

SCIENTIFIC CONSIDERATIONS FOR USING COVID-19 VACCINATION CERTIFICATES

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ISSUE

This report provides an overview of the relevant scientific knowledge and considerations regarding the use of COVID-19 vaccination certificates to support a safe return to travel and other economic activities. Several vaccines, developed using different technology platforms, have proven effective at protecting against severe forms of COVID-19 and are being rolled-out worldwide. Fully vaccinated individuals have a significantly decreased risk of SARS-CoV-2 infection and likely have a decreased risk of spreading the infection to others. Some countries have started issuing “vaccination passes/certificates” to vaccinated individuals, allowing them to access public places and services without restrictive measures. Proof of vaccination is also set to be used to reopen international borders without the need for some existing COVID-19 measures, such as traveler testing and quarantine. The use of COVID-19 vaccination certificates to access crowded venues is predicated on the effectiveness of the different vaccines to mitigate the risk of importing or spreading SARS-CoV-2 and its emerging variants. The use of these certificates for non-medical purposes also raises social-ethical-legal questions that merit careful consideration.

CONTEXT

The [Chief Science Advisor Expert Panel on COVID-19](#) convened with additional experts to review the scientific, ethical, social, legal considerations and potential uses of COVID-19 vaccination certificates. This report is informed by discussions held on February 26 and March 5, 2021, as well as the special meeting on SARS-CoV-2 infection, vaccination and immunity held on March 18, 2021. The list of participating experts is provided at the end of this document.

The COVID-19 pandemic caused by the SARS-CoV-2 virus has had devastating health, social and economic consequences around the world. In the absence of effective medical countermeasures, preventing disease and minimizing the spread of infection has required exceptional public health measures, including lockdowns, travel restrictions and quarantine. The development and administration of vaccines against COVID-19 has been broadly communicated as a key step to returning to pre-pandemic conditions. Thanks to unprecedented global efforts and public-private partnerships, several highly effective vaccines are being produced, and mass vaccination is underway in many countries, including Canada, since January 2021.

As more people get vaccinated, there is an expectation that this will lead to lifting some restrictions and/or gaining access to public places, gatherings or services. Some countries are indeed considering, or have already implemented, a proof

of vaccination system for people to gain access to certain places. For example, Israel has issued a **Green Pass**, which is required for access to certain venues. The European Commission is proposing to roll out a **Digital Green Certificate** that will allow individuals who have received an approved COVID-19 vaccine or who have antibodies from a natural infection to travel freely within the European Union. The United Kingdom is also considering making such COVID-19 health certificates mandatory to help reopen the economy. To ensure accurate information on passengers' COVID-19 health status – including proof of vaccination – the global airlines group, International Air Transport Association (IATA), is working on launching a digital **Travel Pass**. However, given uncertainties about SARS-CoV-2 transmission post-vaccination and limited global access to vaccines, the World Health Organization (WHO) recommended against requiring proof of COVID-19 vaccination for international travel in an **interim position paper**.

SCIENTIFIC CONSIDERATIONS

How we decide to use vaccination certificates requires careful consideration of the effectiveness of each available vaccine at preventing disease and limiting viral transmission – including against SARS-CoV-2 variants. Other important information includes the level and duration of protection in different age and population groups. Some data are already

available, and it is expected that scientific knowledge will continue to evolve over the coming months. A summary of the relevant scientific knowns and uncertainties about vaccines, immunity, and transmission is outlined below.

Scientific knowns

Unprecedented global research and development efforts have already resulted in the production and testing of several safe and effective COVID-19 vaccines using traditional (inactivated vaccines, protein subunit) as well as novel platforms (RNA, adenovirus vector). As of early January 2021, there were 63 candidate vaccines in human clinical trials, including 12 in or post Phase III and more than 172 candidates in preclinical development worldwide.¹ Table 1 below provides information on the vaccines that are currently being used for mass COVID-19 vaccination in different countries. Most countries have used interim, emergency use, or conditional authorization pathways, based on early data, while Phase III trials continue for long-term safety follow-up.

Table 1: COVID-19 vaccines currently in use in different countries

Platform	Name	# of Doses	% Efficacy**
mRNA:	Moderna*	2	~ <u>94</u>
	Pfizer-BioNTech*	2	~ <u>95</u>
Viral vector:	AstraZeneca & Serum Institute of India*	2	~ <u>76</u>
	Janssen*	1	~ <u>66</u>
	CanSino	1	~ <u>65</u>
	Gamaleya ('Sputnik')	2	~ <u>92</u>
Inactivated virus	Sinovac	2	~ <u>50</u>
	Sinopharm (Beijing)	2	~79
	Sinopharm (Wuhan)	2	~72
	Bharat Biotech	2	~ <u>81</u>
Protein/VLP	Vektor Institute/EpiVacCorona	2	N/A

*Vaccines approved for emergency use in Canada.

**Efficacy refers to the percent reduction of disease in a group of people fully vaccinated in a clinical trial study; efficacy measures cannot be directly compared as each trial may be collecting data differently.

To date, five vaccines have received emergency use authorization from Health Canada, including the Oxford-AstraZeneca vaccine and a related version from the Serum Institute of India. They belong to two different platforms: mRNA vaccines (Pfizer-BioNTech and Moderna) and viral vector vaccines (Janssen and the AstraZeneca/Serum Institute vaccines).² A sixth vaccine, Novavax (protein subunit platform), is currently under review by Health Canada and domestic production is being secured. All COVID-19 vaccines **authorized by Health Canada** are efficacious against symptomatic COVID-19 disease in adults 18 years and older (16 and older for Pfizer-BioNTech). They require a two-dose vaccination course, except for Janssen, which requires one. Individuals are considered fully vaccinated two weeks after receiving the second dose. So far, the duration of protection post-infection

is documented for eight months or longer;³ as vaccines are new, ongoing studies will shed light on the duration of protection post-vaccination. Of note, all five vaccines have shown (from clinical trials and real-world evidence) 85% to 100% protection against severe forms of the disease leading to hospitalization and death.^{2,4-9} Some have shown reduced viral loads upon infection.¹⁰

Clinical trials and real world evidence indicate that protective immunity is observed starting about two weeks (or longer in some cases) after the first dose and maximal protection is reached after the second dose, except in the case of single-dose vaccines (such as Janssen). For vaccines requiring a two-dose course, the antibody response raised by the first dose depends on the age and health status of the vaccinated individuals and the time from inoculation.¹¹⁻¹³

Of note, the current COVID-19 vaccines were developed against the original SARS-CoV-2 strain. However, newer variants of the parent virus have emerged and some have become the prevalent variant in certain countries, notably the B.1.1.7 that was first identified in the UK, the B.1.351 that was first identified in South Africa and the P.1 variant that was first identified in Brazil. These variants are present in Canada and B.1.1.7 may become the prevalent variant in the coming months. The efficacy of existing COVID-19 vaccines against these variants is an area of active study. The vaccines currently authorized in Canada are effective against disease caused by the B.1.1.7 variant and offer differential levels of protection against the other two variants.¹⁴⁻¹⁷

Scientific uncertainties

Given the short time since the COVID-19 vaccines have become available, it is not surprising that many scientific uncertainties persist and are the subject of intense ongoing studies. They include 1) the ability of vaccines to reduce/eliminate SARS-CoV-2 transmission, 2) duration of immunity, 3) correlates (indicators) of protection, 4) vaccine efficacy/effectiveness in specific populations and in individuals with prior infection, and 5) protection against infection/reinfection by different virus variants.

Such knowledge directly impacts the utility of vaccination certificates in different contexts. Additional uncertainties include the impact of lengthening the dosing interval on vaccine efficacy and duration of immunity, and the effects of the first dose on viral transmission and protection against SARS-CoV-2 variants.

- 1) *Ability of vaccines to reduce/eliminate SARS-CoV-2 transmission:* The vast majority of Phase III clinical trials were designed to detect symptomatic infections. Whether the vaccines also protected against asymptomatic infections was not specifically evaluated. In other words, it has not been directly established yet whether **vaccinated individuals become the equivalent of asymptomatic carriers who can continue to infect others.** However, preliminary evidence suggests that the two-dose course of the Pfizer-BioNTech mRNA vaccine (administered at a 21-day interval) reduces viral shedding and sub-clinical infection, thereby minimizing onward SARS-CoV-2 transmission post-vaccination.^{10,18,19} Similarly, during the Moderna trial, participants were tested twice, one month apart, for the presence of viral RNA and a 2/3 decrease in asymptomatic infections was observed in fully vaccinated individuals.⁵ The AstraZeneca trial also observed decreased viral load in a group of vaccinated versus unvaccinated participants.²⁰ This, together with the decline in infections in places with high vaccination rates, may point to an indirect beneficial effect due to decreased transmission from vaccinated people. A more definitive answer to this important question, including how well different vaccines block chains of transmission, will likely emerge in the coming months.

- 2) *Duration of immunity:* Given the recent history of COVID-19, duration of immunity following natural infection or vaccination beyond 8 to 10 months is uncertain. Rates of reinfections have been generally low but will need to be carefully monitored, especially with the emergence of new variants of concern (VOCs). Longer-term studies are ongoing to evaluate how long immunity and protection from COVID-19 disease lasts. A recent observational study suggests that reinfection risk increases with age.²¹
- 3) *Correlates of protection:* It is not yet known what specific, measurable immune markers are most predictive of protection against infection and population immunity. Drawing from animal studies, antibodies may serve as good correlates of immunity.²² Furthermore, the mRNA vaccines induce a very strong antibody response, much stronger compared to an individual fighting a SARS-CoV-2 infection (convalescent).^{23,24} The viral vector vaccines induce a lower antibody titer, but are comparable to convalescent individuals.^{25,26} Early data from protein-based vaccines (e.g. Medicago, Novavax) also induce strong antibody responses.² While studies use neutralizing antibody levels (titers) and neutralizing activity as correlates of protection, existing studies have shown that, three weeks post-immunization with the first dose of a mRNA vaccine, there is observed efficacy even in the absence of neutralization activity, suggesting that immune components other than neutralizing antibodies may be at play.²⁷ For example, non-neutralizing antibodies with other immune stimulating properties may contribute to vaccine-induced protection; if confirmed by further studies, this could offer an accessible way to determine protection in vaccinated and previously infected individuals by assaying for total anti-spike antibodies. T cells are another key component of the immune response and are also known to play a role in COVID-19 immunity.^{28,29} The ability to measure an immune marker of protection would help monitor protection over time for the different types of vaccines and vaccine platforms. It will answer key questions of the threshold required for protection and durability.
- 4) *Vaccine efficacy:* Available COVID-19 vaccines have different levels of efficacy against symptomatic disease caused by the original virus and by variants of concern as measured in clinical trials, illustrated in the table in Annex 1. It will be important to establish how efficacy against disease in clinical trials is correlated with the results observed in the general population.
- 5) *Prior infection:* Immunity post-vaccination and immunity post-recovery are not the same. Currently, vaccination is recommended for all eligible individuals, even those who have recovered from COVID-19 disease. Interestingly, preliminary evidence suggests that one dose of a two-dose vaccine regimen may be sufficient to elicit maximal immune response in individuals with prior COVID-19 infection.³⁰⁻³² However, the impact on disease transmission is uncertain. Of note, prior infection with the original SARS-CoV-2 may not protect against

infection by new variants of the virus, as suggested by COVID-19 resurgence in Manaus, Brazil.

In summary, when administered according to manufacturer specifications, current COVID-19 vaccines show high level protection against severe forms of the disease that lasts at least six to eight months. However, the protection they confer against asymptomatic infection and how effective they are at stopping viral transmission may be variable. Additionally, the efficacy of different vaccine platforms against newer SARS-CoV-2 variants differs. Thus, important scientific information for COVID-19 vaccine certificates, such as durability of immunity and efficacy at reducing infection and virus transmission, will need to be considered separately for each class of vaccines.

USAGE CONSIDERATIONS

A **personal immunization record** is usually issued to vaccine recipients as part of routine health-record keeping. With this record, healthcare providers understand their patients' vaccination history, and can help keep to the recommended vaccine schedules to prevent illness. Public health programs also track vaccination rates to focus efforts where needed to manage outbreaks based on evidence. Assuming that vaccines limit disease spread, proof of COVID-19 vaccination may also be used to facilitate safer domestic and international travel or for safer reopening of the economy. As mentioned above, present evidence suggests that fully vaccinated individuals, i.e., those who have received the full two-dose vaccine

regimen, have a decreased risk of spreading the SARS-CoV-2 virus. In all instances, consideration must be given to individuals not eligible to be vaccinated (e.g., children under 16, or those with medical conditions) and alternatives offered. For example, some countries are considering including information on immunity from natural infection and recent negative COVID-19 diagnostic tests in their COVID-19 certificates. The following examples illustrate the potential use of vaccination certificates to facilitate people's movement and access to public places.

To facilitate travel

Domestic travel: Some Canadian provinces and territories have put in place quarantine requirements for interprovincial travellers or restricted travel access in order to control the pandemic. There could be interest in using vaccination certificates to permit safe travel between provinces, eliminate the need to quarantine, and protect remote and vulnerable communities.

International travel: To prevent ongoing transmission of SARS-CoV-2 around the globe, **travel restrictions** to enter and leave Canada are in place. Unless exempt, eligible international travellers age five and over entering Canada must take an approved COVID-19 test prior to departure and upon arrival, and then quarantine. COVID-19 vaccination certificates could facilitate travel to countries that demand proof of vaccination, similar to those for yellow fever or polio vaccinations, where an International Certificate of Vaccination is required under the WHO's International Health Regulations (IHR). The WHO has also released interim guidance for developing a **Smart Vaccination Certificate**.

Several countries are using or considering the use of COVID-19 vaccination certificates for travel with digital solutions; in the future the requirement for a negative COVID-19 test and quarantine could be replaced with a vaccination certificate or a combination of test and vaccination certificate.³³ Current costs of travel related to testing and quarantine are significant. If vaccination certificates increase safety and ease some costs, this could be a significant benefit for Canadians, many of whom have been unable to visit their families within and outside Canada for some time.

To access public spaces and services

For many Canadians, an important benefit of vaccination is a return to normal, pre-COVID life, including access to certain venues and activities. Vaccination certificates could be used to congregate in larger gatherings such as sporting events, music concerts and festivals. They could also be used to physically return to work, especially in higher-risk workplaces where mask wearing and/or maintaining physical distance is difficult or impossible.

Restricting access to activities or places based on criteria imposed by government or business is not a new concept. At the industry level, efforts are already underway to build digital vaccination certificates to be required in businesses and workplaces. Polls indicate that a majority of individuals are willing to be vaccinated if required by their employer or if it gives them access to desired activities such as travel, concerts, etc.^{34,35}

ETHICAL AND SOCIAL CONSIDERATIONS

Equity and fairness are important ethical concerns regarding the use of vaccination certificates.^{36,37} In the absence of universal access to vaccines, if vaccination certificates are used to gain access to different spaces, this could create a “haves” and “have nots” dynamic between those who are vaccinated and those who are not, and lead to tensions among communities. In addition, special attention needs to be directed to certain racialized, Indigenous and disadvantaged communities. These communities may lack trust in established medical institutions and/or their governments due to historical harms, such as experimentation without consent in residential schools and persistent inequitable care experienced in the medical system, leading to comparatively low vaccination intentions.^{38,39} This could amplify the already disproportionate impact of the pandemic on these groups. Access to vaccines also requires consideration of the disproportionate impact that COVID-19 is having on population groups with pre-existing social and medical vulnerabilities.⁴⁰ For example:

- Essential workers, such as grocery store staff and bus drivers who face the public directly, but who may not have been prioritized for vaccination, could be temporarily disadvantaged by vaccination certificates.
- The use of vaccination certificates in workplaces could affect job opportunities for those who do not have access to the vaccine or who are exempt for medical reasons. For example, young adults are not

currently prioritized to be vaccinated and those under 16 are not authorized; they may face higher unemployment as a result.

It should also be noted that while the anticipation of more freedom may be an incentive for some to get vaccinated, vaccine acceptance could decrease in others if there was a sense of coercion tied to using vaccination certificates.

LEGAL CONSIDERATIONS

- *Jurisdictional*: Vaccination records are considered part of a health record, issued within provincial and territorial (P/T) health-care jurisdictions. For international travel, a Canadian COVID-19 vaccine certificate may be required. P/T authorities provide a paper record of vaccination, and some, like Manitoba, have an electronic record. Manitoba has online [COVID-19 result and immunization display](#). Provinces lack interoperable vaccine registries and there is no standardized, secure technology system in place yet that could be built upon.
- *Privacy*: Privacy implications of vaccination certificates should be anticipated and addressed. These depend on the design of the certificates themselves, and the manner and circumstances in which they are delivered and can be presented. The concept of vaccination certificates is premised on individuals sharing sensitive information about their health in order to gain access (or

preferential access) to certain spaces (e.g., “Show your certificate, get into the stadium”). In so doing, individuals are sharing health information with a third party – raising privacy concerns and questions of data ownership. This can be further complicated by the need, in some cases, for additional health information such as past infection history. Clarity and transparency with respect to how these data are managed, including storage and sharing, will be essential to maintain public trust and privacy rights.

- *Authenticity*: If certificate requirements become common, a credible proof of COVID-19 vaccination to anyone who has been vaccinated will be needed, regardless of where they are in the country. There will be a need to ensure authenticity and minimize fraud. Several private sector enterprises are developing technologies and platforms to prevent counterfeiting. It will be essential that such certificates be obtainable in both electronic and paper form to ensure that those who do not have cell phones are not discriminated against.
- *Legitimacy*: The processes by which vaccine certificates are issued and controlled need to be fraud proof, both the Canadian version(s) and the incoming international certificates. Some groups or communities who have suffered historic biases and profiling may face increased scrutiny. Clearly defining in law the contexts in which vaccination certificates must be presented could avoid vaccination certificates becoming a predicate for harassing racialized populations.

CONCLUSION

As with any vaccination, a record of COVID-19 vaccination will be available to vaccinated individuals. Because COVID-19 vaccination is viewed as a key element in preventing disease spread and reopening the global economy, vaccination certificates are being considered for safe international travel and for gaining access to domestic services and venues. Compared to other vaccination certificates, such as that for yellow fever, COVID-19 vaccination certificates present more complexity due to factors such as the multiplicity of available COVID-19 vaccines and the uncertainty regarding their efficacy against the different virus strains spread across the globe, among others.

The utility of COVID-19 vaccination certificates beyond healthcare settings is predicated on the effectiveness of the vaccines at eliminating or reducing viral transmission and the duration of the protection they confer. Answers to these important scientific questions will continue to be generated over the coming months. Results may differ among the various authorized COVID-19 vaccines currently being administered worldwide. The length of time for which a vaccination certificate will be valid before a new one is required will need to be established for each vaccine and will depend on duration of immunity. In addition, varying efficacy at reducing infection by new variants and eliminating viral spread will need to be considered for each class of vaccines.

When it comes to the use of COVID-19 vaccination certificates for international travel, the federal government will undoubtedly need to coordinate with international organizations and partners. Vaccination certificates have the potential to facilitate departure and arrival logistics and decrease airport crowding which in turn increases health safety for travellers and airport workers alike. Issues such as the state of local epidemics (of the home and destination countries) and acceptability of vaccines approved by different regulators will have to be considered in determining pre- and post-arrival measures. Due to limited vaccine supplies and the fact that certain age and population groups are not eligible for vaccination, alternatives to vaccination certificates need to be available for the foreseeable future.

The domestic use of vaccination certificates raises additional socio-ethical-legal questions that need careful consideration in order to promote both vaccine acceptance and social cohesion. When using vaccination certificates beyond an immunization record, equity, human rights and privacy must be respected to achieve the delicate balance of necessity and proportionality, especially in the context of the evolving COVID-19 vaccine science.

This is a rapidly advancing area and governments can play a role to develop effective policies and frameworks to

protect the interests of all citizens before private companies implement ad hoc mandates for proof of vaccination.

As such, all levels of government could work together to develop a framework that:

- Defines who is considered “vaccinated” in a two-dose vaccine regimen when the dosing interval deviates significantly from what was used to determine efficacy;
- Provides guidance on data standardization for vaccination certificates within Canada and aligns where possible with international standards;
- Minimizes fraud, inappropriate use and potential negative impacts on vulnerable populations of vaccination certificates; and,
- Maximizes consistent post-vaccine monitoring, ongoing research, and epidemiologic data-sharing, all of which provide the essential scientific basis for the utility of vaccination certificates within and outside the healthcare context.

ANNEX 1: EFFICACY OF DIFFERENT VACCINES AGAINST CIRCULATING VARIANTS OF CONCERN

Table 1. Summary Results on SARS-CoV-2 Vaccine Trial Efficacy and Viral Neutralization of the B.1.1.7, P.1, and 501Y.V2 Variants, as Compared with Preexisting Variants.*

Vaccine (Company)	Preexisting Variants			Neutralization by Pseudovirion or Live Viral Plaque Assay			Efficacy in Settings with 501Y.V2 Variant
	Sample Size	Efficacy in Preventing Clinical Covid-19	Efficacy in Preventing Severe Covid-19	B.1.1.7 Variant	P.1 Variant	501Y.V2 Variant	
	no.	% (no. of events with vaccine vs. placebo)					%
Ad26.COVS.2 (Johnson & Johnson)	43,783	66 (NA)	85 (NA)	NA	NA	NA	57†, 85‡
BNT162b2 (Pfizer)	34,922	95 (8 vs. 162)	90 (1 vs. 9)	Decrease by 2×	Decrease by 6.7×	Decrease by ≤6.5×	NA
mRNA-1273 (Moderna)	28,207	94 (11 vs. 185)	100 (0 vs. 30)	Decrease by 1.8×	Decrease by 4.5×	Decrease by ≤8.6×	NA
Sputnik V (Gamaleya)	19,866	92 (16 vs. 62)	100 (0 vs. 20)	NA	NA	NA	NA
AZD1222 AstraZeneca	17,177	67 (84 vs. 248)	100 (0 vs. 3)	NA	NA	Decrease by ≤86× to complete immune escape	22§
NVX-CoV2373 (Novavax)	15,000	89 (6 vs. 56)	100 (0 vs. 1)	Decrease by 1.8×	NA	NA	49§
CoronaVac (Sinovac)¶							
Brazil	12,396	51 (NA)	100 (NA)	NA	NA	NA	NA
Turkey	7,371	91 (3 vs. 26)	NA	NA	NA	NA	NA
BBIBP-CorV (Sinopharm)	NA	79 (NA)	NA	NA	NA	Decrease by 1.6×	NA

* Data were available up to March 18, 2021. The definitions of mild, moderate, and severe coronavirus disease 2019 (Covid-19) vary across the vaccine trials. A list of references associated with these vaccines is provided in the Supplementary Appendix, available with the full text of this letter at NEJM.org. NA denotes not available, and SARS-CoV-2 severe acute respiratory syndrome coronavirus 2.

† Shown is the efficacy of the vaccine, as compared with placebo, against moderate-to-severe Covid-19.

‡ Shown is efficacy of the vaccine, as compared with placebo, against severe Covid-19 and hospitalization.

§ Shown is efficacy of the vaccine, as compared with placebo, against symptomatic Covid-19.

¶ Data are shown separately for the trial sites in Brazil and Turkey.

Source: Salim S. Abdool Karim, M.B., Ch.B., Ph.D., *New SARS-CoV-2 Variants – Clinical, Public Health, and Vaccine Implications*, NEJM, March 24, 2021 DOI: 10.1056/NEJMc2100362

ANNEX 2: EXPERT PANEL CONTRIBUTORS

Meetings held on February 26 and March 5, 2021

Participating Experts

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Disease modelling

- Caroline Colijn PhD, Simon Fraser University
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Invited Experts

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- David Castle PhD, University of Victoria and Office of the Chief Science Advisor Researcher in Residence
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Special meeting on SARS-CoV-2 infection, vaccination and immunity held on March 18, 2021

Participating Experts

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