Critically Thinking About Covid-19 – Part III: September 30, 2020

Dr. Christopher DiCarlo

Almost three months have now passed since my second commentary on the Covid –19 pandemic. Since then, much has developed in terms of testing, restrictions, vaccination development, and public policies. As usual, in light of our epistemic model for knowing where we're now at, it is always important to remember Rumsfeld's Rule:

"There are known knowns. There are things we know that we know. There are known unknowns. That is to say, there are things that we now know we don't know. But there are also unknown unknowns. There are things we do not know we don't know."

So we must ask ourselves again: at this point in time, what do we *know*, and what do we know we *don't know* about this particular virus?

Controlling the Spread of the Disease:

As we have known since early in the pandemic, what makes the spread of this virus particularly difficult to contain is that a significantly large percentage of those infected with it, show no symptoms. This characteristic – the fact that carriers can be **asymptomatic** – is *the* single greatest reason we are all living under the conditions we now find ourselves.

To keep things in perspective, let's remember from previous papers that a global viral pandemic will *always* follow this exact pattern of reaction:

Testing, Isolation, Anti-virals, and Vaccine (or TIAV)

To return to our acronym – **TIAV**, let's now look at each element in light of current information:

Testing:

There have been so many developments in testing since my last paper that it's very difficult to keep up. So I will only focus on what appear to be among the most promising of tests. Currently, the Holy Grail of Covid-19 testing – a quick and accurate home saliva test – is not yet widely available. However, there have been quite a few advancements over the last few months. For example, in case some of you may be

https://academic.oup.com/jxb/article/60/3/712/453685

wondering how the NBA basketball, and the NHL hockey playoffs were possible, you can thank Yale University's School of Public Health for a new test called: SalivaDirect.

"The SalivaDirect test for rapid detection of SARS-CoV-2 is yet another testing innovation game changer that will reduce the demand for scarce testing resources," said Assistant Secretary for Health and COVID-19 Testing Coordinator Admiral Brett P. Giroir, M.D. "Our current national expansion of COVID-19 testing is only possible because of FDA's technical expertise and reduction of regulatory barriers, coupled with the private sector's ability to innovate and their high motivation to answer complex challenges posed by this pandemic."

Players in both leagues have been kept in 'bubbles' and are tested on a regular basis. It's an accurate and fairly quick test which is less invasive than nasal swab tests:

"Providing this type of flexibility for processing saliva samples to test for COVID-19 infection is groundbreaking in terms of efficiency and avoiding shortages of crucial test components like reagents," said FDA Commissioner Stephen M. Hahn, M.D. "Today's authorization is another example of the FDA working with test developers to bring the most innovative technology to market in an effort to ensure access to testing for all people in America. The FDA encourages test developers to work with the agency to create innovative, effective products to help address the COVID-19 pandemic and to increase capacity and efficiency in testing."

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However, here in Canada, the approval for this type of testing has been put on hold. Health Canada initially declined to approve at-home testing and have received considerable criticism from public health experts:

Dr. Colin Furness, an infection control epidemiologist and assistant professor at the University of Toronto, said that at-home testing could be a powerful way of preventing viral spread. If everyone in Canada were able test themselves every day, he said, then "you'd have no pandemic." "I think it's a travesty that Health Canada would stand in the way of home testing with saliva/paper tests," he said in an e-mail. Health Canada, which regulates what medical and diagnostic tests are available on the market, won't be approving at-home tests for COVID-19 because of concerns about their accuracy when used by the public. "While Health Canada recognizes that home self-testing could make it possible for a greater

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² https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-yale-school-public-health

³ Ibid.

number of people to be tested ... we have concerns about the risks of home self-testing," said Eric Morrissette, spokesman for Health Canada.⁴

Such rapid testing was addressed on September 23rd in the Throne Speech in which Justin Trudeau promised to do more in terms of testing but did not indicate when, exactly, the approval might be given:

Health Minister Patty Hajdu has said her department isn't satisfied that the testing systems submitted for approval yield accurate enough results. In Wednesday's throne speech, the government said it is "pursuing every technology and every option for faster tests for Canadians." Once they are approved, the government promises to deploy them quickly, and is creating a "testing assistance response team" in the meantime to help with the insatiable growth in demand.⁵

The recent long line-ups at Covid-19 testing sites has prompted demand for a better way in which to rapidly diagnose the virus. On a personal note, I must say that I am a bit surprised with the length of time it has taken to develop, access, and apply such new technologies in diagnostics.

"People lining up to be tested is a problem," said Raywat Deonandan, an epidemiologist at the University of Ottawa. Deonandan said he understands why governments are reluctant to wave through tests that aren't delivering the highest quality of results, but he said there are ways to use them without risking safety. "They can be surveillance tools," he said. "This is what I call the failure of imagination on the part of people that are OK'ing this." He said the lower-quality tests tend to deliver more false positives than false negatives, which means people with COVID-19 wouldn't be getting missed. Rather the tests can help quickly ferret out people with possible COVID-19, who can then be sent for clinical diagnosis using the more accurate molecular test to confirm it. 6

This raises an extremely important point: You don't need 100% accuracy in testing in order for it to help. Deonandan likened such lower-quality Covid tests to cancer tests like mammograms where if there is a concern and need for further analysis, a person can be sent for more accurate testing to confirm or rule out cancer.

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⁴ https://www.theglobeandmail.com/canada/article-public-health-experts-criticize-health-canadas-decision-not-to/

⁵ https://www.ctvnews.ca/politics/feds-promise-help-for-surging-covid-19-test-demand-but-won-t-ok-rapid-test-tech-yet-1.5117158

⁶ Ibid.

Perhaps due to professional and public pressure, Health Canada had a change of heart on such tests:

Health Canada is willing to consider approving home COVID-19 tests to screen for the virus, a spokesman for the minister of health told Reuters, in a win for public health experts and doctors who have argued that frequent and inexpensive testing could beat back the pandemic. The health ministry had previously said it was concerned that people might misuse home tests or misinterpret the results. "In response to the evolution of the pandemic, Health Canada is now considering applications for home testing devices for screening purposes," said Cole Davidson, spokesman for the minister of health said in a statement.⁷

It is unfortunate that Canadian agencies, politicians, and medical professionals could not have come to a quicker decision regarding such testing devices.

Ethical Dilemma 1

What are we to do when health experts disagree over the value and benefits of new technologies for the public? Why was Health Canada so reluctant to consider such rapid tests for Covid-19? Why did it require a public outcry from medical professionals and public health experts to change their minds? Such delays have essentially cost considerable money, time, and energy, not to mention actual lives lost due to such delays in effective decision-making. Perhaps Health Canada should adopt a curriculum of Critical Thinking into their methodologies?

If ever there were a phrase to watch for during a pandemic, it's 'game-changer'. You will see this phrase come up repeatedly over the next several months regarding new technologies.

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Recently, developments have been made in attaining and utilizing patient information which some view as a game-changer. In Orillia, Ontario, new techniques are being used to chronicle patient information which can be used at the time of care and for follow up tracing.

The COVID-19 assessment centre in Orillia is using technology to help speed things up as the lineups for testing grow significantly. The new

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⁷ https://ca.reuters.com/article/idCAKBN25S58C

device resembles an old, chunky cellphone, but it works to cut the amount of time health care staff spend registering patients. The device quickly scans a patient's health card and driver's license, saving staff from having to handwrite the information and then transfer it into a computer. Orillia Soldiers' Memorial Hospital's assessment centre is the first hospital-based centre in Ontario to implement the new technology. The COVID testing centre processed its most ever tests in a single day at 300 last week, and with the new technology, staff believe they can bump that up to 500 per day.⁸

Staff say that if the pilot project proves to be successful, it could be used at other COVID assessment centres facing long line-ups across the province.

And speaking of a 'game-changer', a new machine has recently been developed in Canada which can detect Covid-19 in the air:

This could be a game-changer. A new Canadian technology to detect COVID-19 in the air was just launched. The company behind it claims it could help stop outbreaks before they even happen. The company is Kontrol Energy Corporation and their new machine is called BioCloud. They say it's an "unobtrusive wall-mounted technology which detects the presence of COVID-19 in the air." According to a news release about the launch, "immediate applications in schools, hospitals, long term care facilities and mass transit vehicles including planes, trains and buses represent a game changer in the fight against COVID-19." It's been a long time coming. Kontrol's CEO Paul Ghezzi said their "team has been working day and night since the onset of the pandemic to bring this exciting technology to market." They explain that the product has undergone extensive testing and they even partnered with top experts like Western University's Dr. David Heinrichs, who is a microbiology and immunology professor.⁹

It would appear that now that the world has seen its share of epidemics and pandemics, the time is right to develop and utilize this type of technology. But it won't be easy. And it definitely won't be cheap:

The device would continuously sample air quality and if it picks up the new coronavirus floating around, it sends a notification to the facility management, who can then take proper measures to prevent an outbreak.

https://www.narcity.com/news/ca/on/toronto/canadian-technology-detects-covid19-in-the-air-could-be-in-schools-by-november

⁸ https://barrie.ctvnews.ca/orillia-s-covid-19-testing-centre-introduces-game-changing-new-technology-1.5109078

Now it's a matter of getting the technology out there. Kontrol says they hope to have them in Canadian schools by November...They are also preparing to make up to 20,000 of these things a month but it won't be cheap. Every BioCloud unit is expected to cost US\$12,000, that's about CA\$15,800 each.

The future is going to look quite a bit different once such detection devices are put in place. But we must be careful if we are to assume that we can know and control the exact location and virulence of every pathogen we might encounter.

Ethical Dilemma 2

What public health experts need to be considering right now is to what extent is our obsession with cleanliness and avoidance of infection from Covid-19 going to affect our communal immune systems once a vaccination is ready and the world population has been inoculated. In other words, while we are currently bathing in hand sanitizer and other forms of personal hygiene, we must ask ourselves: What are we doing to our collective microbial ecosystems? What effects will our obsession with over-sanitizing have on the mutation rates of other microbes – especially bacteria?

We need to get smart about pathogens. We should not become germaphobes; on the contrary – we need to become 'germ-aware'. And that means we need to know how to co-exist with pathogens and parasites. We are constantly in an arms race against these tiny organisms. So we better learn as much as we can about what kills them, what does not, and what creates environments perfect for nasty mutations to thrive which will then seek out human hosts in order to replicate.

Another encouraging story regarding testing comes again from my hometown of Guelph, Ontario, where a company has just received approval from Health Canada to distribute a portable Covid-19 testing device that can produce results in about 30 minutes.

Health Canada has granted approval for the Hyris bCUBE to be used as a medical device for COVID-19 human testing... The Hyris bCUBE is a portable DNA-testing laboratory in a box, offering Point of Care (POC) testing wherever people are—anytime, anywhere. Controlled by any device with an internet connection, including a smartphone, the scientifically validated bCUBE analyzes test samples through a cloud-based platform that delivers accurate results in minutes... Considered the "gold standard" according to the CDC and WHO's effective testing guidelines, the bCUBE deploys PCR (Polymerase Chain Reaction) technology that has demonstrated a 95%+ accuracy rate in clinical trials...

Songbird Life Science is the exclusive Canadian distributor of the Hyris bCUBE. Along with several DNA/RNA-identification technologies that Songbird can deploy to suit a space or community's specific requirements, the bCUBE is a key component to Songbird's risk-management consultancy services.¹⁰

I recently had the opportunity to speak to one of the Co-Founders and Science Advisors at *Songbird*, Mike Soligo and Dr. Steven Newmaster. The Songbird company is doing some pretty interesting work in detection and diagnostics of various pathogens – including Covid-19. Their company is able to evaluate an entire facility – a school, hospital, factory, store, office, etc., and test the complete environments of each – including surfaces, ventilations systems, water, etc. They can even train people to become pseudo-technicians who can operate the Hyris bCUBE themselves. There are two standard tests for such a device in diagnosing up to 6 human infections: There is a short test – about 26 minutes – which can determine negativity of infection. And there is a longer test – about 90 minutes – which can confirm positivity of infection. Both Soligo and Newmaster said such units were excellent for isolated indigenous communities, private businesses, airports, etc. The very name of the company – Songbird – has been chosen because it represents a sentinel for a problem in the environment. This is the second company to have a diagnostic test approved from Health Canada and interestingly enough, both are from Guelph.

What is Still Needed: Rapid and Relatively Accurate Response Testing

As I have been mentioning for decades, the Holy Grail of testing for any pathogen such as Covid-19 would be a fast and relatively accurate home test that anyone could use. Right now, this doesn't exist. But there are some companies working on making this a reality. For example, researchers are currently adapting CRISPR, synthetic biology, and other creative approaches to detect SARS-CoV-2 nucleic acids outside of the lab or doctors' offices, in the hopes of making diagnostics more affordable and accessible.¹¹

On May 20, Mammoth Biosciences established a partnership with pharmaceutical company GlaxoSmithKline Consumer Healthcare to further develop DETECTR into a handheld, disposable device that would be appropriate for home use and be about as expensive as an at-home pregnancy test. "The way point-of-need and at-home diagnostics will work is if they're truly all-in-one," says Trevor Martin, Mammoth Biosciences'

 $[\]frac{10}{\text{https://www.newswire.ca/news-releases/health-canada-approves-portable-human-covid-19-testing-device-that-delivers-results-in-90-minutes-873864114.html?fbclid=lwAR1b-CPav3wFlT5ay3PlAnXCsfexyMZ0jCbtHzRam3qeCZjkJJmTVLC43r8}$

https://www.the-scientist.com/news-opinion/toward-covid-19-testing-any-time-anywhere67906?utm_campaign=TS_OTC_2020&utm_medium=email&_hsmi=95303425&_hsenc=p2ANqtz-8vALxKzogOJYeW9LrDgolk_sPbuzXv_A6VoBA8pg8kJny4-2BxzBn2vA2nA_2CdZsHkflG_iTiPwj05Y9YggktuS5yQ&utm_content=95303425&utm_source=hs_email

CEO. "It needs to be as easy to use as a pregnancy test, and we're also very much believers that it needs to give you results that are as trusted and accurate as something you would get in the lab."¹²

One of the unanticipated benefits of the development of such testing units now is that they may prove to be beneficial at a future time if or when we are faced with the potential to battle another pandemic or viral or bacterial outbreak.

As for competition, "I don't think that the testing for coronavirus is going to be a winner-take-all situation," [University of Albany biomedical engineer Ken] Halvorsen says. "There really need to be lots of different options. And it may turn out that there are many different testing types that all work in different situations," he adds. "This may not be a short-term problem. We may be testing for years." 13

So is there any hope in the coming months for the 'Holy Grail' of Covid tests? Perhaps. There is a new test called Abbott's BinaxNOW Covid-19 Ag Card which is claimed to be fast, reliable, portable, and affordable.

Abbott (NYSE: ABT) announced today that the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for its BinaxNOW™ COVID-19 Ag Card rapid test for detection of COVID-19 infection. Abbott will sell this test for \$5. It is highly portable (about the size of a credit card), affordable and provides results in 15 minutes. BinaxNOW uses proven Abbott lateral flow technology, making it a reliable and familiar format for frequent mass testing through their healthcare provider. With no equipment required, the device will be an important tool to manage risk by quickly identifying infectious people so they don't spread the disease to others. Abbott will also launch a complementary mobile app for iPhone and Android devices named NAVICA™. This first-of-its-kind app, available at no charge, will allow people who test negative to display a temporary digital health pass that is renewed each time a person is tested through their healthcare provider together with the date of the test result. Organizations will be able to view and verify the information on a mobile device to facilitate entry into facilities along with hand-washing, social distancing, enhanced cleaning and mask-wearing.¹⁴

¹² Ibid.

¹³ Ibid.

https://abbott.mediaroom.com/2020-08-26-Abbotts-Fast-5-15-Minute-Easy-to-Use-COVID-19-Antigen-Test-Receives-FDA-Emergency-Use-Authorization-Mobile-App-Displays-Test-Results-to-Help-Our-Return-to-Daily-Life-Ramping-Production-to-50-Million-Tests-a-Month

For the record, Admiral Brett Giroir, Coronavirus Task Force Member for the Trump Administration, ordered 150 million of the BinaxNOW tests for use in the US.

And just a few hours ago, a press release announced that:

Health Canada regulators today approved the ID NOW rapid COVID-19 testing device for use in this country — a move that could result in millions more tests for communities across the country grappling with a surge in coronavirus cases. The Abbott Laboratories-backed molecular devices can be administered by trained professionals at like places like pharmacies, without the need for a laboratory to determine if someone is infected with the virus.¹⁵

The federal Ministry of Health just announced that it will be purchasing 7.9 million ID NOW tests from Abbott Laboratories for distribution in Canada.



[Image: https://www.msn.com/en-ca/news/canada/health-canada-approves-rapid-covid-testing-device-as-canada-braces-for-caseload-spikes/ar-BB19A9f1?li=AAqqNb9&ocid=iehp]

These are point-of-care devices can produce COVID results in 15 minutes. Point-of-care means the testing can be done and analyzed at the same place. In other words, the tests do not need to be sent away to a laboratory for analysis. Instead, within just 15 minutes, people can find out their results. Although it's not the 'Holy Grail' of fast and accurate home tests, it is pretty close. And it will help considerably in knowing who is

https://www.msn.com/en-ca/news/canada/health-canada-approves-rapid-covid-testing-device-as-canada-braces-for-caseload-spikes/ar-BB19A9fl?li=AAggNb9&ocid=iehp

infected and who is asymptomatic, so that we can more accurately trace and control the spread of the virus.

Point-of-care means the testing can be done and analyzed at the same place.

There is a bit of an issue, here, though. This is the third point-of-care device that has been approved by Health Canada; and it is an American company. As you may recall in Part II of this series, I reported that *Precision Biomonitoring* was the first such device approved by Health Canada months ago. And it was produced right here in good 'ol Canada. Why did the Feds wait almost three extra months to purchase and utilize these types of devices when a Canadian company had already received approval? As we noted earlier, during the Throne Speech on September 23, 2020, the Liberal government said it is "pursuing every technology and every option for faster tests for Canadians." But were they? All evidence points to the contrary.

Why did the Feds wait almost three extra months to purchase and utilize these types of devices from the US when a Canadian company had already received approval months before?

I just recently spoke to Mario Thomas, CEO of *Precision Biomonitoring* who informed me that sales of these units have been very good. However, all sales have been to private companies – from mining, to construction and fisheries, and even to movie studios. "Private companies have stepped up and the demand is so high, we cannot keep up," said Thomas, when asked about productivity and sales. However, when I asked him about government interest, he said neither the federal nor the provincial governments were interested in purchasing and utilizing these devices. Let's think about that. If such devices were purchased and utilized en masse at airports, long term care and retirement homes, supply chains, and every other potential hot spots throughout the country, we could have controlled and monitored the spread of the virus as efficiently as other model countries such as Taiwan, South Korea, Viet Nam, etc. But they didn't. And now the second wave is back. These devices could have been in place since early July, and just now we are seeing the government act nearly three months later. Why? As soon as the *Precision Biomonitoring* units were approved by Health Canada, my consulting firm begged the provincial and federal governments to purchase such units and have them put in place prior to the 2nd wave; but they did nothing. I find this lack of action and lack of support for accurate, reliable, and Canadian-made products ethically disgraceful and morally shameful. Not only have the provincial and federal governments failed to support Canadian contributions in the fight of the pandemic, they have postponed our collective abilities to intelligently control the spread of this virus. And that

has invariably caused suffering and death. I am willing to maintain that there may be other reasons of which I am unaware for the delay in attaining such test devices and for the purchase of the US-made Abbott devices. But as it stands, I am unable to fathom the reason for such delays.

We can never forget that, until there is a vaccine which can be distributed widely and quickly, testing is our best defense against this, or any future pathogen. Knowing greater details about infection rates will allow for greater human mobility which will be good for economies and human interaction worldwide. And in regards to testing overall, our governments – at both the provincial and federal levels – have failed us.

Isolation:

Although isolation restrictions had eased in various places around the world, more restrictions are being imposed as we enter into the start of a second wave in Ontario, in Canada, and in many other countries throughout the world. The numbers of infections in Ontario have risen considerably over the last few weeks. The demographics of new infections indicate a strong skewing towards young adults between the ages of 20 and 40. On September 24th, a leaked document from the Ontario Government revealed a plan to avoid another COVID-19 lockdown:

The 21-page draft, provided by a government source this week, acknowledges the recent upsurge in new COVID-19 cases, and lays out three possible scenarios of what the second wave could look like: small, moderate or large. Whichever scenario plays out, the plan favours responding with targeted restrictions, rather than widespread closures or a lockdown. "If there is a resurgence of COVID-19, either locally or provincewide, targeted action may be taken to adjust or tighten public health measures," says the document. "The return to an earlier stage of provincial reopening, or even regional approaches to tightening would be avoided in favour of organization-specific or localized changes."

Given the events of past pandemics such as the 1918 Spanish flu, many scientists anticipated a rise in cases after the summer months. What is very, very important at this stage, is for governments (at all levels) to balance the economy with the benefits for public health. And this is no easy feat.

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Anti-Virals:

There have been some significant improvements in the treatment of patients in ICU's suffering from severe effects of SARS-CoV-2. I had mentioned the steroid dexamethasone in the last paper. Studies are indicating considerable efficacy in treating severely ill Covid patients:

Dexamethasone and other corticosteroid drugs are effective treatments for seriously ill COVID-19 patients, according to a meta-analysis of seven randomized controlled trials including a total of more than 1,700 participants. The analysis, conducted by a team at the World Health Organization (WHO) and published yesterday (September 2) in JAMA, concluded that the drugs reduced the risk of dying within 28 days compared with standard care or placebo. The organization has issued new guidelines recommending use of the drugs in the treatment of patients with severe or critical COVID-19.¹⁷

Although results of using steroids such as dexamethasone have proven largely positive, we must also realize that it may not be the right treatment for all patients varying in degree of severity:

The WHO has cautioned that the findings do not mean that steroids should be given to all COVID-19 patients, and the organization currently recommends doctors not to prescribe the drugs to people with mild disease. One study included in the meta-analysis found that corticosteroids might even increase mortality in non-severe patients.¹⁸

So these antivirals do not come in a 'one-size-fits-all' approach. And there is still so much to learn in regards to combatting the virus once it takes serious hold on an individual's health.

Another form of antiviral that is being tested involves an antibody-based drug which has been hailed as reducing hospitalizations. But what are antibodies? And how can they be used to make a drug to battle Covid-19?

Convalescent plasma treatments, which work by giving a patient a myriad of antibodies from recovered COVID-19 patients, have received emergency use authorization from the US government, but their benefits

18 Ibid.

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https://www.the-scientist.com/news-opinion/steroid-drugs-are-an-effective-treatment-for-severe-covid-19-who-67910?utm_campaign=TS_OTC_2020&utm_medium=email&_hsmi=95002753&_hsenc=p2ANqtz-9PO8beJ1n-aeSRqcFpulpvrh7uY91fqpvN2YeCmcbNhdxdu_JkPbGfduZTB258LB7F64c-RZfbkS_EDAzaXbcZlP65iw&utm_content=95002753&utm_source=hs_email_

are uncertain. Lilly's LY-CoV555 is monoclonal and provides a singular, targeted antibody treatment that can be scaled up and provide consistent dosing. The medicine binds to the spike protein on the SARS-CoV-2 virus, preventing it from infecting cells.¹⁹

In regards to the effectiveness of such a treatment, Eli Lilly reports a 72 percent reduction in hospitalization risk among patients who received its monoclonal antibody compared to those who received a placebo.²⁰ It's still in the early stages of drug therapies, but this approach seems quite hopeful.

"This is a good start," Eric Topol, director of the Scripps Research Translational Institute, who was not involved with the study, tells STAT. "A lot is pinned not only on Lilly but on the whole family of these [monoclonal antibodies], because even though they're expensive and they're not going to make a gajillion doses, they could make a big difference in the whole landscape of the pandemic."²¹

Now as hopeful as this study was, here's where science gets messy. Another antibody study, out of India, found little efficacy in their results.

Despite the lack of survival benefit shown in the ICMR study, some positives gleaned from the trial include improved symptoms and oxygenation and faster viral clearance in patients in the intervention arm compared with the control arm..."I see the cup being half full in terms of the viral load data and the improved oxygenation and so forth," Joyner says. The half empty part, he adds, is that most of the plasma had low titers of antibodies and was given relatively late during the course of the disease—a median of eight days after onset of symptoms. "Those are the two main limitations of the study."

So even though, overall, there was not a strong indication of efficacy of the treatment, this may be due to the low dosage of antibodies that was given to patients who were late during the course of the disease (rather than earlier in its contraction). What we do see when we look closely at this study is that such low dosages late in the course of the

¹⁹ https://www.the-scientist.com/news-opinion/antibody-based-drug-may-reduce-covid-19-hospitalizations-study-67942?utm_campaign=TS_COVID_2020&utm_medium=email&_hsmi=95982719&_hsenc=p2ANqtz-9BQSahkrffLfSRFMG4LVhNy5Uj-haxciNk7BLtM_2bLlCOAGE_N6ag4BStGTvT2hEL9GgMpUijL0wvHTwEpQP0wiDnkg&utm_content=95982719&utm_source=hs_email_20_lhid.

²¹ Ibid.

https://www.the-scientist.com/news-opinion/indian-study-shows-no-survival-benefit-of-plasma-in-covid-19-67931?utm_campaign=TS_COVID_2020&utm_medium=email&_hsmi=95496231&_hsenc=p2ANqtz-hScDr8KTSPXq6hinYGUcjdFLRbJVlwFAEYKevBlQbwiQeW2mVD60dEYLWY7eFYLBaV0z13B7bYmEvZaywFdfKkV-MnQ&utm_content=95496231&utm_source=hs_email

disease still produced improved symptoms and oxygenation and faster viral clearance in patients in the intervention arm compared with the control arm. And that is significant.

In the weeks and months to come, we will keep a close eye on convalescent plasma treatments and recall that was this type of treatment that helped defeat the Spanish flu virus in 1918. This anti-viral therapeutic approach has been around for over a century.

Vaccines:

There has been considerable development of vaccination therapies since Part II of this series. As of September 30, 2020 researchers are testing 43 vaccines in clinical trials on humans, and at least 91 preclinical vaccines are under active investigation in animals. For an update on the development of these vaccines, please click here. But what are vaccines and how do they work?

We saw in Part II of this series that vaccines must go through a series of phases and trials before they are ready to inoculate the public. But there are several different ways in which vaccines can be made and developed. There are genetic vaccines which deliver some of the coronavirus' own genes into our cells to prompt an immune response. This is the type of vaccine Moderna is currently developing and believes will be ready for distribution in early 2021. Then there are viral vector vaccines. These contain viruses bio-engineered to carry coronavirus genes. Some viral vector vaccines enter cells and cause them to make viral proteins. Other viral vectors slowly replicate, carrying coronavirus proteins on their surface.²³ This is the type of vaccine *Johnson &* Johnson is currently developing. And then there are protein-based vaccines. These also contain coronavirus proteins but do not contain any genetic material. Some vaccines may contain whole proteins while others only contain fragments of them. Inactivated or Attenuated Coronavirus Vaccines are created from weakened coronaviruses or coronaviruses that have been killed with chemicals. Sinovac Biotech in China is in Phase 3 of development with this vaccine. And finally, there may already be vaccines in use for other diseases that may also protect against Covid-19. There are numerous universities and biotech companies working with repurposed vaccines:

The Bacillus Calmette-Guerin vaccine was developed in the early 1900s as a protection against tuberculosis. The Murdoch Children's Research Institute in Australia is conducting a Phase 3 trial called the BRACE to see if the vaccine partly protects against the coronavirus.²⁴

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²³ https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

lbid.

In regards to where we're at right now, in late September, 2020, with vaccine development, in an excellent article by Carl Zimmer and Katie Thomas, they state that there are two major players in the race for the Covid-19 vaccine.

In planning documents sent last week to public health agencies around the country, the Centers for Disease Control and Prevention described preparations for two coronavirus vaccines they refer to simply as Vaccine A and Vaccine B. The technical details of the vaccines, including the time between doses and their storage temperatures, match well with the two vaccines furthest along in clinical tests in the United States, made by *Moderna* and *Pfizer*.²⁵

Both *Moderna* and *Pfizer* are developing the newer form of genetic vaccines:

Moderna and Pfizer are testing a new kind of vaccine that has never before been approved for use by people. It contains genetic molecules called messenger RNA. The messenger RNA is injected into muscle cells, which treat it like instructions for building a protein — a protein found on the surface of the coronavirus. If all goes well, the proteins stimulate the immune system and result in long-lasting protection against the virus.²⁶

Both companies are currently testing their candidates in Phase 3 trials. In both of their earlier human studies, neither vaccine produced serious side effects and provoked test subjects' immune systems to create antibodies that can neutralize the Covid-19 virus. Although this is hopeful, both companies need to wait until Phase 3 trials have been completed; because only Phase 3 trials will determine whether or not such vaccines are safe to use widely throughout the world's populations.

A Phase 3 trial collects data about the symptoms volunteers experience after their injection, and whether they become infected with the coronavirus. After "unblinding" the data, researchers compare the rates of infection and adverse side effects between people who receive the vaccine and those who receive the placebo. If significantly more people get Covid-19 on the placebo than the vaccine, that is evidence that the vaccine is effective. The F.D.A. has indicated that vaccine makers should aim for 50 percent protection in order to be considered effective.²⁷

You might now be thinking, doesn't a vaccine need to be 100% effective? Just as we saw that testing for Covid-19 does not have to be 100% all of the time to be effective, so

 $^{{\}color{red} {}^{25}} \ {\color{red} {}^{https://www.nytimes.com/article/covid-vaccine-a-b.html?smid=tw-share}}$

²⁶ Ibid.

²⁷ Ibid.

too, with vaccines. As Dr. Francis Collins says: "50% is a long way from 0%. Most influenza vaccines are 50% and they save a lot of lives each year." 28

But when will these vaccines become available?

That is the most important question facing the world right now. But the answer is a little tricky and depends upon who you ask:

Pfizer recently said it was "on track" for seeking government review "as early as October 2020." *Moderna* has said it expects to complete enrollment in its Phase 3 trial in September, but has not provided an estimate about when the vaccine might be ready for the public. Federal officials said in May that the first doses of a vaccine being developed by *AstraZeneca*, in partnership with the University of Oxford, could be delivered by October. But *AstraZeneca*, which recently began Phase 3 trials of the vaccine in the United States, is now saying it could supply the first doses of the vaccine in the United States by the end of 2020.²⁹

But I thought Russia already discovered a vaccine and is already inoculating its citizens? Well, yes and no. Yes, Russia has "developed" a vaccine and yes, they are administering it. But there are some medical and ethical questions to consider with their vaccine.

But when will these vaccines become available?

To date, almost 40 scientists have signed an open letter, pointing out suspicious patterns in the data and a general lack of transparency because Russian scientists are withholding complete data.

The first data detailing Russia's COVID-19 vaccine—nicknamed Sputnik—was published last week (September 4) in *The Lancet*. Almost immediately, other scientists began to call attention to unlikely patterns in the data, asking for raw numbers to verify the study's conclusions. Enrico Bucci, a systems biologist and bioethicist at Temple University, published an open letter on his blog September 7 to draw *The Lancet's* attention to suspected data manipulation. While he stresses that the letter is not an allegation, "the presentation of the data raises several concerns which require access to the original data to fully investigate... "It's like you enter a room with nine people and you add their ages together and find that that

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https://www.cnn.com/videos/health/2020/09/10/entire-september-10-coronavirus-town-hall-part-two-sot-vpx.cnn

²⁹ Ibid.

number is exactly the same as the combined weight of those people," Bucci tells *Chemistry World*. "It is strange. But we don't have access to the data and we can't really assess what is going on.""³⁰

So, even if Russian scientists have developed a viable vaccine against Covid-19 – known as $Sputnik\ V$ – they are being extremely elusive and opaque in demonstrating its efficacy with data. It will be interesting to see how this plays out over the next few months.

There is one very interesting development to note regarding the race to find a Covid-19 vaccine. On Tuesday, September 8th, nine major drug companies signed a pledge stating that they would "stand with science" and not develop a vaccine prematurely unless and until it had gone through rigorous testing for public safety and effectiveness.

The companies did not rule out seeking an emergency authorization of their vaccines, but promised that any potential coronavirus vaccine would be decided based on "large, high quality clinical trials" and that the companies would follow guidance from regulatory agencies like the Food and Drug Administration. "We believe this pledge will help ensure public confidence in the rigorous scientific and regulatory process by which Covid-19 vaccines are evaluated and may ultimately be approved," the companies said.³¹

Dr. Francis Collins, Director of NIH, stated³² that the Data and Safety Monitoring Board (DSMB) watches over vaccine trials. He stated that they are scientists – *not* politicians, and they literally watch over the testing of vaccines to see who receives it and who receives a placebo to see whether or not there is strong, statistically-convincing data which indicates either that the vaccine works, doesn't work, or if there are other problems. Collins stated that members of this board are like gate-keepers who assure that nothing gets approval without strong scientific evidence. He also stated that the FDA also adheres to very strict guidelines with their own advisory committee – the Vaccine and Related Biological Products Advisory Committee (VRBPAC). And he also mentioned that CEO's of large pharmaceutical companies would not submit potential vaccines to the FDA unless they had substantial reasons to believe in its efficacy. This assures that there are a lot of protective steps in place to assure that once a vaccine is ready for wide inoculations, it is both safe and effective.

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https://www.the-scientist.com/news-opinion/scientists-voice-concerns-over-russian-covid-19-vaccine-study-67926?utm_campaign=TS_COVID_2020&utm_medium=email&_hsmi=95496231&_hsenc=p2ANqtz--a2cwCe98EkzmWZ7GcqQZp_d6muwpOzzU0qMZjZU-

oOS8GZQcJkhCu2wzzAt3clmU0EJZbyosJRfXrplOCNR20XyeP0g&utm content=95496231&utm source=hs email

https://www.nytimes.com/2020/09/08/health/9-drug-companies-pledge-coronavirus-vaccine.html

In an interview with Anderson Cooper on CNN, September 10, 2020.

On that note, we have recently learned that Prime Minister Justin Trudeau has just purchased 20 million doses of Oxford University COVID-19 vaccine:

The government has signed multiple agreements for more than 150 million doses of COVID-19 vaccines, from several potential vaccines, but until Friday had not signed a deal with *AstraZeneca*, a British firm who are manufacturing the Oxford vaccine. Canada is now invested in six major vaccine candidates and Trudeau said the government is prepared to do all it can to secure a working vaccine. "Canadians must have access to a safe and effective vaccine against COVID-19 as quickly as possible, no matter where it was developed," he said. 33

But Trudeau also said that we cannot just think about Canadians when it comes to vaccinations availability:

The prime minister also announced Canada would provide \$440 million to the Vaccine Global Access Facility (COVAX). The COVAX program is designed to have wealthier countries finance vaccines for poorer ones by sharing the cost. COVAX is invested in nine vaccine candidates, including the Oxford one. Canada's investment is split in two with \$220 million to acquire 15 million doses for domestic use and \$220 million dedicated to bringing vaccines to poorer countries.³⁴

In order to mitigate risk, Trudeau's cabinet has purchased vaccines from several different companies worldwide:

In addition to the Oxford/AstraZeneca deal, Canada has signed deals with Sanofi and GlaxoSmithKline, Johnson & Johnson, Novavax, Pfizer, and Moderna. In total there are orders for more than 150 million doses spread across the six companies. Assuming the vaccine candidates pass clinical trials, [Procurement Minister Anita] Anand said all of the companies should make deliveries to Canada in early 2021.35

One of the things to keep in mind at this stage is that we are seeing record-breaking efforts in the development of a viable vaccine for Covid-19. Generally, we know such vaccines take anywhere from 5 to 10 years to develop. So if we were to see one ready for distribution by Halloween or Christmas, it really would be something akin to a medical miracle. But let's face it – even when a vaccine becomes available, it's going to

35 Ibid.

³³ https://www.msn.com/en-ca/news/canada/trudeau-announces-purchase-of-20000-doses-of-oxford-university-covid-19-vaccine/ar-BB19qwis?li=AAggNb9&ocid=iehp

34 lbid.

take quite some time to produce billions of doses and distribute them worldwide. So in terms of living in a pre-pandemic world again, we should be looking at next spring or summer at the earliest.

Covid- 19 Fears: Returning to Work:

Even though we are now facing a second wave of infections, many businesses – including schools – have reopened and workers are somewhat trepidatious about returning to work. This apprehension may be the result of levels of uncertainty regarding our current state in battling this particular virus. And so, at its heart, lies an epistemic problem of battling levels of ignorance regarding the safety concerns of returning to work.

Let's look at it this way: Consider two numbers: 0 and 1. And let 0 represent the value that it is impossible to contract the Covid-19 virus and let 1 represent the value that contracting the virus is certain. Between the numbers 0 and 1 lay the realms of probability.

Consider two numbers: 0 and 1

For example, if one were to live isolated in a cabin in the woods far from any contact with humans and could survive without the need for outside human contact or intervention, then in all probability, this person's likelihood of contracting Covid-19 approaches or even reaches a 0 chance of probability of occurring. On the other hand, if one were to attend a large gathering – say, an indoor event in which thousands of people are gathered and are not physically distancing or wearing masks, then the probability quickly begins to edge towards 1. As in the case of former Republican Presidential candidate, Herman Cain, this became a very unfortunate reality. Mr. Cain contracted the virus (he was in attendance at Trump's Oklahoma rally on June 20, 2020) and unfortunately died as a result.

So people have been returning to work and are dealing with levels of uncertainty. They might be asking themselves questions like:

- Who might have the virus and be asymptomatic?
- Will I be able to physically distance?
- What PPE will be available?
- What if fellow workers start relaxing guidelines?
- What happens to me or my family if I contract the virus?

When people are uncertain, they feel less empowered and less in control of their lives. We must understand that the search for security and control is hard-wired into us.

Humans crave the feeling of stasis or equilibrium and work very hard to reach it e.g. working to save for retirement, living in countries with stable economies, etc. When faced with uncertainty, people don't really know how close to 0 and 1 they actually are. And because we are all also hard-wired with a flight-or-fight response to danger or perceived threats, we will often act irrationally if we are either lacking in information or receiving potentially false information.

That brings us to our next concern.

Covid-19 and Conspiracy Theories:

The last aspect of Covid-19 we need to consider at this point is the level of misinformation and disinformation that has become available online and what its effects might be to the general public and especially, to those struggling with mental health issues.

A new study published today in the journal *Social Science & Medicine* found that conspiracy theories regarding COVID-19 have been persistent from March to July and are associated with the reluctance to adopt preventive behaviours, such as mask-wearing and vaccination in the future.³⁶

History is filled with examples of how quickly false information can spread and become adopted when large groups of people are faced with uncertainties. From the Black Death plague to the attacks of 9/11, people have been blaming governments, minorities, Big Science, and even aliens for the causes of such world calamities.

History is filled with examples of how quickly false information can spread and become adopted when large groups of people are faced with uncertainties.

But we must be vigilant and patient during times of uncertainty. For science is a slow and methodical process; but it is unquestionably the best one we've got.

Researchers found the most common COVID-19-related conspiracies had to do with three main issues: the perceived threat of the pandemic, taking preventive actions (such as mask wearing) and the safety of vaccines... "Conspiracy theories are difficult to displace because they provide explanations for events that are not fully understood, such as the current pandemic, play on people's distrust of government and other

 $\frac{36}{\text{https://www.ctvnews.ca/health/coronavirus/researchers-say-belief-in-conspiracy-theories-poses-barrier-to-controlling-the-spread-of-covid-19-1.5114446}$

powerful actors, and involve accusations that cannot be easily fact-checked," co-researcher Kathleen Hall Jamieson said in a statement. The study suggests that those who did not believe in the conspiracies were 1.5 times more likely to wear a face mask every day outside of the home when in contact with others compared to those who most strongly believed in the conspiracies.³⁷

So how do we deal with such misinformation? We arm ourselves with the skill set of Critical Thinking. We check resources, we corroborate information, we carefully consider the known knowns and especially the known unknowns, and we use the scientific method. We should also be extremely wary of the trustworthiness of social media platforms like Facebook, Twitter, and Instagram where anyone, anywhere, and at any time can say whatever they like without any shred of evidence. "Researchers say that counteracting the effects of conspiracy beliefs will require persistent public health campaigns and straightforward messaging particularly on platforms where COVID-related conspiracies have flourished." 38

Finally, we must realize that living under pandemic conditions has increased levels of stress, anxiety, and depression amongst the general population. The pandemic has exacerbated mental health conditions in many people, isolated others, and complicated lives in a variety of ways. And it certainly doesn't help when we see news stories with headlines like: 'UW chemistry professor calls COVID-19 'fake emergency'³⁹ Apparently, a chemistry professor by the name of Mike Palmer "stands alone" amongst his colleagues and administrators but had written in an outline for one of his courses: "Because of the fake COVID emergency in-class exams cannot be made mandatory. I have therefore decided to cancel them entirely. Evaluation will accordingly be based entirely on assignments." Since he has not responded to any requests for an interview, we are left wondering why such a person, who holds such an esteemed position in science, would say such a thing. It would be interesting to hear his argument and know a little more about his biases. When left as it is, the public has no way of dealing with this information but only see that a person in a position of authority is stating counter information to that sent out by the rest of the scientific community.

And then there's Dr. Stella Immanuel, a physician working in Texas, who has made some extremely bizarre claims regarding the Covid-19 virus and other ailments. In late July, Dr. Immanuel, who is also a Christian pastor, gave a speech on the steps of the US Supreme Court in Washington, where she claimed that she had treated over 350 Covid – 19 patients with hydroxychloroquine and not had one death. Even though

³⁷ Ibid.

³⁸ Ibid.

³⁹ https://www.newhamburgindependent.ca/news-story/10187764-uw-chemistry-professor-calls-covid-19-fake-emergency-/

⁴⁰ Ibid.

studies prove otherwise, she has insisted that taking hydroxychloroquine is not harmful because it is widely taken in her home country of Cameroon, where malaria is endemic.

"Dr." Immanuel is also a pastor and the founder of *Fire Power Ministries* in Houston, an organization she uses to spread other conspiracies about the medical profession.

Five years ago, she alleged that alien DNA was being used in medical treatments, and that scientists were cooking up a vaccine to prevent people from being religious. Some of her other claims include blaming medical conditions on witches and demons - a common enough belief among some evangelical Christians - though she says they have sex with people in a dream world. "They turn into a woman and then they sleep with the man and collect his sperm... then they turn into the man and they sleep with a man and deposit the sperm and reproduce more of themselves," she said during a sermon in 2013.⁴¹

Aside from these extremely bizarre beliefs, Dr. Immanuel believes that gay marriage results in adults marrying children and she also claims she can remove generational curses from placentas with a specific prayer. In a better world, Dr. Immanuel would have her medical licence revoked. To date, she is still practicing medicine.

There are other even more ludicrous theories circulating online, from the idea that the virus was created in a lab in China and has been released as a bioweapon, to the belief that wealthy elites like Bill Gates manufactured it so he could make money from vaccination production, to the concept that it's no worse than the common flu, to the belief that we don't need to wear masks, or that 5G technology has weakened our immune systems and allowed the virus to take hold throughout the world.

We know that the pandemic has generated considerable anxiety and unease throughout the world. Many of those already battling mental health issues prior to the pandemic found their conditions worsened due to fears of contracting the virus, employment and financial uncertainties, and exposure to conflicting information from the media – especially, conspiracy theories. There has never been a time in history when we have seen such a proliferation of conspiracy theories. But why? And why now? And why so many? And why are some either coming from or being endorsed by the current President of the United States as well as other world leaders? It is indeed ironic that, after spreading so much false information about the coronavirus, we have just learned that both President Trump and his wife have now contracted Covid-19.⁴²

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⁴¹ https://www.bbc.com/news/world-africa-53579773

⁴² https://www.ctvnews.ca/world/america-votes/trump-first-lady-positive-for-covid-19-u-s-president-has-mild-symptoms-1.5129420

Unlike any other time in history, we are inundated with information from many sources of media. And we are racing to catch up to what is reliable, dependable, and true – all the while, feeling deep, emotional, attachments to our personal understanding of important issues. It has unfortunately become quite fashionable today to claim that what people feel about issues should be taken as seriously as the facts about those issues. Emotional attachment to specific viewpoints and the facts about the world are often two completely different things. It's not as though a person's feelings are not to be validated; they are. However, one's feelings should only be validated up and until the point where they conflict with the facts.

Conspiracy theorists can be our brothers, sisters, parents, kids, neighbours, or anybody.

But what if facts have no bearing in a conversation with a conspiracy theorist? Are we to rely then, purely on logic? We might think so; but seldom is the case that logic is at the forefront of a conspiracy theory. So, if conspiracy theorists don't care much for logic and facts, what do they care for? Being heard; being unique; and gaining status in society because of their exclusive insights and access to information. So the first lesson in how to talk to a conspiracy theorist is to listen. Let them do the talking; because they will but only if they have some feeling of trust in the dialogue. The next steps involve the development of a Socratic method of dialogue combined with the therapeutic counselling of Cognitive Behavioural Therapy. Trying to understand the underlying needs for such status, we can gradually come to better appreciate the context and biases under which a conspiracy theorist developed their views. With this understanding, we are in a much better position to begin to introduce, gradually, inconsistencies or contradictions in their beliefs. Over time, it is possible to have more meaningful dialogue with conspiracy theorists. And ultimately, this is what we want to be able to do more successfully – because they are our brothers and sisters, or parents, or kids, or neighbours, or anybody.

Recommendations – What Needs to be Done *Now*:

As we saw in Part II of this series, what the world needs right now is the development and distribution of hundreds of thousands of portable, fast, and accurate testing devices throughout the world – especially those locations and countries most affected. I am indeed saddened and disheartened to learn that our governments squandered the opportunity to ramp up quicker, more accurate point-of-care testing units at key locations throughout the country back in early July. So I am hopeful that the recently purchased US Abbott NOW Testing Units will be utilized widely throughout our own province and country, at hospitals, retirement homes, police, ambulance, and fire

stations, all supply side and food distributors and processors, migrant workers, borders, airports, bus stations, etc.

Conclusion:

I am hopeful that a vaccine will be ready for distribution by late 2020 or early 2021. And I am hopeful that better testing becomes utilized more quickly than it has been. We need to move forward intelligently and with compassion for those who are suffering most during this pandemic. Let us hope then, that our leaders become a little more capable of using Critical Thinking and Ethical Reasoning skills when it comes to dealing with the next phases of this pandemic.