

A resource for HEALTH CARE PROVIDERS





IMMUNIZATION COMMUNICATION TOOL 2021



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Graphic Design Tom Norman, Kapow Creative

Introduction

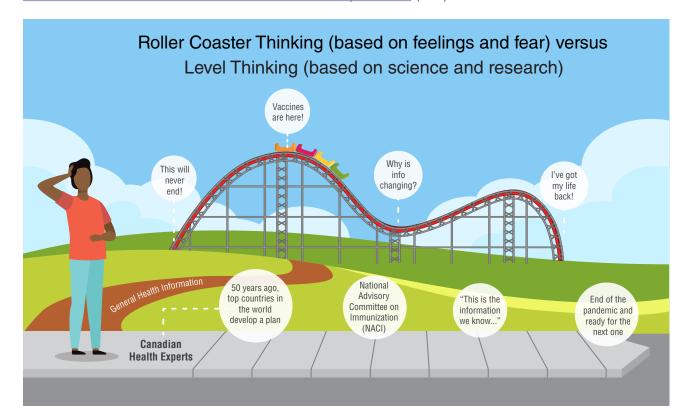
We find ourselves in unprecedented times. The information surrounding the COVID-19 pandemic seems to change on a daily basis. Health care providers are not only challenged to gain competency in COVID-19 immunization programs but also to find answers to their own questions and address the concerns of their clients.

As new information emerges daily, this tool provides a communication approach that removes the need to memorize vast amounts of information.

We invite you off of the media rollercoaster with the daily wave of changing information and on to the moving train which follows the stable, robust immunization systems that are based on ethical and evidence-based processes. Transparency around what we do know and honesty around what we have yet to learn is important but "we don't do science by press releases" (Dr. Theresa Tam, Canada's Chief Public Health Officer).

This tool will provide some key concepts to support healthcare providers to address COVID-19 vaccine hesitancy.

For more support on immunization communication and addressing vaccine hesitancy, refer to the <u>5 step approach to discussing vaccines and addressing vaccine hesitancy</u> in the <u>2021</u> Immunization Communication Tool for health care providers (ICT)

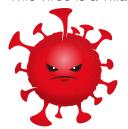


Steps	Rationale & Discussion Points
Acknowledge your client's concerns	 Trust in a health care provider is key in supporting vaccine acceptance Building a trusting relationship is essential particularly amidst changing information that is hard for the public to access and confirm Listening to your client helps you to better understand their specific needs and deliver vaccine information in a caring and compassionate manner
Focus on the right risk	 The risk of COVID-19 infection and disease must be discussed in any immunization conversation For a vaccine to be approved in Canada, the benefits must significantly outweigh any risk The risks and harms of COVID-19 disease in this pandemic far outweigh any potential side effects of a COVID-19 vaccine
Describe the trustworthiness of Canada's immunization system	 New and emerging data are released frequently making it difficult for health care providers and clients to stay up-to-date Be confident in the knowledge that Canada has excellent public health systems which actively and continually monitor for vaccine effectiveness and safety Learning about these systems normalizes for both health care providers and the public how immunization programs may change over time Reinforcing the ethical processes that govern Canada's public health programming can instill trust and remove the urgency to consume and respond to daily media claims Recognize that Canada's health care system has not been and is not a safe or trust worthy setting for some populations such as Indigenous peoples and that cultural humility is foundational to support building of trust
Make a strong recommendation	The strength of a health care provider's recommendation can greatly influence a person's decision to vaccinate their child or get vaccinated themselves

1. The Virus (SARS-CoV-2)

Key messages for the public

This virus is a villain!



- Easily spread (SPREADS)
- Potentially fatal (KILLS)
 - Illness can vary from no symptoms or mild symptoms, to hospitalization and death
- Can change and adapt (ADAPTS)

SARS-CoV-2 comes from a family of viruses called Coronaviruses because they have spikes on the outside wall which look like a crown.



More information for health care providers

Coronaviruses have been identified as human pathogens since the 1960s. To date, seven coronaviruses have been shown to infect humans, including SARS-CoV-2. The disease caused by the new severe acute respiratory syndrome Coronavirus 2 or SARS-CoV-2, and responsible for this global pandemic, has been named COVID-19.

Seven coronaviruses affect humans:

- Four cause the common cold (mild, highly contagious, upper airways only)
- One caused SARS in 2002 (severe, not very contagious, lower lungs)
 - 8,000 cases and 774 deaths
- One caused MERS in 2012 (more severe, not very contagious, lower lungs)
 - 2,500 cases and 858 deaths
- One causes COVID-19 (is BOTH highly contagious and can cause severe disease, lower lungs)



SARS-CoV-2 Variants

Viruses change over time and can lead to new variants. Some variants of SARS-CoV-2, known as Variants of Concern can spread more easily, cause more serious illness and maybe less impacted by current vaccines. Research on the relationship between current vaccines and the new Variants of Concern is ongoing.

SARS-CoV-2 Virus Characteristics	Potential COVID-19 Vaccine Implications
We don't know how long protection (immunity) lasts after COVID-19 infection	We don't know how long protection lasts after COVID-19 vaccination so we may need booster doses in the future
Spreads easily and quickly from person to person	Higher vaccination rates are needed to achieve community (herd) immunity
Even with low and undetected person to person spread, the virus can re-emerge and result in large clusters or outbreaks in non-immune populations	We may need an ongoing vaccine program even if there is no current spread in our communities
Can be spread from person to person without any symptoms (asymptomatic transmission)	Until the majority of the population is vaccinated, public health measures (e.g., wearing masks, maintaining physical distance, washing hands regularly etc) will need to continue as no vaccine is 100% effective at preventing infection
Advanced age is the most significant risk factor for severe health outcomes	We may need higher doses of antigen or use of adjuvants in the vaccines to boost the immune response in the elderly
Changes and adapts, resulting in variants (e.g., spreading more easily or causing more severe disease)	The vaccines may be less effective

Client Question: "Why do I need the vaccine? COVID-19 isn't really that bad."		
STEP	SUGGESTED RESPONSE	
Acknowledge your client's concerns	"I hear what you're saying - a lot of people have found it hard to confirm the number of hospitalizations and deaths which can make it hard to understand how dangerous this virus can be"	
Focus on the right risk	"COVID-19 is considered very dangerous because it spreads as easily as the common cold but can have severe outcomes" "It is much safer to get the vaccine than it is to stay unprotected against COVID-19 during this pandemic" "Some people who choose not to vaccinate often do so to avoid risk, but choosing not to vaccinate is the riskier choice, putting both themselves and others at risk" "We are still learning about this virus including any lasting effects from COVID-19 infection" "If cases continue to rise, it has the potential to overwhelm the health care system and care may not be available to those who need it the most"	
Describe the trustworthiness of Canada's immunization system	"In Canada, immunization programs are set up to stop the spread of diseases that are dangerous and vaccine preventable" "Immunization not only protects people who have received the vaccine, it also protects those who may be vulnerable, including those who are unable to get the vaccine" "Canada has been dedicated to vaccine safety for decades. Because vaccines are given to healthy people, including children, they are held to the highest safety standard—even higher than most drugs used for treatment"	
Make a strong recommendation	"As a health care provider, I recommend that you receive this vaccine to protect you against COVID-19 which is spreading in B.C. and around the world" "As a health care provider, I trust Canada's Public Health systems. My family and I receive all recommended vaccines"	

2. Types of COVID-19 Vaccines

Key messages for the public

- All of the different types of COVID-19 vaccines approved for use in Canada are safe and effective at preventing serious disease, hospitalizations and death
- The technology behind the mRNA vaccines was developed 20+ years ago
- Viral vector vaccines are a well-established technology
- None of the vaccines can change your own genes (DNA)

More information for health care providers

A comparison of the COVID-19 vaccine platforms

Platform	Strengths	Limitations
mRNA	High potency therefore no adjuvant needed to boost the immune response	 Storage and delivery challenges with ultra low-temperature formulations
5	 Interchangeable antigen affords easier and faster production 	 Newer technology leads to questions/concerns from the
	 No risk of genomic integration (can not enter the DNA of the cell) 	public, may result in distrust
	 No live virus, so no risk of the vaccine causing COVID-19 disease 	
Did you know? Moderna and Pfizer did not suddenly produce mRNA vaccines in under a year. They used the mRNA vaccine platform that scientists had spent 20+ years developing. This platform gave them the technology to insert the necessary genetic code and complete the design for an effective COVID-19 vaccine. The manufacturing of mRNA vaccines has fewer steps which shortens the length of time required to get regulatory approval.		

Limitations **Platform Strengths Viral Vector** • Well-studied in clinical trials Previous antibodies to the viral vector (from wild type virus or • Induces immune system memory vaccine) may lessen the immune without an adjuvant response to future COVID-19 No live virus, so no risk of the vaccines using the same viral vaccine causing COVID-19 vector disease Complex to manufacture and produce Viral vector vaccines have been used in recent Ebola outbreaks and played Did you know? a key role in containing the Ebola virus. Well-established technology Often more vaccine doses are **Protein Subunit** needed Easy to design in the lab Recombinant An adjuvant is required to boost the Less risk of side effects immune response No live virus, so no risk of the Slower manufacturing vaccine causing COVID-19 disease We have used protein subunit recombinant vaccines for decades in B.C., Did you know? including the Hepatitis B and HPV vaccines.

Client Question:		
"I'm worried that these vaccines will change my DNA"		
STEP	SUGGESTED RESPONSE	
Acknowledge your client's concerns	"Thanks for bringing this up with me. This is a topic that has got a lot of media coverage and I'd like to know more about what you've heard."	
Focus on the right risk	"COVID-19 is a serious virus that spreads fast and can have severe outcomes"	
	"The risk of COVID-19 disease far outweighs any risk of getting the vaccine. We need to keep focused on this real and present risk"	
	"COVID-19 vaccines do not change your DNA"	
Describe the trustworthiness of Canada's immunization system	"All vaccines approved for use in Canada meet strict criteria for safety and effectiveness" "We've studied vaccines for a long time and we know that the vast majority of adverse reactions will emerge within 6 weeks after the immunization. That is why the vaccine regulators around the world required the manufacturers to provide 8 weeks of safety data, and continue to monitor the situation"	
Make a strong recommendation	"As a health care provider, I recommend that you receive this vaccine to protect you against COVID-19 which is spreading in B.C." "As a health care provider, I trust Canada's Public Health systems. My family and I receive all recommended vaccines"	

3. Efficacy of COVID-19 Vaccines

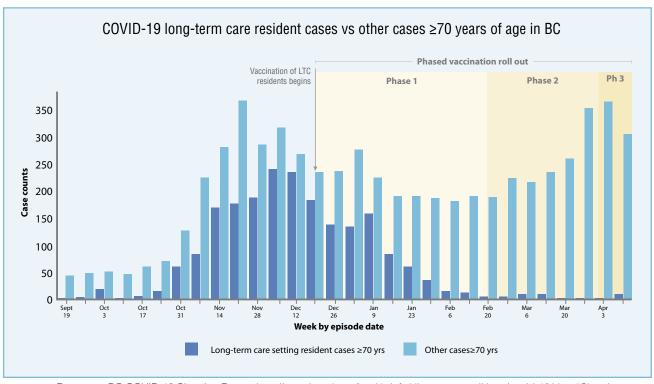
Key messages for the public

- Health Canada only approves vaccines that have shown that they are safe and work well
- After approval, Canada's Public Health system monitors how the vaccines work in the real world
- All the vaccines that are approved for use in Canada are safe and effective.
- Accept the first vaccine that you are offered, to ensure that you will have the best protection as soon as possible
- It is not known how long vaccine protection lasts yet, but we do know that it will provide protection now during the pandemic while the virus continues to spread

More information for health care providers

Key Concepts	What is it?	Why does it matter?
Vaccine Efficacy	The measure of how well a vaccine works in a clinical trial. Efficacy is true for that trial at that time in that group of people.	The clinical trials must demonstrate that the vaccine works and is safe before it can be approved in a general population. There are no clinical trials comparing different COVID-19 vaccines to assess their effectiveness relative to one another.
Vaccine Effectiveness	The measure of how well a vaccine works in the real world. Effectiveness is true for large groups of people of different ages, medical conditions, and ethnicities. For example: Early surveillance	To ensure that the vaccines work in the real world protecting different populations that were not included in the clinical trials (health conditions, ages, ethnicities).
	data of COVID-19 cases among long term care (LTC) residents showed a dramatic decrease after the start of the vaccine roll out in BC with fewer hospitalizations and deaths - see graphic on next page.	

Key Concepts	What is it?	Why does it matter?
Correlates of Protection	For many viruses, antibody levels are measured to determine the level required for protection or immunity.	To determine if there is a measurable level of antibodies that indicate immunity to the COVID-19 virus after vaccination.
Clinical Endpoints	An event or outcome that can be measured objectively to determine whether the vaccine being studied is beneficial.	Because the COVID-19 vaccine trials had to rely on clinical endpoints that were different, you can't compare the vaccines directly.
Duration of Protection	After a COVID-19 infection, the antibody development is rapid but wanes over time, which is consistent with other coronavirus infections where lasting immunity is rare.	In the event of an exposure or outbreak it is important to understand who is immune, who needs to quarantine and who should be offered the vaccine.



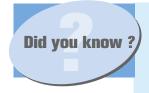
Resource: BC COVID-19 Situation Report http://www.bccdc.ca/health-info/diseases-conditions/covid-19/data#Situationreport

Client Question: "Does this vaccine really work? Aren't some brands better than others?"		
STEP	SUGGESTED RESPONSE	
Acknowledge your client's concerns	"I've had several patients ask me about how the vaccines work and if one is better than the other. Tell me more about what concerns you"	
Focus on the right risk	"All vaccines approved for use in Canada work, regardless of the brand. The vaccines we're using protect against the risks of COVID-19 disease and severe (serious) health outcomes such as hospitalization, ICU admissions and death"	
	"It's important to remember that COVID-19 is a serious disease spreading in our communities. We need to protect people soon as possible"	
	"We are in a race against this virus before it changes so much (i.e., variants of concern) that the vaccines become less effective"	
	Accepting the vaccine you are offered first will ensure that you will receive the best protection as soon as possible	
Describe the trustworthiness of Canada's immunization system	"We have systems in place to make sure that vaccines are working in real life. We monitor vaccine effectiveness by following up every case and outbreak of COVID-19 to see who was vaccinated, who got sick and to determine if there were any serious outcomes"	
	"Canada's National Advisory Committee on Immunization (NACI) recommends how we use each of the COVID-19 vaccine types or brands. Each of the brands have to show that they protect you against serious outcomes"	
	"NACI monitors for any variants of concern and decides whether or not the vaccines are less effective against those variants"	
Make a strong recommendation	"As a health care provider, I recommend that you receive this vaccine to protect you against COVID-19 which is spreading in B.C."	
	"As a health care provider, I trust Canada's Public Health systems. My family and I receive all recommended vaccines"	

4. COVID-19 Vaccine safety

Key messages for the public

- Canada holds vaccines to the highest safety standards because they are given to healthy people
- Health Canada ensures safety standards were met during the clinical trials before a vaccine is approved for use in Canada
- Health Canada then continues to watch for safety signals that were too rare to have been found in the clinical trials
- If any safety concerns are identified, they are investigated and actions are taken if needed



Based on more than 100 years of data, scientists know that almost all adverse events will occur within 6 weeks following any vaccination. That is why the FDA required their vaccine manufacturers to observe vaccine trial participants for a minimum of 8 weeks. Despite this fact, public health systems across the globe continue to seek out and watch for all emerging issues related to vaccine safety and effectiveness.

More information for health care providers

What is a safety signal?

As with all immunization programs, we watch for any safety signals. A safety signal is a new and potential association between a vaccine and an adverse event that warrants further investigation.

Although the clinical trials for the COVID-19 vaccines involved tens of thousands of volunteers, very rare adverse events can not be detected until millions of people are vaccinated. That is why Canada's immunization system continues to watch for potential severe reactions that were not observed in the trials.

How do we determine causality?

It's often difficult to determine if an adverse event following immunization (AEFI) was caused by the vaccine, or by something else that happened around the same time the vaccine was given (e.g., an infection or onset of a chronic condition that would have occurred even if the person was not vaccinated).

AEFI REPORT The details of all AEFI reports are carefully reviewed. Rates of adverse events in people who are vaccinated are compared to rates of the same events in people who are not vaccinated. This can help to determine if there is a true safety concern with the vaccine.

More information about AEFI reporting in BC can be found on the <u>Monitoring vaccine uptake</u>, <u>safety and effectiveness</u> page on the BCCDC website. BC's weekly report on adverse events can be found under the Monitoring adverse events in BC section.

"I'm concerned there may be serious side effects that we don't know about yet."		
STEP	SUGGESTED RESPONSE	
Acknowledge your client's concerns	"I want to make sure I've correctly understood your concernare you worried that there may be serious side effects from the COVID-19 vaccines?"	
Focus on the right risk	"Serious adverse events following immunization are very rare. On the other hand, we know that COVID-19 is causing severe outcomes such as hospitalization, ICU admissions and even death" "Many people who had COVID-19 disease are experiencing negative effects for many months after"	
Describe the trustworthiness of Canada's immunization system	"I'm so thankful that Canada holds vaccines to the highest safety standards" "Health Canada watches for any safety signals and will make any changes to our immunization programs if needed"	
Make a strong recommendation	"As a health care provider, I recommend that you receive this vaccine to protect you against COVID-19 which is spreading in B.C." "As a health care provider, I trust Canada's Public Health systems. My family and I receive all recommended vaccines"	

5. Canada's Public Health Systems

Key messages for the public

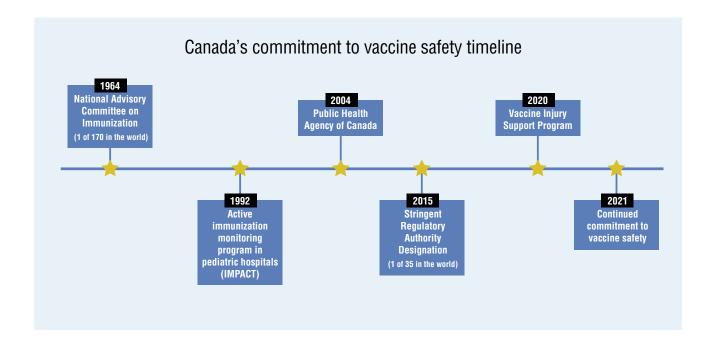
- Canada has advanced, longstanding, and trustworthy public health systems that ensure our vaccines meet all safety standards
- This includes large and diverse groups of scientific, medical, technical, ethical, and economic experts who follow strict scientific processes
- The Public Health Agency of Canada (PHAC) has access to early and emerging data from international organizations that inform Canada's vaccine response



In December 2020, PHAC announced the first, pan-Canadian no-fault vaccine injury support program for all Health Canada-approved vaccines.

"Our publicly funded health care system is a source of pride, and this program will make it even better. Canadians can have confidence in the rigour of the vaccine approvals system, however, in the rare event that a person experiences an adverse reaction, this program will help ensure they get the support they need..."

Patty Hajdu Canada's Minister of Health



More information for health care providers

Key Player	Who is it?	Why does it matter?
National Advisory Committee on Immunization (NACI)	A national immunization technical advisory group that uses the best practices and data available to make sound, evidence-based recommendations on immunization. The WHO directed all countries to create their own advisory group by 2020. NACI was created in 1964.	Canada is 1 of 170 countries that are part of this global data-sharing and collaboration community. This enhances NACI's ability to efficiently make evidence-informed recommendations through global collaboration and cooperation.
Immunization Monitoring Program ACTive (IMPACT)	IMPACT is a national pediatric hospital-based active surveillance network. IMPACT looks for adverse events in children following immunization and selected infectious diseases that are or will be vaccine-preventable.	IMPACT provides real world data on how well vaccines are working in children. IMPACT can identify adverse or rare events not seen in clinical trials in children.
Public Health Agency of Canada (PHAC)	A national agency that is focused on preventing disease and injuries, promoting good physical and mental health, and providing information to support informed decision-making. It values scientific excellence and provides national leadership in response to public health threats. PHAC was created in 2004 in response to SARS-CoV-1.	PHAC provides national leadership to anticipate and respond effectively to public health threats.
Stringent Regulatory Authority (SRA)	An SRA is a national drug regulatory authority recognized by the WHO. SRAs govern vaccine research, production and distribution processes. Canada is only 1 of 35 countries worldwide with the SRA designation.	Canada applies stringent standards for quality, safety, and efficacy in its regulatory review of vaccines for marketing authorization. Timely access to international databases and information.

Client Question:

"Why do the vaccine recommendations or programs keep changing? How can I trust that Public Health really knows what they're doing?"

STEP	SUGGESTED RESPONSE	
Acknowledge your client's concerns	"What I hear you saying is that you're concerned that the programs keep changing and you're not sure you can trust us. Is that right?"	
Focus on the right risk	"Canada's public health systems have responded quickly to new and emerging information in order to keep Canadians safe. It can be easy to think that these program changes are unsafe, but the real risk would be to keep the immunization program the same in light of new data"	
Describe the trustworthiness of Canada's immunization system	"As studies continue and we learn more about how well the vaccine works in real life, Canada's many groups of experts use this information to ensure our immunization program is safe" "It is normal for immunization programs to change, especially in the beginning as new studies come out with additional information. For example, in B.C., we have changed our hepatitis B and HPV grade six immunization programs to ensure children get the optimal dose and schedule"	
Make a strong recommendation	"As a health care provider, I recommend that you receive this vaccine to protect you against COVID-19 which is spreading in B.C. and around the world" "As a health care provider, I trust Canada's Public Health systems. My family and I receive all recommended vaccines"	

List of abbreviations

ACIP	Advisory Committee on Immunization Practices (U.S.)
AEFI	Adverse Event Following Immunization
BCCDC	British Columbia Centre for Disease Control
CDC	Communicable Disease Control (U.S.)
COI	Conflict of Interest
ЕМА	European Medicines Agency
FDA	Food and Drug Administration (U.S.)
НС	Health Canada
IMPACT	Immunization Monitoring Program ACTive
NACI	National Advisory Committee on Immunization
PHAC	Public Health Agency of Canada
РНО	Provincial Health Officer
RCT	Randomized Clinical Trial
	Randomized Control Trial
SARS	Severe Acute Respiratory Syndrome
SOGC	Society of Obstetricians and Gynecologists of Canada
WHO	World Health Organization

Glossary

Adjuvant	An ingredient that helps a vaccine work better
Antigen	A foreign substance that causes the production of antibodies like a virus
Antibody	A protein in the blood that recognizes and kills viruses and bacteria
Asymptomatic Transmission	One person passing the virus on to another person even though they have no signs or symptoms
Community Immunity	The more people in a community who are vaccinated, the harder it is for a disease to spread and the chance of an outbreak greatly decreases. This type of protection is known as community (or herd) immunity.
	Immunization rates need to be high for community immunity to work. Depending on several factors, vaccination levels must reach 75% or greater to achieve community immunity.
Incubation Period	The amount of time between when someone is exposed to a virus and when they develop their first symptom
MERS-CoV	The coronavirus that caused Middle East respiratory syndrome (MERS) was first discovered in 2012
Placebo	A medication or vaccine that has no therapeutic effect and is used as a control in testing new medications or vaccines
R0	R0 (pronounced 'R naught') is the number of people infected with the virus where there is no immunity. This is a measure of how infectious the disease is when no measures are taken to prevent its spread and nobody has recovered from the illness or received a vaccine
Safety Signal	A new and potential association between a vaccine and an adverse event that warrants further investigation
SARS-CoV-1	The coronavirus that caused Severe Acute Respiratory Syndrome (SARS) was first discovered in 2003
SARS-CoV-2	The severe acute respiratory syndrome coronavirus 2 that causes COVID-19 disease, first discovered in 2020
Vaccine Efficacy	Measuring how well the vaccine worked in a controlled clinical trial setting (e.g., RCT) at that point in time
Vaccine Effectiveness	Measuring how well the vaccine works in the real world where large groups of people of different ages, medical conditions, ethnicities are all immunized and then Public Health systems continue to monitor for outbreaks and safety signals
Variants	Changes or mutations in the virus that are significant and could make it more contagious and/or cause more severe disease
Wild Type Virus	The naturally occurring, non-mutated strain of a virus

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Canada

Association of Medical Microbiology and Infectious Disease Canada www.ammi.ca/

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Government of Canada COVID-19 <u>www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/vaccines.html</u>

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National Advisory Committee on Immunization (NACI): Statements and Publications

www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html

Pan-Canadian Public Health Network Special Advisory Committee on COVID-19 www.phn-rsp.ca/sac-covid-ccs/index-eng.php

International

GAVI, The Vaccine Alliance www.gavi.org/

Vaccine Safety Network <u>www.vaccinesafetynet.org/</u>

World Health Organization (WHO) Coronavirus disease (COVID-19) pandemic www.who.int/emergencies/diseases/novel-coronavirus-2019

WHO National Immunization Technical Advisory Groups www.who.int/vaccine_safety/initiative/communication/network/nitag/en/

WHO List of Stringent Regulatory Authorities www.who.int/medicines/regulation/sras/en/

WHO SAGE Strategic Advisory Group of Experts on Immunization www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/

United States

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