test to return to Canada? Quarantine in a Government of Canada-approved hotel? Take a COVID-19 molecular test on arrival?** - **Yes**, regardless of immunization status, travelers must present proof of a negative COVID-19 test result (either paper or electronic) to an airline prior to boarding a flight to Canada. Travelers must also reserve a room in a Government of Canada-approved isolation hotel, and must take a COVID-19 molecular test on arrival.
British Columbia Centre for Disease Control (BCCDC). Getting a Vaccine. http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/getting-a-vaccine	• Last updated March 1, 2021 • Information about what to expect when getting a COVID-1 vaccine and considerations if one has additional health conditions	After the vaccine: • Extremely important to **continue to practice all the preventive measures that have been recommended**, including washing your hands, maintaining a safe physical distance, wearing a mask, and staying home when sick • **Everyone who receives the vaccine will still need to follow public health guidance and abide by orders from the Provincial Health Officer**
Government of Ontario. Getting a COVID-19 vaccine in Ontario.	• Website content and information updated regularly • Information and guidelines on the COVID-19 vaccine in Ontario	• Until vaccines are **widely available for everyone to receive two doses and enough people are vaccinated** to stop the spread, we all must: - **Continue to follow local public health advice and restrictions**

https://covid-19.ontario.ca/getting-covid-19-vaccine-ontario		- Take the necessary health precautions, like practicing physical distancing, washing hands and using masks or face coverings - Stay home-only go out for necessities
Travel Canada. Mandatory Quarantine or Isolation. https://travel.gc.ca/travel-covid/travel-restrictions/isolation	• Last updated February 21, 2021 • New quarantine requirements for travel to Canada	• If you can enter Canada and you have no symptoms, you must quarantine for a minimum of 14 days • **You are not excluded from quarantine even if you have**: - tested negative for COVID-19 - **been vaccinated for COVID-19** • recovered from COVID-19
Minnesota Department of Health. COVID-19 Recommendations for Health Care Workers. https://www.health.state.mn.us/diseases/coronavirus/hcp/hcwrecs.pdf	• Last updated February 21, 2021 • Recommendations for health care workers suspected of (or confirmed as having) COVID-19, living with a person suspected of having COVID-19, or who have been exposed to a patient, co-worker, or social contact with COVID-19	• MDH recommends that HCW with high-risk exposures participate in voluntary quarantine for 14 days after the exposure date • If a health care facility has exhausted all other staffing options and is experiencing a staffing shortage, asymptomatic HCW who have experienced a high-risk exposure but not tested positive for COVID-19 may be asked to return to work during the voluntary quarantine period. HCW who return to work in that time must wear a medical-grade facemask for source control at all times • **Vaccinated HCWs are not required to quarantine outside of work if asymptomatic following COVID-19 exposure, are fully vaccinated (> 2weeks following receipt of final vaccine dose), and within 3 months following receipt of final vaccine dose** • Recommendations are relevant for vaccinated or unvaccinated HCW who have had a high-risk workplace exposure to COVID-19 and HCW with household, intimate or close community contacts who have confirmed or suspected COVID-19 - HCW should quarantine from work for 14 days following a high-risk exposure - **HCW who have received a SARS-CoV-2 vaccination are still required to follow the 14-day quarantine guidance listed below following a high-risk exposure. HCW should not be vaccinated if they are currently in a 14-day quarantine** **Facilities should ask exposed HCW to return to work in the following order**: • Vaccinated HCW with high-risk exposure to a patient, resident, co-worker, social contact, recent return from non-essential travel or household member. Vaccinated HCW must meet all of the following criteria - Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine). - Are within 3 months following receipt of the last dose in the series • HCW (unvaccinated or >3 months following receipt of last vaccine dose in the series) with high-risk • exposure to a patient, resident, or co-worker • HCW (unvaccinated or >3 months following receipt of last vaccine dose in the series) with high-risk exposure to a social contact or recent return from non-essential travel • HCW (unvaccinated or >3 months following receipt of last vaccine dose in the series) with high-risk exposure to a household member; HCW with a household exposure

		should only return if able to isolate from the positive household member
Timeout News. Here are all the countries that are letting in vaccinated travelers. **https://www.timeout.com/news/here-are-all-the-countries-that-are-letting-in-vaccinated-travellers-020321**	• Last updated February 18, 2021 • Status of jurisdictional requirements for proof of vaccination as an alternative to existing testing and quarantine requirements *Primary source/jurisdictional documents could not be located online; media source provided	• **Poland**, which has announced that **anyone who's been vaccinated against Covid-19 will now be exempt from a mandatory quarantine on arrival – only for those individuals from specified EU (and other) countries** • **Iceland** and **Romania waving strict testing and quarantine requirements if travelers can show vaccination certificate** • **Cyprus (from March 1)** to **allow vaccinated travelers** • **Seychelles** to **allow vaccinated travelers from any country who can prove** they've had **a final dose of any vaccine at least 2 weeks pre-arrival**
BAL Global. COVID-19: Quarantine exemption announced for vaccinated travelers **https://www.balglobal.com/bal-news/qatar-covid-19-quarantine-exemption-announced-for-vaccinated-travelers/**	• Last updated February 25, 2021 • Status of quarantine requirements for vaccinated Qatari citizens and residents *Primary source/jurisdictional documents could not be located online; media source provided	• **Qatari citizens and residents** must **meet the following conditions to be exempt from quarantine requirements:** - Fourteen days must have elapsed since receiving the second vaccination - Individuals must have been vaccinated in Qatar, not in foreign countries - A negative COVID-19 PCR test result must be presented upon returning to Qatar or after being in touch with someone who has tested positive for COVID-19 • **The quarantine exemption period begins 14 days after the second vaccination and lasts three months from that date**

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