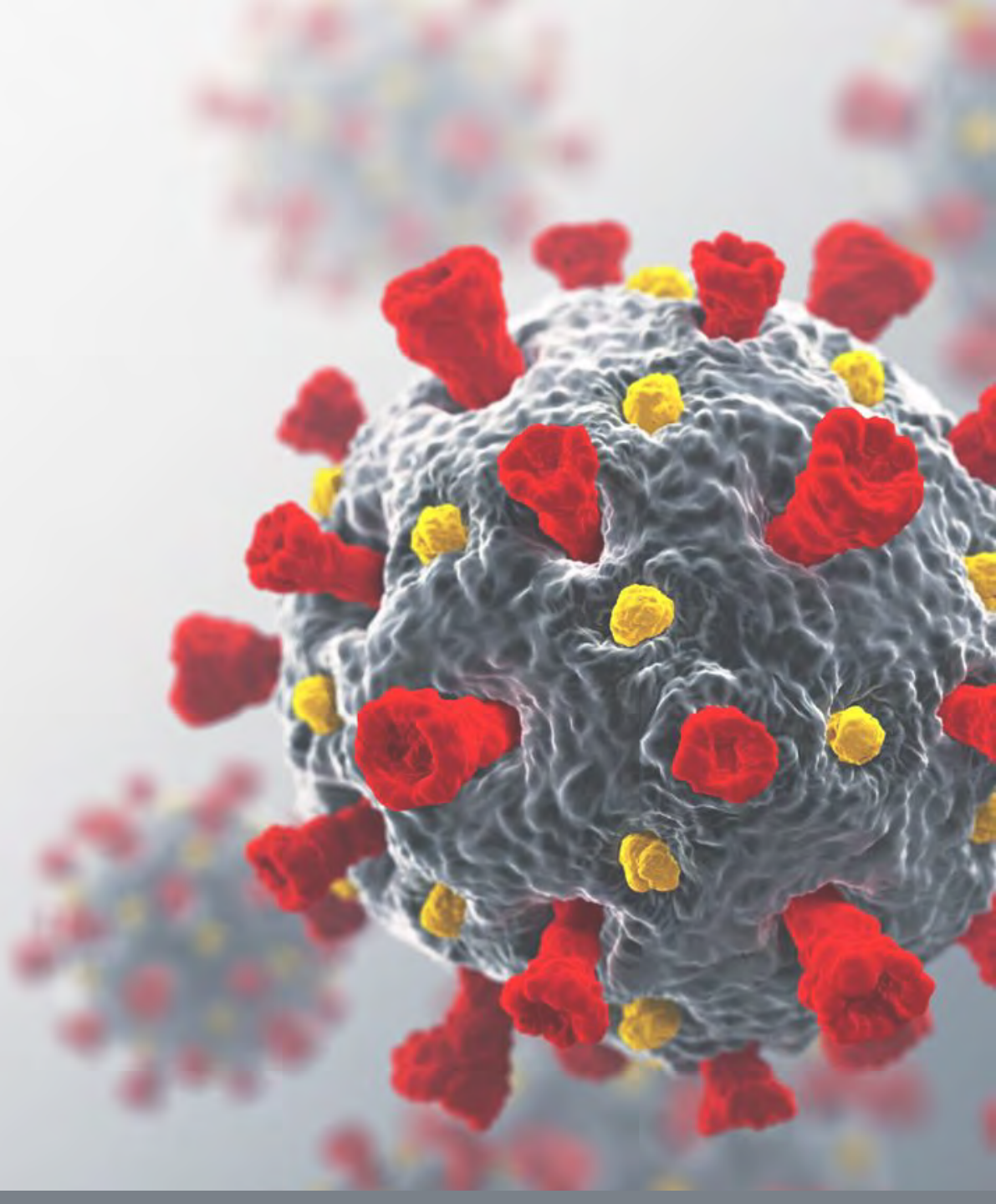
COVID-19 Vaccine Development: An Update

September 29, 2020



CANADIAN PUBLIC HEALTH ASSOCIATION
ASSOCIATION CANADIENNE DE SANTÉ PUBLIQUE

This webinar is hosted by the Canadian Public Health Association through an unrestricted educational grant from Medicago Inc.

Land Acknowledgement

- The Canadian Public Health Association's office is located on the ancestral unceded territory of the Algonquin Anishinabeg people
- We welcome participants from all corners of Turtle Island and beyond
- CPHA is committed to working with all First Nations, Inuit, and Métis peoples and their governments in realizing meaningful truth and reconciliation

Funding

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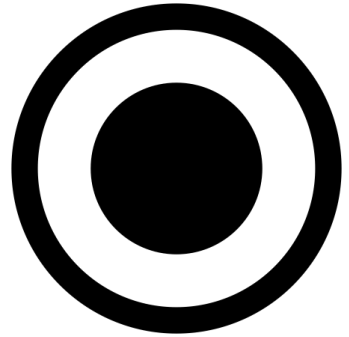
zoom

Use the Q&A feature to ask a question

Q&A Chat Raise Hand Exit



The meeting is being recorded.

https://www.youtube.com/c/CanadianPublicHealthAssociation/

Faculty Panel

Bonnie Henry, MD, MPH, FRCPC
Provincial Health Officer for
British Columbia

Gary Kobinger, PhD
Director, Infectious Disease
Research Centre
Université Laval, Québec

Marianne Stanford, PhD
VP, Research & Development, IMV
Adjunct Professor, Microbiology and
Immunology, Dalhousie University
Halifax, Nova Scotia

Brian Ward, MD, MSc
Professor, McGill University, Montreal
Medical Officer, Medicago Inc.

Expert Panelists Disclosures

Dr Bonnie Henry does not have conflicts of interest to disclose.	Dr Gary Kobinger is a professor and director at Université Laval and president of a non-for-profit (GuardRx) focused on affordable diagnostic vaccines and therapeutics. Gary is in collaboration with Medicago and Inovio, and a project with Merck is being discussed.	Dr Marianne Stanford is an employee of IMV Inc.	Dr Brian Ward holds positions at both McGill University and Medicago Inc.

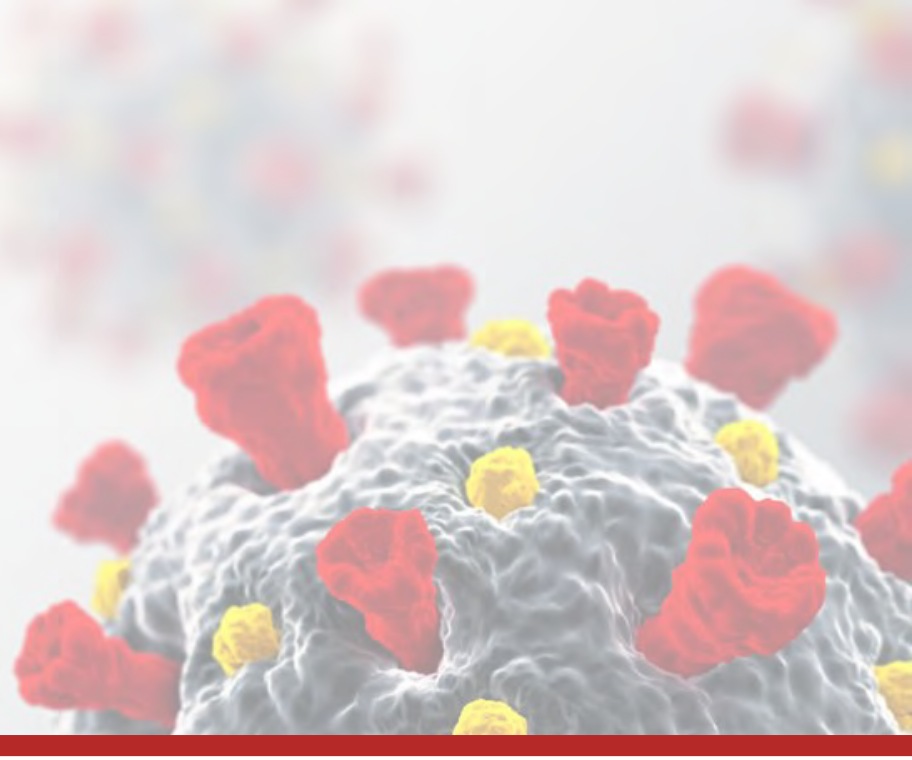
This webinar is hosted by the Canadian Public Health Association through an unrestricted educational grant from Medicago Inc.

Today's Objectives

- Provide an overview of the COVID-19 experience to date, including disease burden and a review of the latest worldwide epidemiology, with a focus on Canada
- Review challenges in pandemic preparedness and prevention of COVID-19 without an approved vaccine as experienced in Canada
- Discuss considerations for future pandemic responsiveness and key learnings from the evolving COVID-19 mitigation strategy
- Evaluate factors that may impact future COVID-19 vaccination in Canada, including target population, scaling of vaccine production, and challenges in supply chain
- Provide an update on the emerging scientific landscape for vaccines against COVID-19 in Canada

Today's Agenda

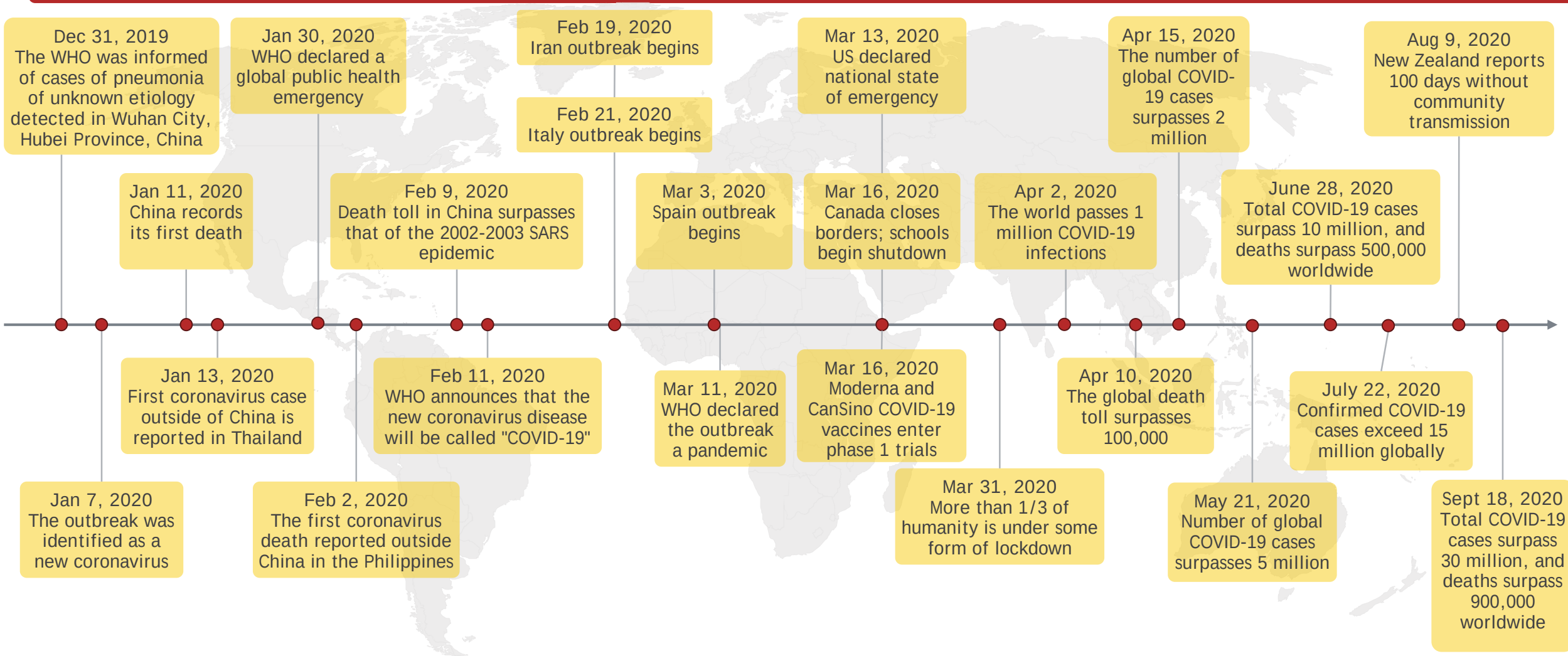
Time	Topic	Speaker
12:00-12:05	Welcome and Introductions	Ian Culbert
12:05-12:10	Latest Epidemiology of COVID-19 in Canada and Worldwide	Bonnie Henry, MD, MPH, FRCPC
12:10-12:50	Vaccine Development Update • Where do we stand on the development of COVID-19 vaccines? • Once successful vaccine candidates are identified, how will they be rolled out in Canada? • How would an internationally developed vaccine get to Canada? • What is Canada's role in making a vaccine available to populations at risk around the world?	Bonnie Henry, *Moderator* *Panelists* Gary Kobinger, PhD Marianne Stanford, PhD Brian Ward, MSc, MD
12:50-13:15	Q&A	All



Latest Epidemiology of COVID-19 in Canada and Worldwide

Bonnie Henry, MD, MPH, FRCPC

COVID-19: A Global Pandemic[1-5]



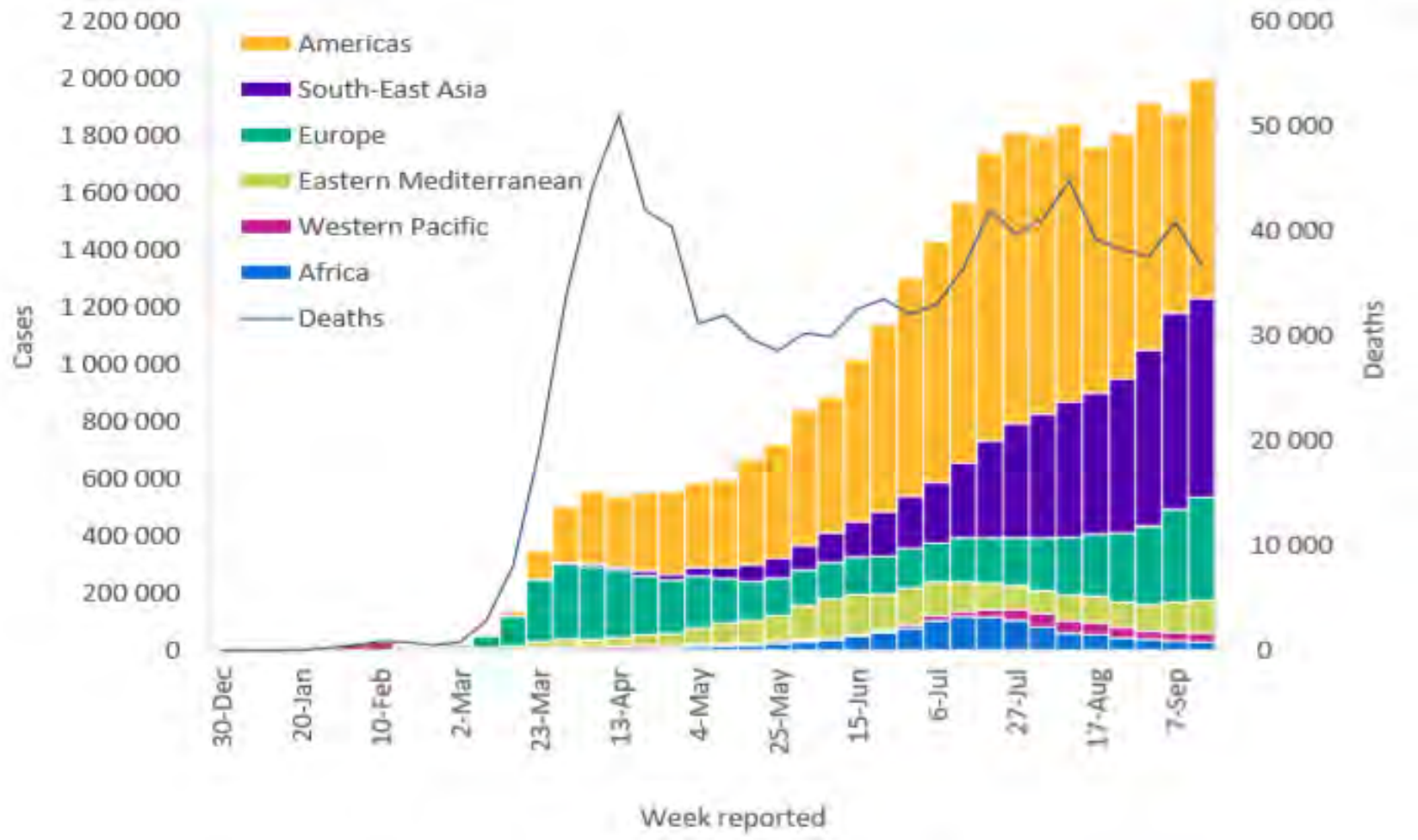
WHO, World Health Organization.

1. Medscape News. https://www.medscape.com/viewarticle/927474. Accessed April 16, 2020. 2. Business Insider. https://www.businessinsider.com/coronavirus-pandemic-timeline-history-major-events-2020-3. Accessed September 28, 2020. 3. NBC News. https://www.nbcnews.com/health/health-news/coronavirus-timeline-tracking-critical-moments-covid-19-n1154341. Accessed April 16, 2020. 4. Zhu FC, et al. *Lancet*. 2020;395(10240):1845-1854. 5. Devex. https://www.devex.com/news/covid-19-a-timeline-of-the-coronavirus-outbreak-96396. Accessed September 24, 2020.

Human Confirmed Cases of COVID-19 Worldwide

December 30, 2019, to September 20, 2020

Number of COVID-19 cases reported weekly by WHO region and global deaths

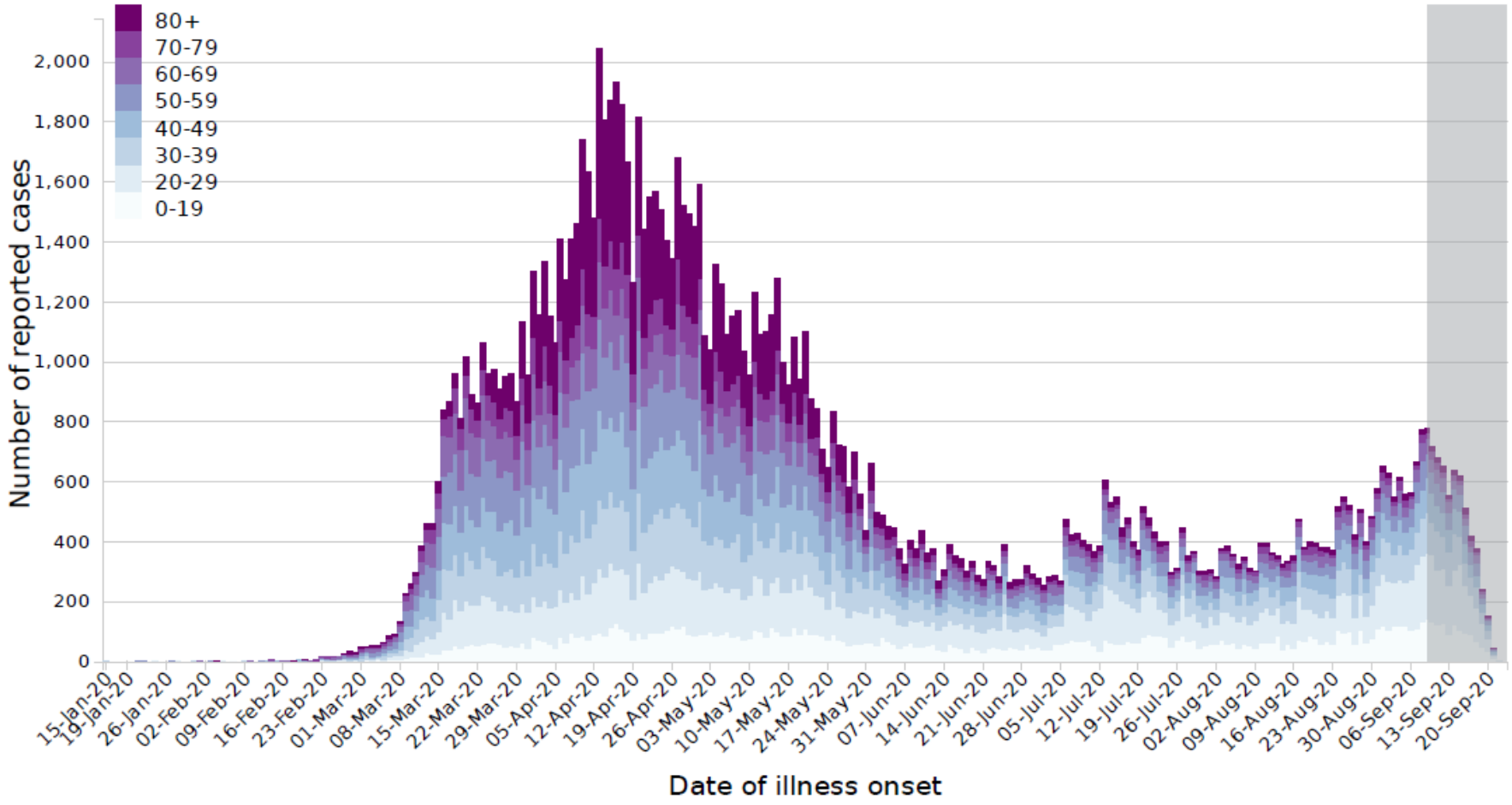


World Health Organization. https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200921-weekly-epi-update-6.pdf?sfvrsn=d9cf9496_6 2. Accessed September 24, 2020.

Persistence of COVID-19 in Canada, by Age Group

As of September 23, 2020

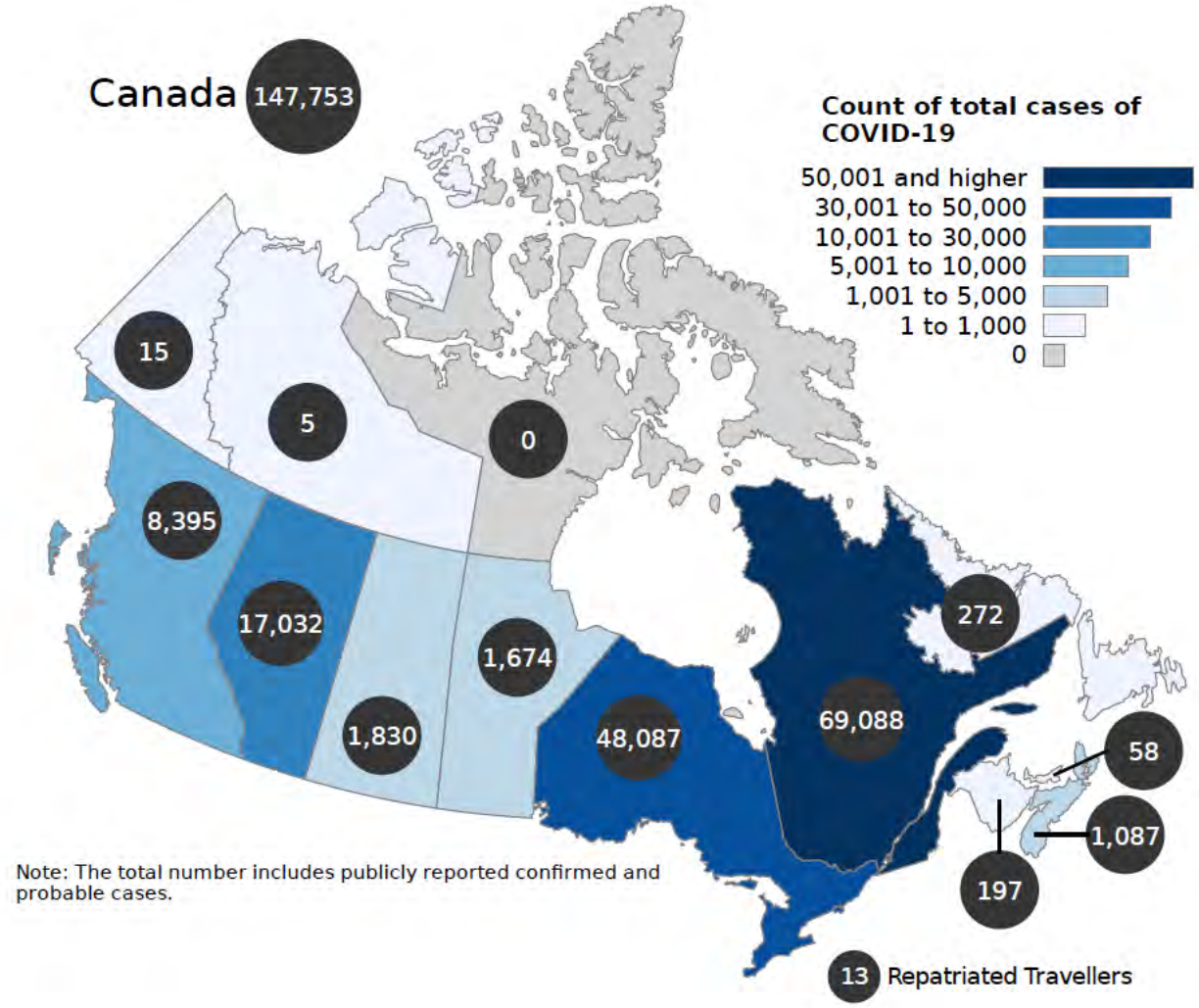
COVID-19 cases (n=140,561) in Canada, by date of illness onset and age



Government of Canada. https://health-infobase.canada.ca/src/data/covidLive/Epidemiological-summary-of-COVID-19-cases-in-Canada-Canada.ca.pdf. Accessed September 24, 2020.

COVID-19 in Canada: Distribution of Cases by Province

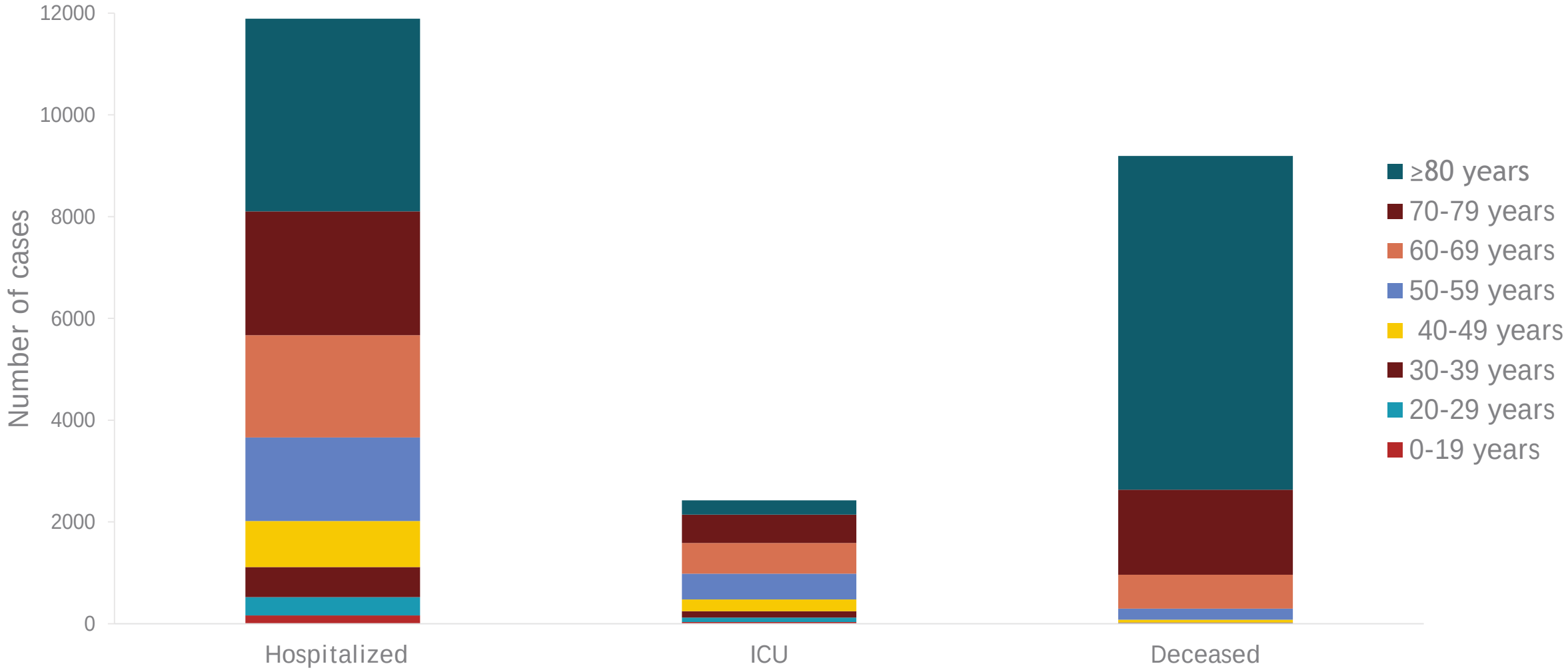
As of September 23, 2020



Government of Canada. https://health-infobase.canada.ca/src/data/covidLive/Epidemiological-summary-of-COVID-19-cases-in-Canada-Canada.ca.pdf. Accessed September 24, 2020.

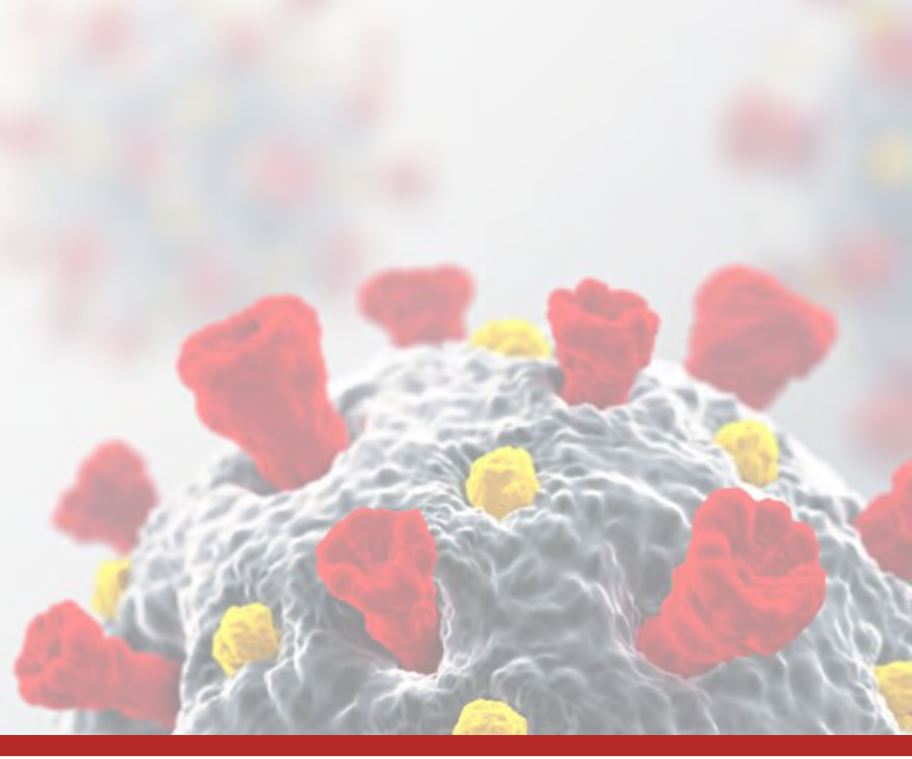
Age Distribution of Hospitalization, ICU Admittance, and Death Among Canadian COVID-19 Patients

As of September 23, 2020

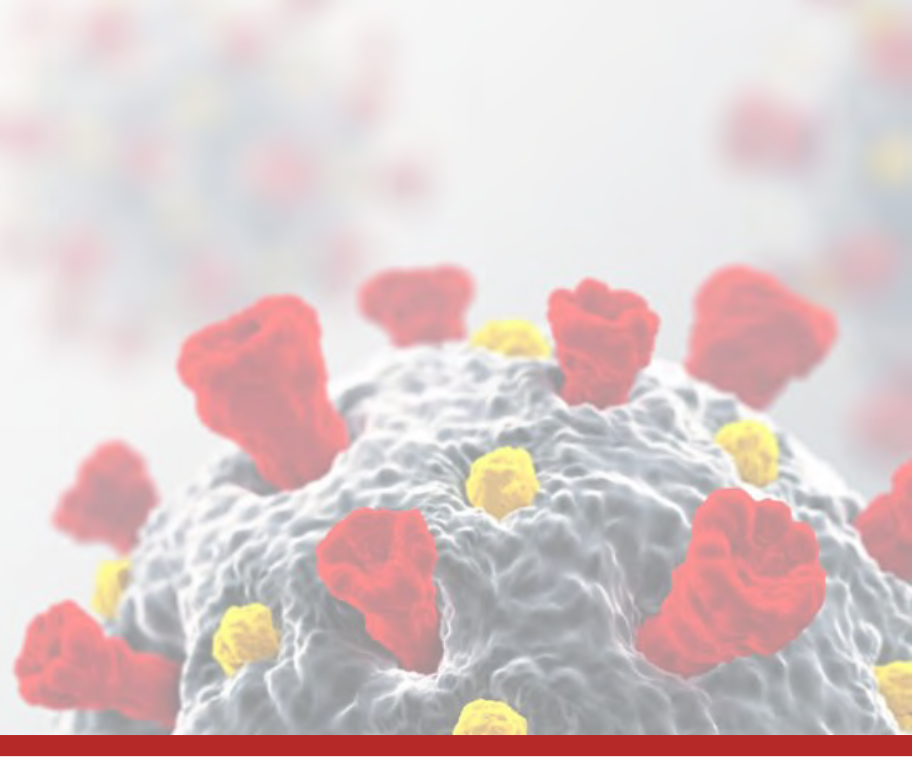


ICU, Intensive Care Unit.

Government of Canada. https://health-infobase.canada.ca/src/data/covidLive/Epidemiological-summary-of-COVID-19-cases-in-Canada-Canada.ca.pdf. Accessed September 24, 2020.



Vaccine Development Update

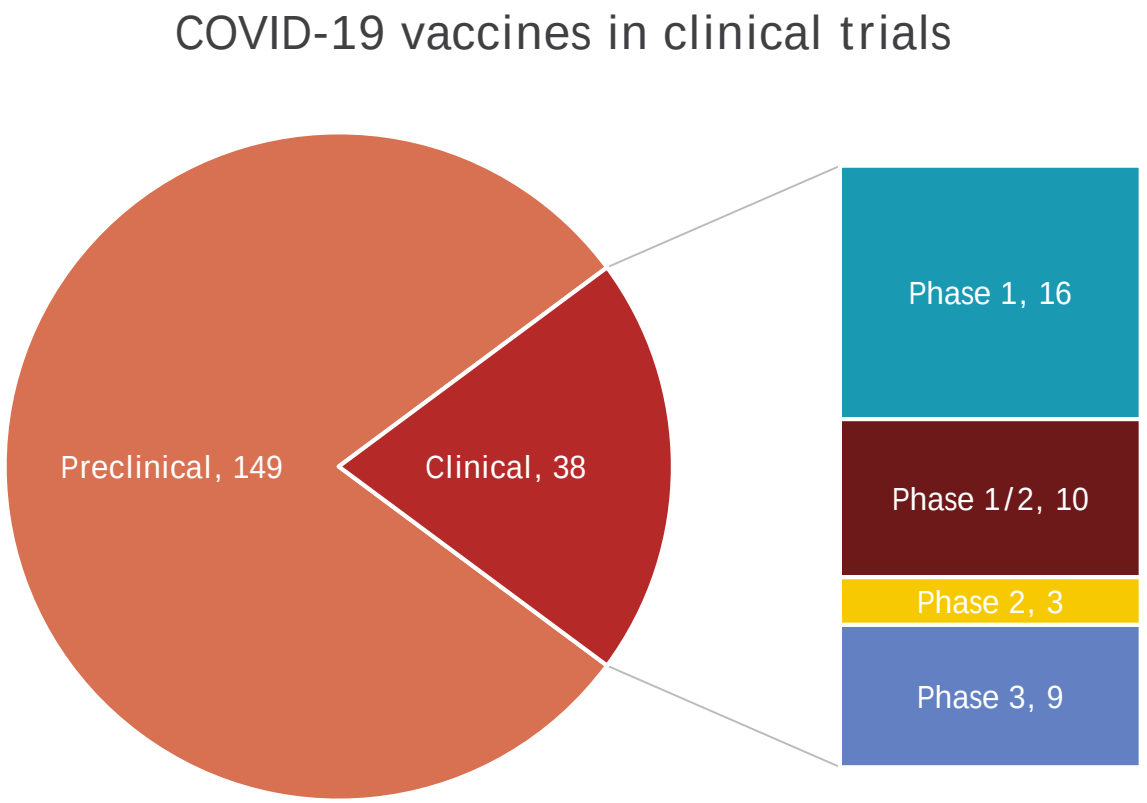


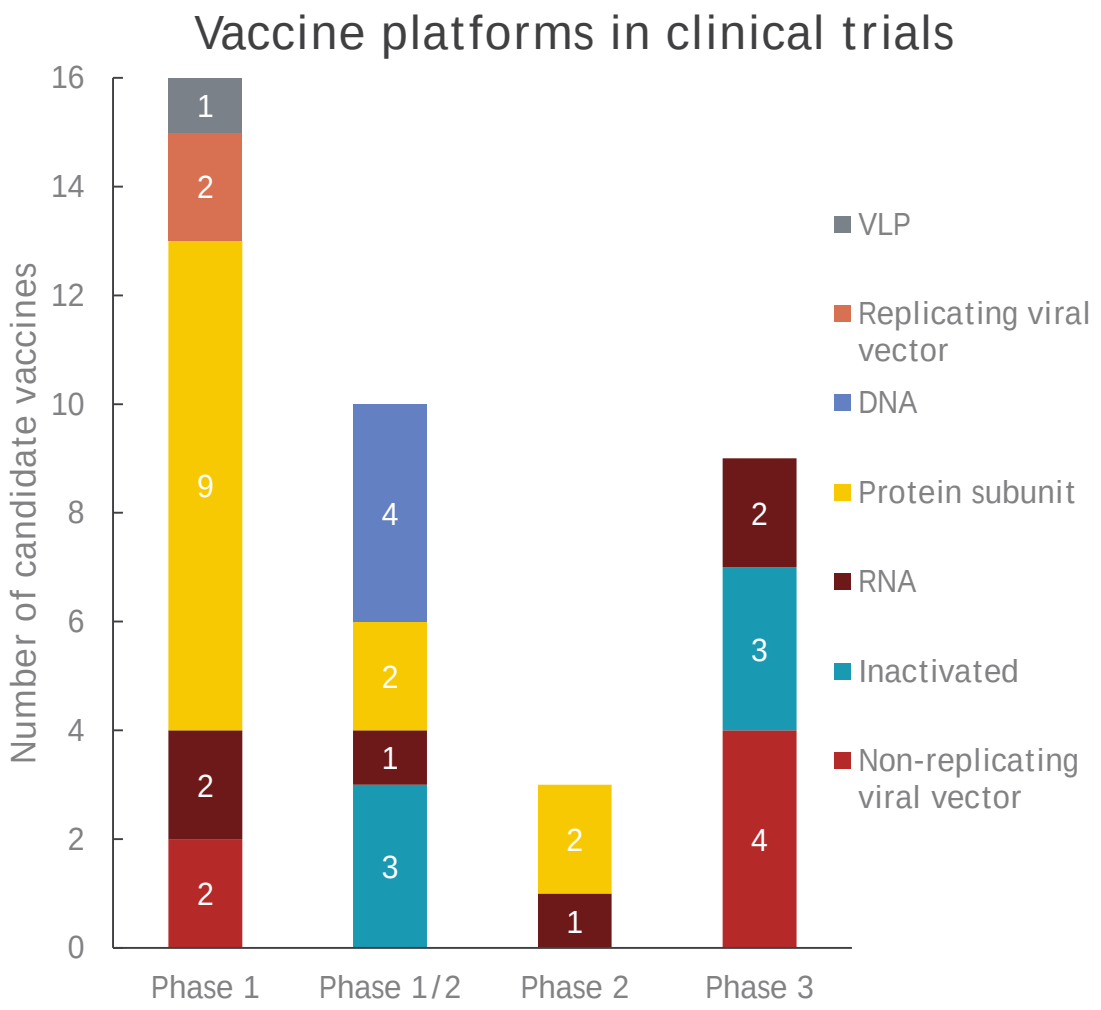
Where Do We Stand on the Development of COVID-19 Vaccines Worldwide?

Gary Kobinger, PhD

WHO: Landscape of COVID-19 Candidate Vaccines in Preclinical and Clinical Trials

As of September 22, 2020

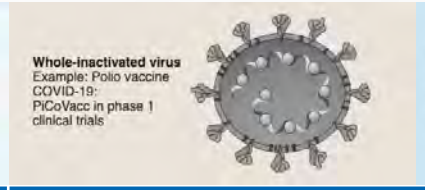


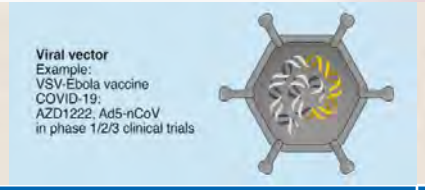


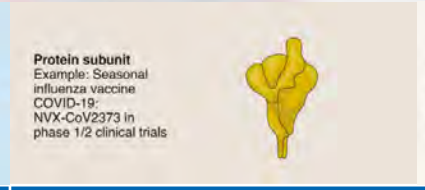
VLP, Virus-like Particle.

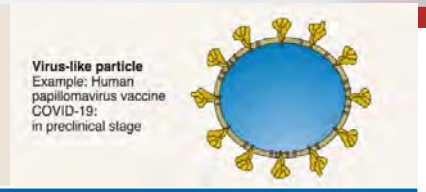
World Health Organization. https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines. Accessed September 9, 2020.

Overview of Different Platforms for COVID-19 Vaccine Development[1-9]









Genetic		Viral		Protein/VLP	
RNA (no approved product)	DNA (no approved product)	Inactivated (eg, influenza, polio)	Viral vector (eg, Ebola)	Protein subunit (eg, influenza, HPV, HepB)	Plant-based (eg, flu vaccine under review by BGTD)
o Existing platforms could accelerate development o RNA = adjuvant	o Existing platforms could accelerate development	o Well-established development pathway o Wide range of immunogenic targets	o Established platform could accelerate development o Scalable manufacturing	o Established scalable manufacturing o Safety profile generally recognized as good	o Proven technology o Scalable manufacturing
o Tolerability and reactogenicity concerns o Nontraditional manufacturing	o Genomic integration o Complex delivery o High dosage requirements	o Risk of accidental administration of infectious agent o Require freeze-drying for transport and storage at low temperature	o Existing memory response to vector may limit efficacy and repeated use	o Concerns for long-lasting immunity (may require boosters)	o Complex outsource manufacturing o Lack of surge capacity at this moment

BGTD, Biologics and Genetic Therapies Directorate.

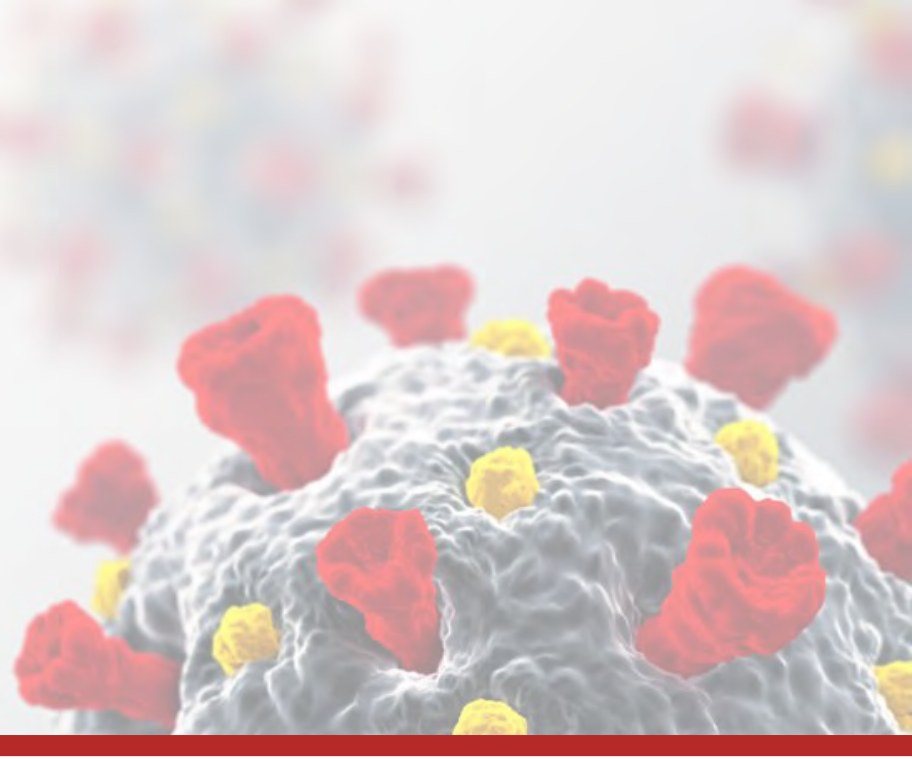
1. van Riel D, et al. *Nat Mater*. 2020;19(8):810-820. 2. GatesNotes. https://www.gatesnotes.com/Health/What-you-need-to-know-about-the-COVID-19-vaccine. Accessed September 24, 2020. 3. UK Health Centre. https://www.healthcentre.org.uk/vaccine/advantages-disadvantages-dna-vaccines.html. Accessed September 24, 2020. 4. World Health Organization. https://www.who.int/biologicals/areas/vaccines/dna/en/. Accessed September 24, 2020. 5. UK Health Centre. https://www.healthcentre.org.uk/vaccine/advantages-disadvantages-inactivated-vaccines.html. Accessed September 24, 2020. 6. Callaway E. *Nature*. 2020;580(7805):576-577. 7. UK Health Centre. https://www.healthcentre.org.uk/vaccine/advantages-disadvantages-subunit-vaccines.html. Accessed September 24, 2020. 8. Data on file, Medicago Inc. 9. Huang X, et al. *NPJ Vaccines*. 2017;2:3.

Canada Has Agreements With Several COVID-19 Vaccine Developers[1,2]

Company	Type of vaccine	Current phase
Pfizer	RNA	Phase 3
Moderna	RNA	Phase 3
Johnson & Johnson	Non-replicating viral vector	Phase 3
Novavax	Protein subunit	Phase 2
Sanofi/GlaxoSmithKline	Protein subunit	Phase 1/2

To date, all contracted vaccine manufacturers are based outside of Canada.

1. Bloomberg. https://www.bloomberg.com/press-releases/2020-09-22/government-of-canada-signs-new-agreements-to-secure-additional-vaccine-candidate-and-treatment-for-covid-19. Accessed September 24, 2020. 2. World Health Organization. https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines. Accessed September 24, 2020.



Where Do We Stand on the Development of COVID-19 Vaccines in Canada?

Brian Ward, MSc, MD

COVID-19 Vaccines in Development in Canada[1-4]

Developer	Type of vaccine	Current phase
Medicago Inc. (QC)	Plant-derived virus-like particles[2]	Phase 1
University of Manitoba (MB)	Virus-like particles[3]	Preclinical
University of Manitoba (MB)	Dendritic cell targeting replicating viral vector[3]	Preclinical
University of Western Ontario (ON)	Replicating viral vector[3]	Preclinical
Mediphage Bioceuticals/U Waterloo (ON)	Intranasal DNA-based (engineered bacteriophage)[3,4]	Preclinical
Entos Pharmaceuticals (AB)	Recombinant plasmid DNA[3]	Preclinical
University of Alberta (AB)	Protein subunit[3]	Preclinical
University of Saskatchewan's VIDO-InterVac (SK)	Adjuvanted microsphere peptide (protein subunit)[3]	Preclinical
IMV Inc. (NS/QC)	Peptide epitope in lipid nanoparticles (protein subunit)[3]	Preclinical

Table updated September 24, 2020.

1. CBC News. https://newsinteractives.cbc.ca/coronavirusvaccinetracker/#dna. Accessed September 24, 2020. 2. Medicago COVID-19 programs. https://www.medicago.com/en/covid-19-programs/. September 28, 2020. 3. World Health Organization. https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines. Accessed September 9, 2020. 4. Waterloo news. https://uwaterloo.ca/stories/news/university-waterloo-developing-dna-based-covid-19-vaccine. Accessed September 28, 2020.

Selected Canadian Vaccines[1-6]

- Spike peptides
- "No-release" lipid-based delivery system
- Data: cancer immunotherapy and RSV
- Focus: antibody and T cells
- Status: preclinical

- Spike protein
- Human Ad5 vector
- Data: Other viruses (eg, Ebola)
- Focus: antibody and T cells
- Status: clinical/phase 3 (Brazil, Pakistan, ~~Canada~~, Saudi Arabia, Chile, and others)*

- Spike protein subunit
- Combination adjuvant
- Data: animal models
- Focus: antibody and T cell
- Status: Preclinical—good results in ferret model

*In partnership with Petrovac Pharma.[2]

1. IMV Inc. https://www.imv-inc.com/product-pipeline. Accessed September 25, 2020. 2. IMV Inc. https://www.imv-inc.com/product-pipeline/dpx-covid-19. Accessed September 24, 2020. 3. pharmaphorum. https://pharmaphorum.com/news/losing-ground-in-covid-19-vaccine-race-cansino-turns-to-russia/. Accessed September 24, 2020. 4. University of Saskatchewan. https://news.usask.ca/articles/research/2020/promising-pre-clinical-results-for-usask-vido-intervac-covid-19-vaccine.php. Accessed September 25, 2020. 5. Aviation Analysis. https://www.aviationanalysis.net/built-in-canada-covid-19-vaccine-effort-and-hard-work-slowed-by-production-hold-off/. Accessed September 24, 2020. 6. World Health Organization. https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines. Accessed September 9, 2020.

Medicago's Plant-Derived Virus-Like Particle Vaccine: CoVLP

1

Gene synthesized from sequences of candidate vaccine viruses

Synthesis

2

Vacuum Infiltration

Genetic material introduced into *Nicotiana benthamiana* plants through vacuum infiltration

3

Plants incubated for 4-10 days in growth chambers for protein expression and VLP formation

Incubation

4

Harvest

Plants are harvested to extract VLP

5

VLPs are purified to obtain final material

Purification

6

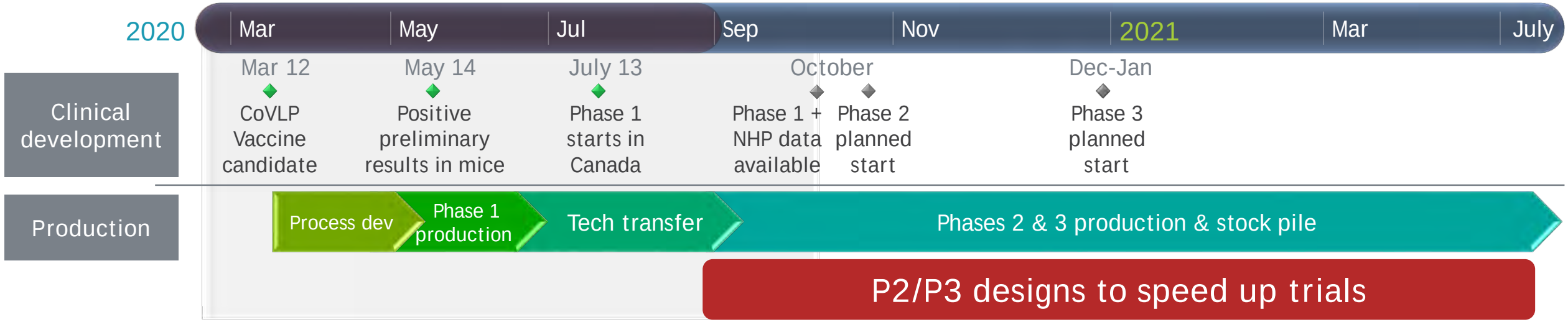
VLP

Resulting VLP matches protein expected from candidate vaccine virus

Medicago's Plant-Derived Virus-Like Particle (VLP) of SARS-CoV-2

Data on file, Medicago Inc.

Medicago's CoVLP Vaccine Development Program



Phase 1 (18-55)

- 180 subjects
- Dose-finding safety and immunogenicity study in seronegative adults
- Dose-escalation, slow enrolment, open-label
- 2 adjuvants, unadjuvanted, 3 dose levels and prime-boost investigated

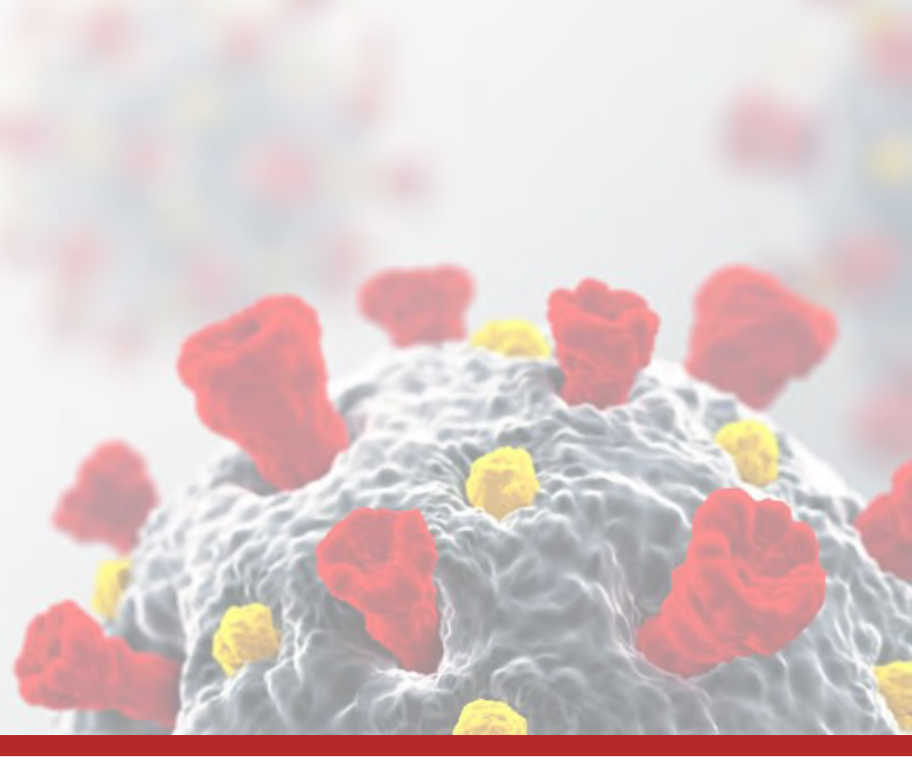
Phase 2 Oct 2020

- Dose-confirmation safety & immunogenicity
- 4 target populations investigated:
  - Children 5-17y
  - Adults 18-64y
  - Older adults 65+
  - Adults with comorbidities 18+

Phase 3 Dec 2020 Interim Q2 2021

- 30,000 subjects expected
- Randomized placebo-controlled study to evaluate efficacy of CoVLP vaccine at prevention of COVID-19 disease
- Global study

Data on file, Medicago Inc.



Vaccine Acceptability and Rollout in Canada

Marianne Stanford, PhD

Future Impact of COVID-19 Vaccination in Canada

Addressing vaccine hesitancy in light of rapid vaccine development

- Safety and acceptability of a COVID-19 vaccine
- Knowledge gaps around efficacy of candidate vaccines

Capacity for global biomanufacturing and distribution

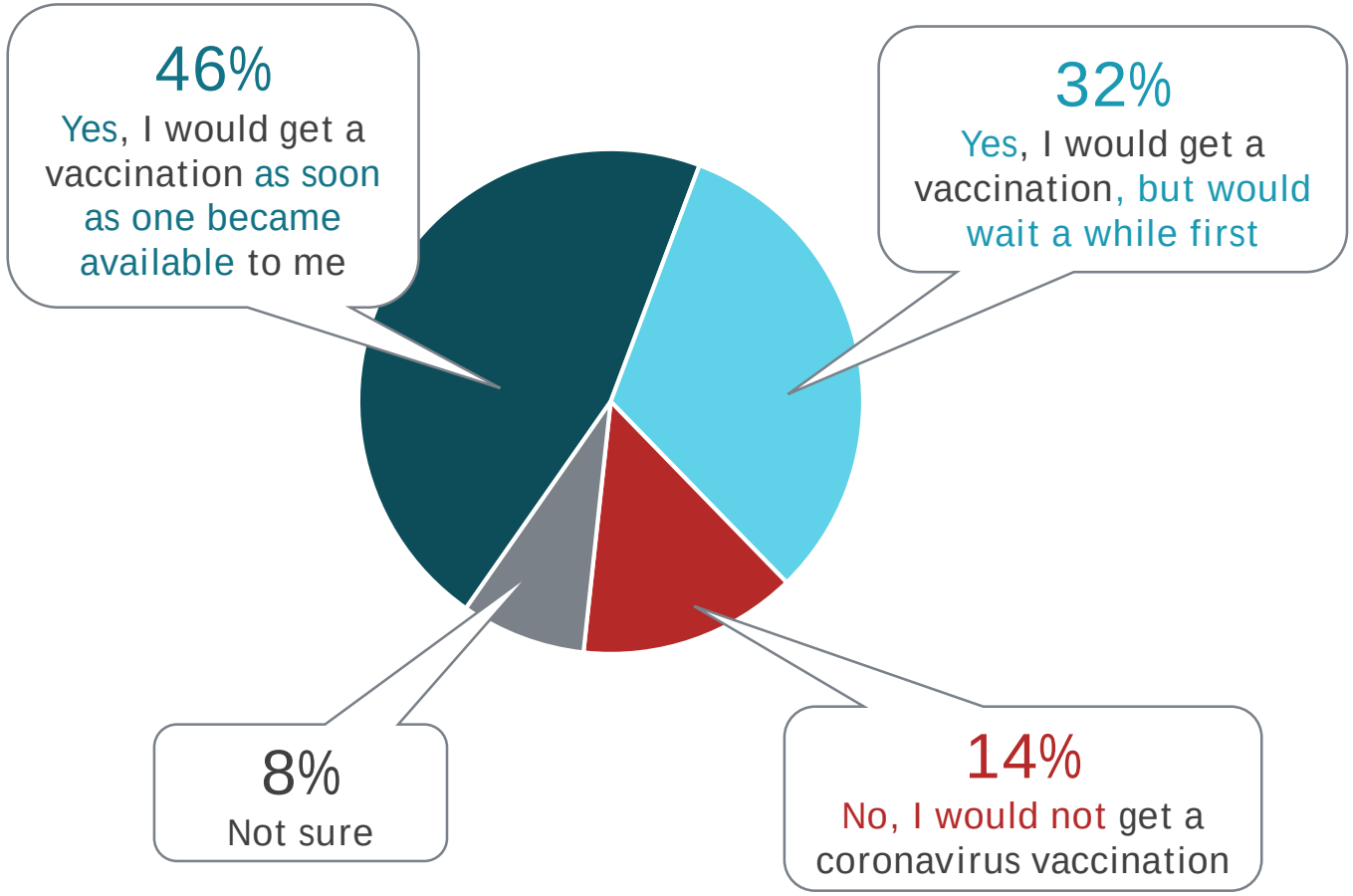
- Securing the amount of doses required to immunize the Canadian population

Prioritizing groups to receive the vaccine

- Minimize serious illness and overall deaths, including from causes other than COVID-19
- Minimize societal disruption, including reducing the burden of health care resources

Addressing the Challenge of Public Acceptance of a New Vaccine

If a vaccine against the coronavirus became available to you, would you get vaccinated, or not?



- Potential side effects remain a concern among those willing to be vaccinated
  - 76% of those who will wait
  - 37% of those eager to be vaccinated
- ~75% of Canadians say that a coronavirus vaccine should be mandatory in extended care homes and for health care workers
  - 63% say this of schools
- The vast majority of Canadians say that life will not go back to normal in their community until people are vaccinated
  - 59% of rural residents
  - 77% of urbanites

Angus Reid Institute. http://angusreid.org/coronavirus-vaccine/. Accessed September 22, 2020.

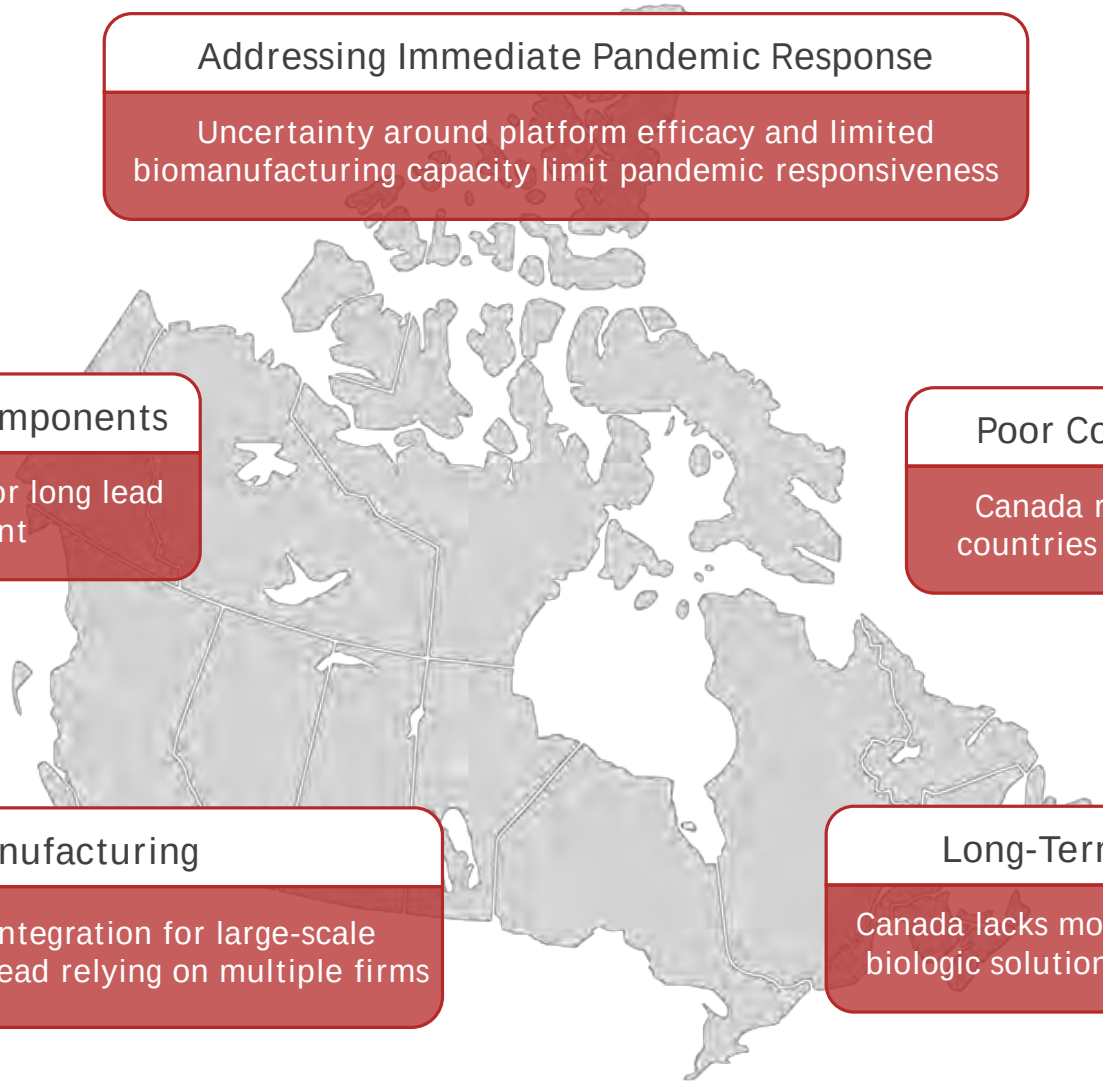
Canadian Biomanufacturing Faces Difficulties With Large-Scale Manufacturing and Distribution

Addressing Immediate Pandemic Response

Uncertainty around platform efficacy and limited biomanufacturing capacity limit pandemic responsiveness

Competition for Equipment and Components

High demand and limited supply make for long lead times when procuring equipment



Poor Connection With the Global Market

Canada relies largely on production from other countries rather than companies based in Canada

Large-Scale Manufacturing

Canadian firms lack vertical integration for large-scale production and distribution, instead relying on multiple firms

Long-Term Pandemic Preparedness

Canada lacks modern facilities for the production of biologic solutions in the event of future pandemics

Presented at CIHR and Public Health Canada COVID-19 Vaccine Clinical Trial Discussion Forum Scientific Webinar Series: Module 3: Vaccine Biomanufacturing, Wed Sept 16, 2020.

Investigation of COVID-19 Vaccine Candidates
Early Phase Clinical Trials

Primary Priority Populations

Establish vaccine safety, immunogenicity, and efficacy

Adults 18 to <60 years of age without underlying health conditions

Adults 60 years of age and older without underlying health conditions

Secondary Priority Populations

Safety concerns, potential suboptimal immune response to vaccination, potential for severe COVID-19 illness

Adults 18 to <60 years of age without underlying health conditions

Immunocompromised children, adolescents, and adults

Pregnant women (any trimester)

Government of Canada. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/research-priorities-covid-19-vaccines.html. Accessed September 22, 2020.

Investigation of COVID-19 Vaccine Candidates
Late Phase Clinical Trials

Priority Populations

Increased risk of illness from COVID-19

18-60 years of age with 1 or more of the following:

- Hypertension
- Diabetes mellitus
- Cardiovascular disease
- Chronic lung disease

60 years of age and older with 1 or more of the following:

- Hypertension
- Diabetes mellitus
- Cardiovascular disease
- Chronic lung disease

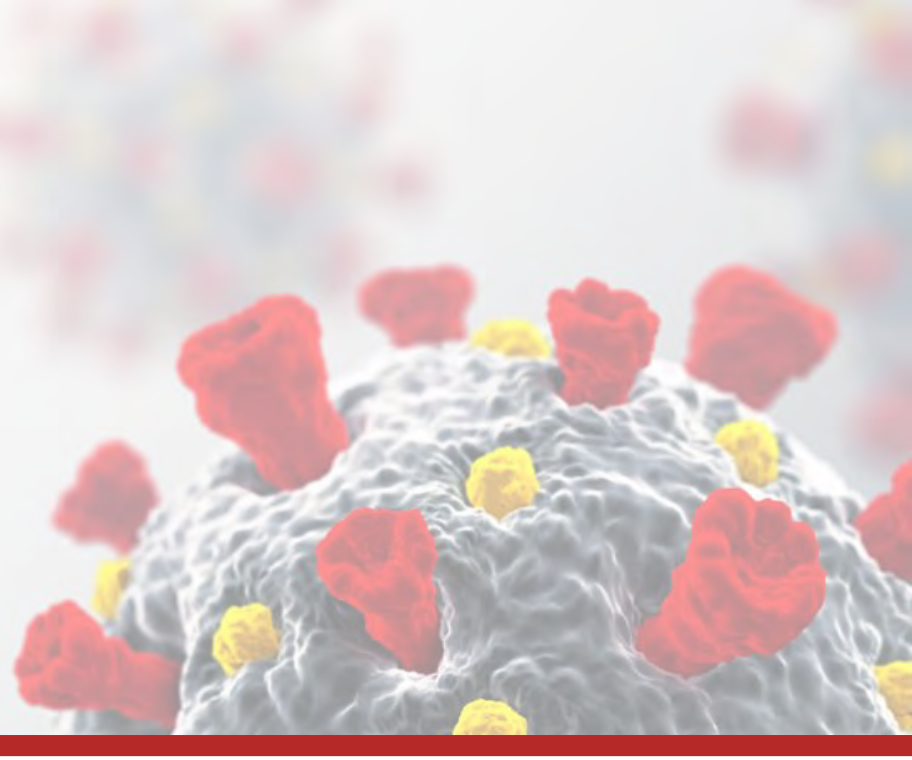
Children and adolescents with 1 or more of the following:

- Asthma
- Other conditions identified by evolving epidemiology in pediatrics

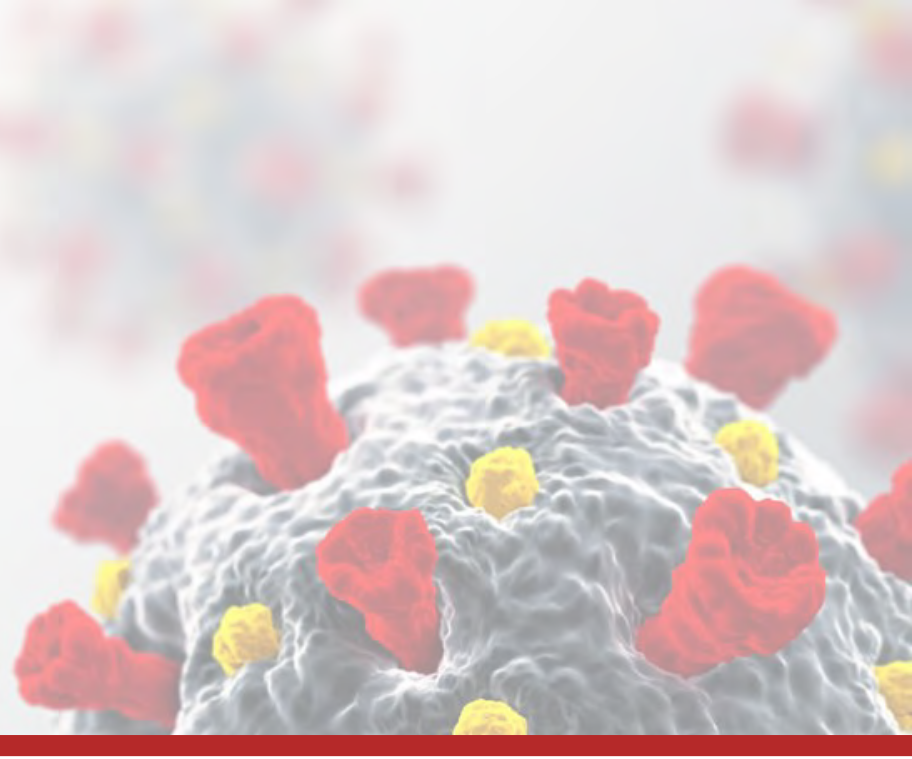
Individuals with social and/or occupational risks, including:

- Health care workers
- Emergency workers
- Those in high degree of social contact
- Travelers

Government of Canada. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/research-priorities-covid-19-vaccines.html. Accessed September 22, 2020.

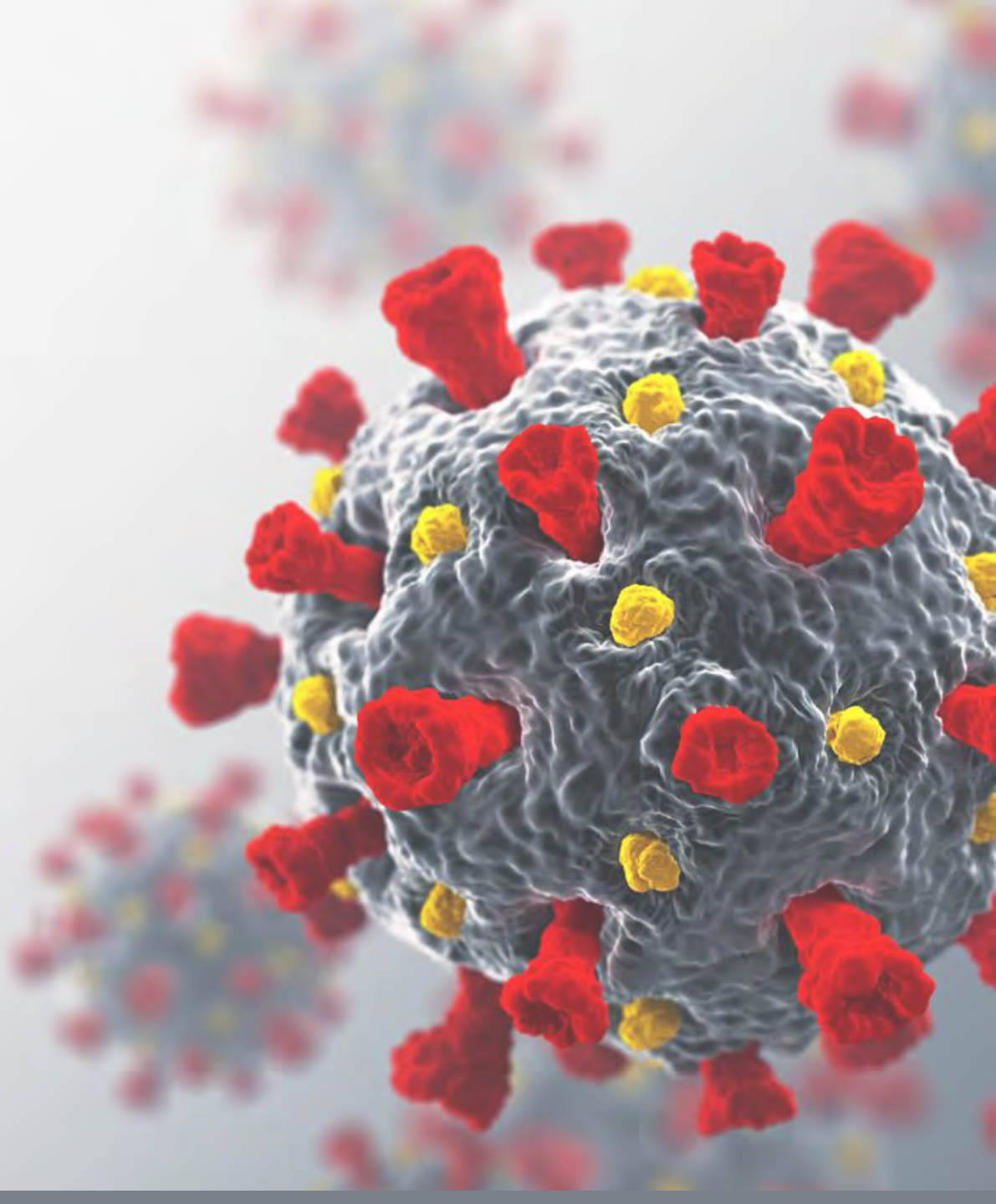


Panel Discussion



Q&A Session

Thank you for joining us today!



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