COVID-19 Vaccine Development: An Update

September 29, 2020

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

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

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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.
<table>
<thead>
<tr>
<th>Expert Panelists Disclosures</th>
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<tbody>
<tr>
<td><strong>Dr Bonnie Henry</strong> does not have conflicts of interest to disclose.</td>
</tr>
<tr>
<td><strong>Dr Gary Kobinger</strong> 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.</td>
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<tr>
<td><strong>Dr Marianne Stanford</strong> is an employee of IMV Inc.</td>
</tr>
<tr>
<td><strong>Dr Brian Ward</strong> holds positions at both McGill University and Medicago Inc.</td>
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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

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

Bonnie Henry, MD, MPH, FRCPC
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

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

COVID-19 in Canada: Distribution of Cases by Province
As of September 23, 2020

Note: The total number includes publicly reported confirmed and probable cases.

Age Distribution of Hospitalization, ICU Admittance, and Death Among Canadian COVID-19 Patients As of September 23, 2020

ICU, Intensive Care Unit.
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

COVID-19 vaccines in clinical trials

Vaccine platforms in clinical trials

VLP, Virus-like Particle.
Overview of Different Platforms for COVID-19 Vaccine Development

<table>
<thead>
<tr>
<th>Genetic</th>
<th>Viral</th>
<th>Protein/VLP</th>
</tr>
</thead>
<tbody>
<tr>
<td>RNA (no approved product)</td>
<td>Inactivated (eg, influenza, polio)</td>
<td>Virus vector (eg, Ebola)</td>
</tr>
<tr>
<td>DNA (no approved product)</td>
<td></td>
<td>Protein subunit (eg, influenza, HPV, HepB)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Plant-based (eg, flu vaccine under review by BGTD)</td>
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</tbody>
</table>

- **RNA**
  - Existing platforms could accelerate development
  - RNA = adjuvant
  - Tolerability and reactogenicity concerns
  - Nontraditional manufacturing

- **DNA**
  - Existing platforms could accelerate development
  - Genomic integration
  - Complex delivery
  - High dosage requirements

- **Inactivated**
  - Well-established development pathway
  - Wide range of immunogenic targets
  - Risk of accidental administration of infectious agent
  - Require freeze-drying for transport and storage at low temperature
  - Existing memory response to vector may limit efficacy and repeated use

- **Viral vector**
  - Established platform could accelerate development
  - Scalable manufacturing
  - Established scalable manufacturing
  - Safety profile generally recognized as good
  - Concerns for long-lasting immunity (may require boosters)
  - Complex outsource manufacturing
  - Lack of surge capacity at this moment

- **Protein/subunit**
  - Established platform could accelerate development
  - Scalable manufacturing
  - Safety profile generally recognized as good
  - Proven technology
  - Scalable manufacturing

- **Plant-based**
  - Proven technology
  - Scalable manufacturing

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BGTD, Biologics and Genetic Therapies Directorate.
Canada Has Agreements With Several COVID-19 Vaccine Developers\(^1,2\)

<table>
<thead>
<tr>
<th>Company</th>
<th>Type of vaccine</th>
<th>Current phase</th>
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</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>RNA</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Moderna</td>
<td>RNA</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>Non-replicating viral vector</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Novavax</td>
<td>Protein subunit</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Sanofi/GlaxoSmithKline</td>
<td>Protein subunit</td>
<td>Phase 1/2</td>
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To date, all contracted vaccine manufacturers are based outside of Canada.

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

Brian Ward, MSc, MD
# COVID-19 Vaccines in Development in Canada

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

Table updated September 24, 2020.
Selected Canadian Vaccines¹-⁶

¹ In partnership with Petrovac Pharma.²


- 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

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

*In partnership with Petrovac Pharma.
Medicago’s Plant-Derived Virus-Like Particle Vaccine: CoVLP

**Synthesis**
- Gene synthesized from sequences of candidate vaccine viruses

**Vacuum Infiltration**
- Genetic material introduced into *Nicotiana benthamiana* plants through vacuum infiltration

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

**Purification**
- VLPs are purified to obtain final material

**Harvest**
- Plants are harvested to extract VLP

**Resulting VLP matches protein expected from candidate vaccine virus**

Data on file, Medicago Inc.
Medicago’s CoVLP Vaccine Development Program

2020

Clinical development

Mar 12
CoVLP Vaccine candidate

May 14
Positive preliminary results in mice

Jul 13
Phase 1 starts in Canada

Sep
October

2021

Mar
Dec-Jan

May 14
Phase 1 + NHP data available

Jul
Phase 2 planned start

Sep
Phase 3 planned start

Data on file, Medicago Inc.

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

P2/P3 designs to speed up trials
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?

- **46%** Yes, I would get a vaccination as soon as one became available to me
- **32%** Yes, I would get a vaccination, but would wait a while first
- **14%** No, I would not get a coronavirus vaccination
- **8%** Not sure

- 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

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

**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

**Poor Connection With the Global Market**

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

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)

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

Panel Discussion
Q&A Session
Thank you for joining us today!