Canadian Covid Care Alliance
Alliance canadienne pour la prévention et prise-en-charge de la covid

What is Informed Consent and How Does It Apply to COVID-19 Vaccinations?

Introduction

The COVID-19 pandemic has brought with it the need to navigate a complex system of scientific, medical, public health, legal, and ethical considerations. At the level of the individual, we have been tasked with making challenging choices for ourselves, our families, and our communities. Among these decisions is vaccination. Like any other medical decision, communication between patients and their healthcare providers about vaccination benefits, risks, side effects and alternatives is fundamental to the principles of informed consent and ethical care.

What is informed consent?

Informed consent is the process by which a healthcare provider obtains permission from a patient before providing treatment, sharing personal health information, or initiating a clinical research trial in which the patient is participating. All individuals have the right to agree to or refuse any medical treatment. Obtaining informed consent is a necessary prerequisite for ethical and legal medical care, and for protecting against medical errors and abuse.

Healthcare providers who fail to obtain informed consent can be subject to professional penalties, civil liability and/or charged with criminal negligence. In Canada, the laws pertaining to informed consent are upheld by the Supreme Court of Canada and legislated provincially. For example, Ontario's Health Care Consent Act (HCCA) outlines the legal and ethical obligations of healthcare providers in Ontario.

Specific criteria must be met in order for informed consent to be valid and ethical. These include the principles of information, competence, and voluntariness.

Information

Healthcare providers are responsible for presenting patients with clear and complete information about proposed medical interventions, and for answering all questions related to treatment. The information must be contextualized for each patient's individual situation, taking

into account variables such as age, gender, and medical history. The information must be adequate, true and include an explanation of treatment benefits, side effects, risks, alternatives, and the consequences of not receiving treatment. In some cases, information about the clinical trials that support the safety and effectiveness of the treatment is also necessary, particularly when specific groups of people have been excluded from the trials.

Competence

The principle of competence refers to a person's capacity to understand the recommended medical treatment, its significance, and the consequences of their decision. Competence also includes a person's ability to apply their own reasoning in considering a medical treatment, to accept or refuse treatment and to express their decision.

Voluntariness

Informed consent must be voluntary. After receiving adequate information about a recommended treatment, a person must be in a position to express his or her free will without any controlling influence or coercion. This is particularly relevant to those who are vulnerable, such as children and the elderly.

How does informed consent apply to COVID-19 vaccination?

In the rapidly changing landscape of the pandemic, healthcare providers have had to contend with the many unknowns of providing care amidst a constant stream of emerging research and guidelines. Healthcare providers are obliged to interpret such information and adequately inform themselves and their patients about the benefits, risks and side effects of COVID-19 vaccines, as well as treatment alternatives. Informed consent depends on shared decision making between patients and healthcare providers, the foundation of which is based on a relationship of trust and transparency.

The following points may help navigate discussions with your healthcare provider, and enable you to make an informed decision about COVID-19 vaccination:

Risk of severe disease and benefits of vaccination

The risk of developing severe COVID-19 varies between individuals. Some of the factors that influence the risk of severe disease include age, immune status, and other health conditions. Those at higher risk of severe disease should consider the extent to which vaccination may help mitigate the short- and long-term risk of infection and poor outcome. This is especially relevant as vaccine effectiveness may wane over time and as new variants emerge.

Vaccine side effects and efficacy

Given that COVID-19 vaccines are new, long-term safety and efficacy should be weighed against their benefits and an individual's risk of severe disease. Like all medical treatments, COVID-19 vaccines carry the risk of side effects – both minor and severe. Many of the transient, short-term side effects of the vaccines are known, as are the potential for rare yet much more serious harms, including blood clots, myocarditis/pericarditis, Guillain-Barré syndrome (GBS), anaphylaxis, and death. However, long-term safety of the vaccines is not known, since Phase III clinical trials of the vaccines are ongoing and long-term endpoints have not yet been reached.

Questions that many citizens have expressed regarding safety and efficacy include: What are the potential long-term safety considerations? Will vaccination offer the same degree of benefit in six months or one year? How many boosters will be required to protect against severe disease over a given period of time? Are there any safety consequences of administering repeated boosters?

Consent to receive a specific vaccine

Consent to vaccination should not be inferred or transferable. That is, consenting to receive a specific COVID-19 vaccine routinely assumes that the particular dosing regimen adheres to the administration protocol that was tested and suggested by the manufacturer. Consent that is transferred to include dosing and timing protocols of other COVID-19 vaccines in ways that have not been tested is antithetical to informed consent.

Alternatives to COVID-19 vaccines

Many healthcare providers may be unaware of the numerous and well-established prevention and treatment protocols for COVID-19, which use various repurposed drugs with a long history of safety in treating other diseases. Treating early and with the right combination and dosage of drugs has been shown to prevent severe disease and death.

Are you being incentivized to accept COVID-19 vaccination?

In the rush to vaccinate Canadians, government and private entities are offering incentives to promote vaccine acceptance. Examples include: prizes, lottery and concert tickets, free food, swag, and the conditional return of freedoms. When contemplating your decision to accept or refuse vaccination, ask yourself whether you are being coerced. If you believe you are being pressured or influenced to provide consent, take pause and consider whether your consent is voluntary, balanced and adequately informed.

Resources

Informed consent to medical treatment is a fundamental human right. Open and honest conversations between patients and healthcare providers is critical to informed consent. While the onus is on healthcare providers to share adequate information, patients who inform themselves in advance of such conversations will be better equipped to ask thoughtful questions and advocate for their own care.

The following list provides links to further explore some of the topics discussed here:

https://rumble.com/vleq43-informed-consent-its-your-right.html

https://www.cmaj.ca/content/184/5/533

CMPA - Consent: A guide for Canadian physicians (cmpa-acpm.ca)

Vaccine administration practices: Canadian Immunization Guide - Canada.ca

https://bottomlineresearch.ca/pdf/informed_consent.pdf

https://www.canlii.org/en/on/laws/stat/so-1996-c-2-sch-a/latest/so-1996-c-2-sch-a.html#sec11subsec2_smooth

https://pmj.bmj.com/content/80/943/277

https://www.nature.com/articles/d41586-021-01897-w

https://www.timesofisrael.com/hmo-those-who-inoculated-early-twice-as-likely-to-catch-covid-as-later-adopters/amp/

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01642-1/fulltext?fbclid=IwAR3CI00yX-YgLsRSXd-0CdBLNm4FDyamzo_Je2wX8GqXwCJPJSnO--2ra7U

Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals - Full Text View - ClinicalTrials.gov

https://torontosun.com/opinion/columnists/kinsella-informed-consent-being-shredded-in-canada-by-az-vaccine-debacle

https://covid19criticalcare.com/covid-19-protocols/

https://www.c19protocols.com/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8248252/

Vaccin-Status-June25-EN-1241pm (canada.ca)

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