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## Crisis Working Group Report: Crisis Working Group on Public Health and Emergency Measures

### Communique #3: National Process Needed to Hasten Vaccine Development

The C.D. Howe Institute has initiated a special project to provide rapid expert insights to help Canadians and Canadian policymakers navigate the COVID-19 crisis. The Working Group on Public Health and Emergency Measures is Co-Chaired by Janet Davidson, Chair of the Board of the Canadian Institute for Health Information and former Deputy Minister of Health (AB) and Tom Closson, Co-Chair of the C.D. Howe Institute Health Policy Council. The membership of the group includes health academics, professionals and business leaders. Meeting weekly, this group discusses policy ideas for addressing various aspects of the COVID 19 crisis, and publicly communicate the results of its discussions via Communiqués.

The most recent meeting of the Public Health and Emergency Measures Working Group was on April 24, 2020. The discussion focussed on vaccines for COVID-19. In particular, the group discussed the time and resources required to develop a new vaccine, strategies for ensuring access for Canadians, domestic production and distribution capacity, and how to encourage efficient and coordinated use of recently announced federal funding for vaccines.

### From R&D to Injection: Vaccine Development

Media outlets, governments and some academics have been suggesting hopefully that a vaccine for COVID-19 could be available in 12 to 18 months. While not impossible, it would be quite a remarkable feat to achieve, considering that it normally takes about [10-15 years to develop a novel vaccine](#). As Dr. Natasha Crowcroft, Director of the Centre for Vaccine Preventable Diseases and a Professor at the Dalla Lana School of Public Health said, 12 to 18 months is an “incredibly optimistic timeline. Nobody has done this before.” The fastest vaccine developed was for Mumps at four years and the Ebola vaccine took five years.<sup>1</sup>

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1 In the case of the Ebola vaccine, five years refers to the time taken to conduct clinical testing and gain market approval. The chemical entity that eventually became the vaccine was identified in [2004](#) and initially licensed in [2010](#). Merck purchased the commercial rights to it in 2014, following the Ebola outbreak in West Africa and the appearance of a small number of cases in the US; the Public Health Agency of Canada maintains ownership of non-commercial rights.



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A vaccine being developed in 12 to 18 months would be a world first. The group discussed some of the reasons the development process is long under normal circumstances and why this time might be different.

Normally, vaccine development proceeds through stages of development in a sequential order: drug discovery, pre-clinical testing, three-phase clinical testing, regulatory approval, and follow-up monitoring for long-term safety and efficacy. Many possible candidates will not pass the drug discovery and pre-clinical phases, more will be eliminated at each phase of clinical trials. Vaccines are also subject to strict safety standards: since they are administered to healthy people, the tolerance for negative side effects is low. As of April 21, there were 93 vaccine candidates in development but only five in the clinical testing phase; all others were in pre-clinical testing.

Vaccine development requires significant academic, industry and government collaboration. It takes significant resources and investment to orchestrate and run adequate clinical trials. Many promising treatments or vaccines identified by researchers don't proceed beyond initial discovery to development into marketable medical products. There are many reasons for this, but the most common is simply that many contenders are eliminated in the clinical or pre-clinical testing phases; when experimental results are not favourable. Once clinical trials are complete, a vaccine must also receive regulatory approval before being made available to the public.

Some of the factors that contribute to long vaccine development times under normal circumstances are not likely to delay development of a vaccine for COVID-19. There is significant demand so pharmaceutical companies have a strong incentive to invest in the development of promising candidates. Governments around the world are investing in research, development and testing of possible treatments, vaccines and diagnostics for COVID-19. For example, the federal government announced \$1 billion "in support of a national medical research strategy to fight COVID-19" on April 23, in addition to the \$275 million previously announced in March. Also, the scale of COVID-19's spread, unfortunately, means that there is no shortage of patients or healthy volunteers to participate in clinical trials. Despite these factors, however, unprecedented collaboration will still be required if a vaccine is to be approved and available to the public within the 18-month timeframe some have optimistically been predicting.<sup>2</sup>

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2 For an example of rather unprecedented collaboration between industry competitors and with governments and academics, see the [International Federation of Pharmaceutical Manufacturers and Association](#) statement on global collaboration to accelerate development.

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The Working Group discussed the already impressive industry, government and academic collaboration occurring around treatments and vaccines for COVID-19 and also some factors that remain a cause for concern, or could be improved to further expedite the development process. In particular, it was unclear to the group how the significant government investments would be distributed and some concern about efficient use of those funds. The group agreed that it is important to remain focussed on the goal of applicable research and not allow the process to become political or allow significant portions to be invested in research that is peripheral to the current crisis.<sup>3</sup> The group also discussed the need to consider the possibility that a vaccine will not be developed within 18 months and necessitate investment strategies for a longer development scenario.

## Securing Canadian Supply

Once a vaccine is developed, there will be massive demand for it since the COVID-19 pandemic has affected almost the entire world. There might also be significant ongoing or recurrent demand, depending on the length of time over which an approved vaccine confers immunity and whether COVID-19 is seasonal. With large global demand and an initially limited supply of vaccine, ensuring that Canadians have access to it as early as possible should be a priority for government. The Working Group discussed strategies related to domestic manufacturing capacity, intellectual property licensing and international clinical trials.

Canada already has extensive vaccine manufacturing capacity, an advantage that should be leveraged for COVID-19 vaccine production. In 2019, Canada exported \$453 million worth of human vaccines to the US and had a positive trade balance of \$253 million (global trade balance was -\$252 million). There is not sufficient excess domestic manufacturing capacity, however, to manufacture efficiently the required volume of a new vaccines. Redeploying the current domestic manufacturing capacity for COVID-19 vaccines would likely result in significant opportunity cost in the form of shortages of other vaccines. Nevertheless, the group concluded that there is significant opportunity for Canada to manufacture an approved vaccine and could likely do so in quantities sufficient to exceed Canadian demand. To do so, however, increases to vaccine manufacturing capacity will need to begin as soon as possible. The group discussed building new manufacturing facilities on existing sites and the possibility of building entirely new facilities. Both appear to be viable options, but building new facilities on existing sites might avoid some regulatory or licencing approvals required for an entirely new one.

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3 A participant noted that there has been a significant decrease in non-COVID-related research funding, so there is likely a perverse incentive for some researchers to apply to COVID-related research funds even if their research is unlikely to significantly contribute to the current crisis or is only tangentially related.

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Once a vaccine has been developed and is being manufactured in significant volumes, the group discussed options for distribution. Relative to development and scaling of manufacturing, the group agreed that distribution is likely the easiest piece of the puzzle. When quantities are limited, targeting the most at-risk populations should be the priority – elderly populations, healthcare workers, for example. If supplies of the vaccine are not limited, then everyone should be able to access it, similar to other population-wide vaccination programs. There was consensus among the group on two particular points. First, access to the vaccine should be as convenient as possible and involve limiting physical contact to the extent possible. While already allowed in some provinces, the scope of practice for pharmacists should be expanded to allow them to administer vaccines to provide convenient access within communities. Second, since comorbidities are a significant factor in the severity of a COVID-19 infection, public health should issue guidance encouraging people to ensure their vaccinations are up-to-date. In particular, since a vaccine is unlikely to be available within the year, encouraging people to get their annual influenza vaccine in higher proportions could contribute to decreasing the severity and mortality of COVID-19.

## Summary and Conclusion

It will likely be quite some time before a COVID-19 vaccine is fully tested, approved, manufactured at scale and available to the public. Significant industry, government and academic collaboration to accelerate the process is already underway, but more will be needed.

One of the factors that contributes to the slow development of new medical treatments and vaccines is that the process normally proceeds sequentially. Given the speed of development and the scale of demand, there is a need to proactively develop standards for evaluation, increase manufacturing capacity, and establish distribution strategies simultaneously. There may be opportunities to use novel approaches to regulatory cooperation and intellectual property licensing given the level of international collaboration among different groups to accelerate development of a vaccine and subsequently manufacture and distribute it at scale as quickly as possible.

Significant investments have been announced related to research and development. There is a need to establish oversight of those investments to ensure a collaborated approach to achieving the goal. A national decision-making process should be established as soon as possible to review on-going research and international experience and, on the basis of evolving evidence, advise governments on the best course of action. Next steps should include (i) establishing the process for evaluating successful trials; (ii) selecting the vaccines for Canadian market approval; and (iii) expanding domestic manufacturing capacity. Canada should leverage its existing advantage in vaccine manufacturing and begin expanding domestic capacity to ensure access for Canadians and the potential to contribute to the global supply through exports.

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## Members of the Public Health and Emergency Measures Working Group

**Dr. R. Sacha Bahtia**, Director of Institute for Health Systems Solutions and Virtual Care, Women's College Hospital.

**Åke Blomqvist**, Health Fellow-in-residence, C.D. Howe Institute; Adjunct Research Professor, Carleton University.

**Tom Closson (Co-Chair)**, Health Policy Council, C.D. Howe Institute.

**Janet Davidson (Co-Chair)**, Senior Fellow C.D. Howe Institute; Chair of the Board Canadian Institute for Health Information.

**Perry Kendall**, Co-Interim Executive Director at the BC Centre on Substance Use; BC Provincial Health Officer (former).

**Christopher Naugler**, Professor, Department of Pathology and Laboratory Medicine, University of Calgary; Associate Dean Undergraduate Medical Education, Cumming School of Medicine

**Duncan Sinclair**, Emeritus Professor, Queens University.

**Colleen Flood**, Professor & Director, uOttawa Centre for Health Law, Policy & Ethics University Research Chair in Health Law & Policy.

**Catharine Whiteside**, Executive Director, SPOR Network in Diabetes, Emerita Professor and Former Dean of Medicine, University of Toronto.

**Rosalie Wyonch**, Policy Analyst and Research Lead, Health Policy Council, C.D. Howe Institute.

## Special Guests

**Mark Lievonon**, President (former), Sanofi Pasteur Canada.

**Kevin Tuer**, Vice President Strategic Initiatives, Communitech.

**Amanda Green**, MedTech Programs Lead; Academic Connections and Research Funding, Communitech.

**Joseph Berger**, Director, Public Policy and Research, McKesson Canada.