

Consent of Individuals with a Developmental Disability – Preparing for COVID-19 Vaccination

PURPOSE

The purpose of this document is to provide some background and guidelines to support DS agencies obtaining consent to administer the COVID-19 vaccination. *Please note that these guidelines do not constitute legal advice.* The guidelines below may be helpful when preparing for a smooth vaccination rollout.

Organizations in this sector are faced with a number of unknowns:

- Timelines and order of the vaccine rollout are not determined.
- Consistent consent forms for the general population are not pre-determined.
- Existing consent forms were initially developed for long-term care and retirement homes, and there appears to be an expectation that they are applicable for other sectors.
- There are no ministry policy guidelines in place.
- There is pressure for the health practitioner to obtain consent from individuals as soon as possible in anticipation of the vaccination rollout.
- A key piece of legislation speaks to the responsibility of individual agencies to provide oversight and accountability in health promotion, medical services, and medication through setting and implementation of policies, procedures and documentation (but consent for treatment is still required under the *Health Care Consent Act (HCCA)*).

DS AGENCIES' ROLE IN CONSENT

Early preparation for the vaccine is critical in the current environment, as there may be insufficient time and resources for the health practitioner administering the vaccine to go through the full informed consent process.

The DS service providers can:

- Explain to the patient what is meant by consent.
- Explain the information being provided about the vaccine including risks, benefits, side effects, what could happen if they refuse the vaccine.
- Ask if they have any questions.

Therefore the DS service providers have a critical role in facilitating the consent process by coordinating logistics and providing the patients and substitute decision makers (SDMs) with the information necessary about the vaccination in a timely fashion, so that health practitioners do not lose a key opportunity to ensure the health and safety for this vulnerable population (especially with the current wait lists.) Delays could even result in further risks if an opportunity to receive the vaccine is deferred or bypassed.

Health practitioners administering the vaccination may need help to facilitate a fast decision, unless there is a compelling clinical concern, e.g., severe allergies or acute illness. A health practitioner must still confirm capacity and seek informed consent at the point of service before giving the vaccination.

A health practitioner must still confirm capacity and obtain informed consent from an individual in this situation by providing sufficient information in simple and understandable language. The health practitioner can then determine whether the individual has the ability to understand the information relevant to making the decision, has the ability to appreciate the consequences of giving or refusing consent, and has given consent.

SUGGESTED GUIDELINES

In preparing these guidelines, a number of documents were reviewed (listed at the end of the document), for guidance on legal requirements for an informed consent, ethical principles, as well as other statutory and health and safety factors as they may apply to the DS sector. Current practice at the Office of the Public Guardian and Trustee and recommendations from the Canadian Medical Protective Association have also been considered, as well as specific consent and capacity issues in this sector. In anticipation of unknown vaccine rollout dates, these guidelines include:

- Key documents to review with individuals and/or Substitute Decision Makers (SDMs).
 - Steps and options to acquire consent from the individual if capable and/or the SDM.
1. **Provide notice and key information as soon as possible to** individuals, caregivers, families, SDMs, as appropriate, informing them that you will be:
 - Seeking their assistance in obtaining consent (verbal or written) from the individual if capable or the SDM as early as possible in order for the vaccination rollout to proceed at your organization.
 - Contacting them/sending them information regarding the COVID-19 vaccination and related procedures.

You may wish to include links to the following useful documents:

- *COVID-19 Vaccine Obtaining Informed Consent - Script for Health Care Providers V 2.0 December 30, 2020:*
http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_obtaining_informed_consent_script_HCP.pdf
 Note: a more up to date version (January 12) of the script has not yet been uploaded by the Ministry. A PDF copy has been emailed and/or uploaded along with this document.
- *Ministry of Health COVID-19 Vaccination Recommendations for Special Populations*
http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccination_recommendations_special_populations.pdf
- *Answering Patient Questions about COVID-19 Vaccines Updated – January 8, 2021, Ontario College of Family Physicians*
<https://www.ontariofamilyphysicians.ca/tools-resources/covid-19-resources/covid-vaccines-patient-questions.pdf>

The people you support may or may not have the ability to consent to the vaccine; however, everyone should have the opportunity to be informed. As part of the consent process logistics, the service provider who is talking with the patient or with SDM should document whether the person is capable (or not) of giving consent. For example, prior relevant documentation may exist

and could be noted e.g., regarding concerns or challenges raised in the past, progress notes, etc. Documentation may be helpful for the health practitioner in their final review, especially with this population where there may be communication challenges. You may also wish to prepare a “social story” or use an existing resource such as the following social stories prepared by DS agencies.

<https://realxchange.communitylivingessex.org/covid-19-vaccine-resources/>

A social story can be used to provide information in clear language about the vaccine and describe the vaccination process.

Other useful documents on consent by the College of Physicians and Surgeons of Ontario (CPSO), and the College of Nurses of Ontario (CNO), can be found at the end of the document in the section for additional resources.

2. **Prepare/provide consent forms based on MOH website documents, in particular the COVID-19 Vaccine Screening and Consent Form V 1.0, December 30, 2020:**

http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/covid19_vaccine.aspx#immunization

Note: The most recent version (December 30) of the form has not yet been uploaded by the Ministry. A PDF copy has been emailed and/or uploaded along with this document.

In addition, if you click on the Ottawa Public Health Link, you will find the same document in a version that you can complete on your computer:

<https://www.ottawapublichealth.ca/en/resources/Corona/COVID-19-Vaccine-Screening-and-Consent-Form.pdf>

It should be noted that informed consent is a process of communication – and not just a form to be completed. Every person and SDM has the right to ask for and receive information and ask questions so that they can make well-considered decisions about their care, or care on behalf of an individual when acting as SDM. They may provide verbal or written consent/refusal on a form or other document. If the consent/refusal is verbal, this should be documented.

This screening and consent form contains health questions with respect to **both the Pfizer-BioNTech and Moderna** vaccines, and can be used in discussions with individuals who have the capacity to provide consent, and/or with the SDMs, who may be required to give consent.

In the event that individuals and/or family members have questions regarding risks, potential adverse impacts, etc., they should be directed to seek advice from a family physician, and can bring or send the form at that time to inform their discussion. The physician can review the screening questions and explain benefits and risks, but cannot provide consent.

3. **Create an inventory of the following categories of individuals giving consent in the order as follows** and begin by *trying to obtain consent first from those who likely have capacity to provide consent, in collaboration with their family/caregivers as appropriate. Family members or caregivers can collaborate in the consent process subject to permission from the concerned individual, due to privacy requirements. In each case, have the individual/SDM/family consult with family physician as appropriate.*

Remember that the physician should review the screening questions, determine the capacity of the person to give or refuse their own consent, explain benefits and risks, etc., to facilitate the consent process for the capable individual and/or SDM, and can verify consent for the health practitioner (if asked), but cannot provide consent.

Note: There may be some individuals who are not capable of providing consent to the COVID-19 vaccination, although previously they were capable of making decisions for all other treatment. Therefore this issue was not discussed with the family. Even though an SDM had not been asked in the past to step in to make a treatment decision for them, they may now have to do so. There may also be individuals who do not have SDMs that can be reached, or the SDMs are unwilling or unable to provide consent. In such cases, in the interest of time, you may ultimately need to seek consent from the Office of the Public Guardian and Trustee (OPGT), as described in section E below.

A. Identify which individuals may have the capacity to provide consent regarding vaccination.

- In consultation with these individuals, identify potential underlying health concerns/allergies per the screening section of the Ministry consent form.
- Review the social story, public health information regarding the vaccine, potential side effects, etc. *as set out in the COVID-19 Vaccine Screening and Consent Form and the COVID-19 Vaccine Obtaining Informed Consent - Script for Health Care Providers.*
- If the individual has concerns regarding risks/impact on current medical condition, assist the individual to contact their family physician for advice.
- Obtain written/verbal consent and document as required, so that the health practitioner administering the vaccine can confirm consent prior to administering the vaccine.

B. Identify which individuals with DD in your agency have SDMs and their contact information.

- These SDMs can identify potential underlying health concerns/allergies per the consent form in consultation with the individual concerned.
- Review the public health information re: the vaccine, potential side effects, etc. *as set out in the COVID-19 Vaccine Screening and Consent Form and the COVID-19 Vaccine Obtaining Informed Consent - Script for Health Care Providers.*
- If the SDMs have any concerns re: risks/impact on current medical condition, etc., ask them to contact the family physician for the concerned individual.
- Obtain written/verbal consent and document as required, so that the health practitioner administering the vaccine can confirm consent prior to administering the vaccine.

C. For those individuals whose SDMs are not noted in their file, identify potential SDMs and their contact information.

- Develop the list **based on the highest ranked eligible person** identified in the hierarchy set out in provincial legislation. This list and related tips can be found below in the section on CONSENT AND CAPACITY REGARDING COVID-19 ISSUES IN THE DS SECTOR.
- These SDMs can identify potential underlying health concerns/allergies per the consent form in consultation with the individual concerned.

- Review the public health information re: the vaccine, potential side effects, etc. *as set out in the COVID-19 Vaccine Screening and Consent Form and the COVID-19 Vaccine Obtaining Informed Consent - Script for Health Care Providers.*
- If the SDMs have any concerns re: risks/impact on current medical condition, etc., ask them to contact the family physician for the concerned individual.
- Obtain written/verbal consent and document as required, so that the health practitioner administering the vaccine can confirm consent prior to administering the vaccine.

D. Identify individuals who already have an assigned Public Guardian and Trustee.

E. For those individuals where it is not possible to find or reach the SDM in time, or where there is no SDM who is willing or able to make a decision regarding the vaccine, you may wish to prepare a list of the residents for the OPGT in the event that they become the last resort SDM.

For the OPGT to consider becoming the SDM, the OPGT will require information as to whether each resident:

- Is incapable of consenting to his/her own COVID-19 vaccination.
- Has no other substitute decision maker available, capable or willing to provide consent.

In addition the OPGT will require confirmation that the list of screening questions on the consent form have been reviewed, that a family physician has been consulted if appropriate, and that there are no other concerns.

4. Collect Documentation

In order for the health practitioner administering the vaccine to confirm consent at the point of service, he/she will need the signed Ministry screening and consent form, and proof of consent if the form has not been signed by the SDM, as well as the individual's health card.

The SDM can provide written consent:

- In an email or note.
- On a signed and scanned Ministry consent and screening form, or
- If available, on a digital copy of the Ministry screening and consent form that permits electronic "DocuSign".

The SDM can also provide verbal consent. In this case, document the verbal consent:

- On the Ministry screening and consent form by hand (or electronically if possible), or
- In a note that can be printed out and attached to or brought along with the Ministry screening and consent form.

5. Monitor and Follow Up Consents

- Use Tracking Sheet to monitor activities and follow up consents.
- Ensure screening and consent forms returned to service provider.

- Notify the OPGT regarding the need to acquire consent on behalf of individuals who already have an assigned OPGT, and send the Ministry screening and consent form and information to the OPGT for consent.
- Identify cases where it is not possible to find or reach the SDM in time and they do not have an assigned OPG.
 - Notify the OPGT regarding the need to acquire consent on behalf of individuals who do not have an assigned Public Guardian and Trustee.
 - Provide information for all individuals in single chart for the OPGT to review and provide consent in a timely fashion.

6. Bring Documentation to Vaccination Appointment!

Remember that the staff present or accompanying the individual must *bring the Ministry screening and consent form and other proof of consent as required, along with a health card*, in order for the health practitioner administering the vaccine to confirm consent prior to administering the vaccine.

DOCUMENTS USED TO INFORM AND DEVELOP THE GUIDELINES

THE ONTARIO HUMAN RIGHTS COMMISSION (OHRC)

The Ontario Human Rights Commission (OHRC) has issued a [Policy statement on a human rights-based approach to managing the COVID-19 pandemic](#).¹

The OHRC notes that the pandemic has led governments across Canada to respond in innovative and often unprecedented ways. The OHRC suggests that implementing programs and policies that align with their policy statement will help protect public health and human rights during the COVID-19 pandemic.

The paper observes that the most vulnerable groups in Canadian society are disproportionately negatively affected by the COVID-19 pandemic. “Vulnerable groups” includes people with disabilities, mental health needs and/or addictions, and older persons.

The OHRC notes some of the human rights impacts of COVID-19 on vulnerable groups including:

- Higher risk of contracting COVID-19 due to social conditions.
- Separation from caregivers.
- Potential involvement of child welfare agencies.
- Negative impacts on the treatment or management of pre-existing disabilities, mental health needs and/or addictions.
- Restricted access to medical or other support services.
- Potential discriminatory enforcement of emergency or public health-related measures.

Given these impacts, the OHRC sets out principles in six categories for a human-rights based approach to managing the COVID-19 pandemic. Relevant excerpts from some of these categories and principles are set out below.

1. Approach preventing and treating COVID-19 as a human rights obligation.

- Recognize that the COVID-19 pandemic engages the right to health and life under Canada's international and domestic human rights laws.
- Recognize that all levels of government have a *legal obligation to take preventative steps to stop the spread of COVID-19 and treat people who have the virus, without discrimination. This may require governments to take additional steps necessary to prevent and treat COVID-19 among vulnerable groups.*
- Recognize that human rights laws require mitigating potential impacts on rights that are interdependent with the rights to health and life, including the rights to food, housing, work, education, equality, privacy, access to information, freedom from cruel, inhuman or degrading treatment or punishment, and the freedoms of association, expression, assembly and movement.

2. Set strict limits on measures that infringe rights.

- Ensure that any public health or emergency-measures that are deemed necessary to prevent the spread of COVID-19 and that restrict the exercise of rights, are time-bound and subject to regular reviews.
- Recognize that the Charter of Rights and Freedoms and Canada's domestic and international human rights obligations require that any measures that restrict the exercise of rights must be demonstrably justified as necessary, legitimate and proportionate.
- Recognize that any restrictive measures that deprive persons of their right to liberty must be carried out in accordance with the law and respect for fundamental human rights. This includes but is not limited to measures related to people detained in mental health institutions, children in care, and older persons in long-term care homes.
- Ensure that rights-based, legal safeguards govern the appropriate use and handling of personal health information.

3. Protect vulnerable groups.

- Anticipate, assess and address the disproportionate impact of COVID-19 and related restrictions on vulnerable groups that already disproportionately experience human rights violations.
- Make sure vulnerable groups have *equitable access to health care* and other measures to address COVID-19, including financial and other assistance.
- *Make decisions with input from vulnerable groups and the most affected communities.*
- ***Ensure that public health and emergency measures consider accessibility and other needs of people with disabilities who face heightened susceptibility to contracting COVID-19 and may face extra challenges to obtaining services and supplies, and accessing food and other basic needs because of restrictive measures.***
- Ensure that any law enforcement of public health or emergency measures does not disproportionately target or criminalize Indigenous peoples, racialized communities, *people who are precariously housed or who cannot self-isolate, or people with mental health disabilities and/or addictions.*

4. Respond to racism, ageism, ableism and other forms of discrimination.

- Ensure that steps taken in response to COVID-19 are based on evidence, and deliberately challenge, reject and dispel stereotypes.
- Anticipate and take into account the potential for certain communities to experience increased racism, ageism and ableism as a result of the government's response to the COVID-19 pandemic.
- In collaboration and cooperation with vulnerable groups, take all necessary steps to proactively protect individuals and communities from hate, racism, ageism, ableism and discrimination propagated by private individuals.

MINISTRY OF HEALTH

Another document to consider is the Ministry of Health (MOH) *Ethical Framework for COVID-19 Vaccine Distribution*². The document notes that application of the five listed principles is to an extent context-dependent and that other values and principles may be relevant to decision-making. The document suggests that the Framework be used in conjunction with the OHRC's policy statement noted above, and there is some overlap. Although the framework is directed towards distribution (which to a large extent is not currently within the purview or control of the DS sector), most of the principles are valuable to consider.

Highlights from the principles in this ethical framework are set out below:

Minimize Harms and Maximize Benefits

- *Reduce overall illness and death related to COVID-19.*
- *Protect those at greatest risk of serious illness and death due to biological, social, geographical, and occupational factors.*
- Promote social and economic well-being.

Equity

- Respect the equal moral status and human rights of all individuals.
- Distribute vaccines without stigma, bias, or discrimination.
- Do not create, and actively work to reduce, disparities in illness and death related to COVID-19, including disparities in the social determinants of health linked to risk of illness and death related to COVID-19.
- Ensure benefits for groups experiencing greater burdens from the COVID-19 pandemic.

Fairness

- Ensure that every individual within an equally prioritized group (and for whom vaccines have been found safe and effective) has an equal opportunity to be vaccinated.
- Ensure inclusive, consistent, and culturally safe and appropriate processes of decision-making, implementation, and communications.

Transparency

- Ensure the underlying principles and rationale, decision-making processes, and plans for COVID-19 vaccine prioritization and distribution are clear, understandable, and communicated publicly.

Legitimacy

- Make decisions based on the best available scientific evidence, shared values, and input from affected parties, including those historically under-represented.
- Account for feasibility and viability to better ensure decisions have intended impact.
- To the extent possible given the urgency of vaccine distribution, facilitate the participation of affected parties in the creation and review of decisions and decision-making processes.

It should also be noted that the framework also references **Jordan's Principle**³. The primary application of these principles is directed to First Nations children and relates to jurisdictional ambiguity. However, an important element is that *the best interests of a child must be considered*. This means that requests for needed products, services, and supports are not only about ensuring substantive equality, but also making sure that *the child's safety and well-being are considered when making decisions*.

PAN-CANADIAN VACCINE INJURY SUPPORT PROGRAM

Even with a rigorous review process and the exacting standards in place for vaccine delivery, a small number of Canadians may experience an adverse reaction after being immunized. The Public Health Agency of Canada (PHAC) has recently announced the implementation of a pan-Canadian no-fault vaccine injury support program for all Health Canada approved COVID-19 vaccines.

Details are pending but the intent of the program is to ensure that fair access to support in the rare event that Canadians experience an adverse reaction to a vaccine.

In the absence of further detail it is unclear yet if the program provides liability protection for physicians and other healthcare providers so that their good faith efforts in recommending and administering the vaccination will not put them at increased legal risk.

CANADIAN MEDICAL PROTECTIVE ASSOCIATION (CMPA)

On their website, the CMPA sets out key medical-legal considerations physicians will want to be aware of during the COVID-19 vaccination rollout. The first page contains questions and answers regarding the [responsibility of physicians](#)⁴, but does give a good general overview of informed consent as follows:

Is the informed consent process different for the COVID-19 vaccination? What if a patient refuses to be vaccinated?

While vaccines are not new, COVID-19 vaccines may be novel in the manner in which they have been developed and approved. As with other novel treatments, special care should be taken when obtaining informed consent to disclose all of the known risks, side effects and discomfort that might be encountered (regardless of how remote the risk might be). In addition, it is generally expected that the

patient will be informed if there may be other risks not yet known and the anticipated benefits may not be achieved.

Generally speaking, the healthcare professional who is proposing the treatment is responsible for ensuring that informed consent is obtained from the patient. However, the act of obtaining informed consent can be delegated to another healthcare provider (e.g., under a medical directive for the administration of the vaccine). Regardless of which healthcare professional obtains the patient's informed consent, it is essential to document the content of the consent discussion with the patient, including reference to the information provided and any questions asked and answered. Many provincial/territorial governments have prepared standard informed consent forms to assist in the consent process. Where a consent form is used, there should still be a mechanism to document additional information and questions addressed with the patient receiving the vaccination.

If a patient is reluctant about receiving a COVID-19 vaccine, you will want to explore and address the reasons for the patient's concern, answer any questions to the best of your ability and consider referring the patient to other relevant resources for additional information. If the patient still refuses to be vaccinated, a detailed note of both the consent discussion and the refusal should be made.

On a related page, the CMPA discusses [How to address vaccine hesitancy and refusal by patients or their legal guardians](#)⁵. (As SDM is the generic term for legal guardian in Ontario, the references in the paper have been changed here to SDM). The CMPA discussion has been updated to include considerations relating to COVID-19 vaccination. The CMPA states that physicians who provide vaccinations should be appropriately aware of their obligations, including providing patients (or patients' SDMs) with sufficient information about recommended vaccines so that they can make an informed decision.

The full CMPA discussion is worthwhile to review for any healthcare providers, as it contains a variety of suggestions.

In summary the CMPA states that because COVID-19 vaccines may be novel in the manner in which they have been developed and approved, special care should be taken when obtaining informed consent to disclose all of the known risks, side effects and discomfort that might be encountered (regardless of how remote the risk might be). Their "**bottom line**" is as follows:

- Provide information to patients or their SDMs about the benefits and any significant risks associated with recommended vaccines, as well as the risks of the disease being prevented.
- Be familiar with the provincial or territorial immunization schedule, legislation, and College policies in your jurisdiction regarding vaccination.
- Engage in a more robust informed consent discussion when recommending new vaccines, such as COVID-19 vaccines.
- Carefully document the information given to patients and their responses in the medical record and/or designated provincial/territorial record (including their reasons for refusing the vaccine, if that is the case).
- Accurately document vaccines discussed with, refused by, or administered to a patient.
- Patients or SDMs have the right to accept or refuse the vaccine. Be patient and empathetic to their needs and beliefs on vaccines and keep lines of communication open.
- Arrange follow up for patients to complete the course of immunization, if required, and document the steps taken.

VACCINATION HESITANCY, CONSENT AND SOCIAL RESPONSIBILITY

In a recent [Journal of Medical Ethics Blog](#)⁶ regarding informed consent, some additional points were raised regarding vaccine hesitancy. The article suggested that in the dialogue between physician/health care practitioners and their patients regarding the COVID-19 vaccine in the UK, it may be helpful to prompt considerations regarding how individual autonomy may be interpreted, even though the discussion may require a bit more consultation time. The article stated:

*“Rather than the individualistic interpretations which stimulate talk of infringed individual liberties and anti-mask opposition, autonomy sits more comfortably as a relational value. The COVID-19 pandemic has demonstrated to great effect that when it comes to disease, we do not live in isolation. Our understanding of autonomy should therefore incorporate some social responsibility. Whilst ultimately upholding the patient’s right to decide whether to incur individual risk, information disclosed to patients should be given from both individual and societal perspective. In this way, patients can be fully informed. The benefits of vaccination should therefore address both benefit to the individual and society, such as the potential for individual and herd immunity. It should also be disclosed that such immunity may not be long-lasting or equally effective across all age-ranges. Risk should be disclosed in terms of both known risks, including common side effects, and potentially unknown risk. **The risk from not vaccinating should also be explained – both to the individual who may be at greater risk of contracting COVID-19 – and to society through increased transmission.** Such risk may include both primary infection and subsequent “Long-COVID”. This will affect both the individual and society as a whole through increased strain on the NHS. Whilst there will still be vaccine refusal, such an approach will engage those who are, as yet, undecided by tackling misinformation and promoting solidarity.”*

LEGISLATION

A key piece of legislation for the DS sector is the [Services and Supports to Promote the Social Inclusion of Persons with Developmental Disabilities Act, 2008, S.O. 2008, c. 14](#)⁷. A supporting regulation of the Act is the [O. Reg. 299/10: QUALITY ASSURANCE MEASURES](#) which addresses health promotion, medical services and medication, and certain safety requirements as follows:

Health promotion, medical services and medication

7. (1) *In addressing quality assurance measures respecting **health promotion, medical services and medication**, each service agency shall have the following:*

1. *Policies and procedures respecting the provision of public health information that may help persons with developmental disabilities who are receiving services and supports from the agency make informed choices about their health.*
2. *Policies and procedures to monitor the health concerns of persons with developmental disabilities who are receiving services and supports from the agency, where the supports have been identified in their individual support plan.*
3. *Policies and procedures, including documentation, regarding,*
 - i. *medical services that are provided to the person with a developmental disability, where the service agency is providing assistance,*
 - ii. *administration of medication, including self-administration by the person with a developmental disability,*

- iii. any medication errors and any refusals to take any prescribed medication,*
- iv. any refusals by the person with a developmental disability to obtain or accept medical services that are recommended by a legally qualified medical practitioner or other health professional, and*
- v. emergency medical services.*

It should be noted that section 7 emphasizes the need for policies and procedures to promote and ensure health and health information, but does not address the need for consent for treatment, as all agencies subject to this legislation are required to comply with the HCCA.

Safety around agency owned or operated premises

11. (1) In addressing quality assurance measures respecting safety around agency owned or agency operated premises, each service agency shall have the following:

1. An approved fire safety plan, where required under Ontario Regulation 213/07 (Fire Code) made under the Fire Protection and Prevention Act, 1997, for each of the premises that the service agency owns or operates.

2. An emergency preparedness plan to address the following emergency situations,

i. emergencies that may occur inside premises owned or operated by the service agency where persons with developmental disabilities are receiving services and supports from the agency, examples of which include power outages, fire, flood, storm damage, pandemic and medical emergency, and

ii. emergencies that may occur outside premises owned or operated by the service agency where persons with developmental disabilities are receiving services and supports from the agency, examples of which include a medical emergency and instances where a person with a developmental disability runs away or becomes lost.

In Ontario, other legislation governing matters regarding mental capacity are the *Substitute Decisions Act, 1992 (SDA)*, the *Health Care Consent Act, 1996 (HCCA)*, the *Mental Health Act (MHA)*, and the *Public Guardian and Trustee Act, 1990*. The *Ontario Human Rights Code* takes precedence over these acts, so when dealing with consent and capacity, it is important to consider human rights principles such as:

- Individualized assessment
- Respect for dignity
- Autonomy
- Confidentiality
- Opting for the least intrusive and restrictive options where possible
- Integration, and
- Full participation wherever possible.

OFFICE OF THE PUBLIC GUARDIAN AND TRUSTEE

The Office of the Public Guardian and Trustee (OPGT) has a role in providing consent for certain individuals in the DS sector. Currently, the OPGT is receiving numerous requests to provide consent for individuals regarding COVID-19 vaccines. You may wish to prepare a list of the residents for the OPGT and ask the OPGT to provide consent for the vaccine.

You must be able to identify whether each resident:

- Is incapable of consenting to his/her own COVID-19 vaccination, and
- Has no substitute decision maker from the hierarchy list* available, capable or willing to provide consent.

In addition you must confirm that the list of screening questions on the consent form have been reviewed, that a family physician has been consulted if appropriate, and that there are no other concerns.

*The list is below in the section on CONSENT AND CAPACITY REGARDING COVID-19 ISSUES IN THE DS SECTOR.

CONSENT AND CAPACITY REGARDING COVID-19 ISSUES IN THE DS SECTOR

Although consent and capacity issues can sometimes be complex, it is always helpful to start with some key principles, such as your role and need to:

- Advocate,
- Apply a Person and Family-Centred approach, and
- Collaborate and Value Partner Relationships.

A key ethical consideration when making planning decisions and seeking consent is that the person's known wishes, best interests, and well-being are the primary considerations. It is also critical to demonstrate respect for the person's rights and decision-making, and for the concept of individual choice.

How do you as a service provider put these principles into action when helping a person with a DD make a decision regarding the COVID-19 vaccination? Try to put yourself in that person's shoes, and to keep the person in control as much as possible. **Do not be afraid to ask questions, or to consult externally, such as getting advice from the Office of the Public Guardian and Trustee, or from other third parties such as a family physician.**

Every person with a DD and their circumstances are unique.

There is a presumption that everyone is capable of making their own decisions unless there is evidence otherwise. You may find that a person with a DD does not have a power of attorney for personal care (POA), or another substitute decision-maker (SDM) from the hierarchy list in the HCCA because they have been capable of making their own health decisions.

Even if a person has a Substitute Decision Maker (SDM), this does not mean that the person should not be consulted or that the person cannot make a decision regarding receiving the COVID-19 vaccination. The SDM only has the authority to make a decision for the person if they are incapable to make this particular treatment decision about the vaccination in the past. In some circumstances, there may be a court appointed guardian of the person or a representative appointed by the Consent and Capacity Board who has authority in their order to make this particular treatment decision.

Many persons with a DD do have the capacity and the power to make decisions about matters affecting their own life, including receiving personal or health care services, and whether to receive treatment.

In Ontario, *adults are presumed to be capable, depending on the type of decision being made, unless there are reasonable grounds to believe otherwise*. Capacity fluctuates and should be assessed on a case-by-case basis, in accordance with the decision that the person is required to make.

Capacity refers to the ability to make a particular decision, at a particular time. It is incorrect to refer to a person as having or lacking capacity for all decisions, at all times. Many individuals will have the capacity to make a decision regarding COVID-19 vaccination.

Generally, a person is considered to have capacity to make decisions if they are able to understand the information that is relevant to making a decision and able to appreciate the reasonably foreseeable consequences of such a decision, or lack of a decision (and this is considered a legal test for capacity.) A person with a DD may be quite capable of consenting to treatment for immediate pain relief e.g., taking an aspirin, but the same person may need assistance regarding consent for the COVID-19 vaccination, in particular if they have underlying medical complexities.

It may help to remember that all adults expect to be asked about medical treatment, and to have their decisions respected. In an emergency (e.g., unconscious), all adults expect to receive treatment if they are not in a position to consent.

The same expectations hold true for adults with a DD, but decisions may be complicated by literacy and communication challenges. Understanding depends on effective communication and accessible information as well as cognitive abilities.

In order to facilitate understanding, a social story could first be used to provide information in clear language about the vaccine and to describe the vaccination process. Sample questions could then be asked to assess understanding such as:

- What is COVID-19? What do you know about COVID-19?
- Do you understand what the COVID-19 vaccine is for?
- Why do you think the vaccine is important?
- Tell me what some of the risks might be if you do not have the vaccine
- Can you help me understand why you've decided to accept/refuse this treatment?

There will be some persons who may not be competent (have the capacity) to make decisions regarding the vaccine.

Under the *Health Care Consent Act, 1996 (s.10)* a person (with capacity) has the right to consent to or refuse treatment. However, if the person does not have the capacity to make a decision regarding the vaccine there are next steps that a health practitioner must take.

A health practitioner has a duty of care to patients, and if an adult lacks capacity the health practitioner providing the treatment is then responsible for assessing the patient's capacity and for asking for any assistance they need to do so.

Section 10 of the *HCCA* also states that when a health practitioner proposes a treatment, the health practitioner must get consent before administering that treatment. Consent for the proposed treatment must come from the patient if capable, or if incapable (according to a legal test referenced above) from the patient's SDM, who will be the highest ranked eligible person identified in the hierarchy

set out in the provincial legislation (the HCCA). In the highest ranking, if there are equally ranked SDMs, i.e., three siblings, and they cannot agree among themselves, the HCCA provides that the OPGT can take over.

The hierarchy for SDMs in Ontario is as follows:

1. Guardian of the person (under the Substitute Decision Act) with authority to provide consent to treatment (Court appointed)
2. Attorney named in a Power of Attorney (POA) for Personal Care (this individual may be a different person than POA for Property)
3. Representative appointed by the Consent and Capacity Board
4. Spouse or Partner*
5. Child at least 16 years of age or older, or Parent (or Children’s Aid Society or other lawfully appointed person)
6. Parent with right of access only (i.e., per custody agreement)
7. Brother or sister
8. Any other relative (related by blood, marriage or adoption)
9. Office of the Public Guardian and Trustee

Note:*In Ontario, a paid care provider cannot function as a SDM, although he/she can come to appointments and convey information to the SDM and health practitioner. A paid care provider can also encourage the person they support to be included in the decision-making process and help the person to understand decisions and follow through.*

*Partners are *not* common law partners. The definition here includes a special status for those who have lived together for over a year, and are in an important and significant relationship e.g., two sisters, two friends, not necessarily a sexual relationship).

FOOTNOTES

1. <http://www.ohrc.on.ca/en/policy-statement-human-rights-based-approach-managing-covid-19-pandemic>
2. <https://files.ontario.ca/moh-ethical-framework-for-covid-19-vaccine-distribution-en-2020-12-30.pdf>
3. <https://www.sac-isc.gc.ca/eng/1568396042341/1568396159824>
4. <https://www.cmpa-acpm.ca/en/covid19/vaccination>
5. <https://www.cmpa-acpm.ca/en/advice-publications/browse-articles/2017/how-to-address-vaccine-hesitancy-and-refusal-by-patients-or-their-legal-guardians>
6. <https://blogs.bmj.com/medical-ethics/2020/11/23/the-covid-19-vaccine-informed-consent-and-the-recruitment-of-volunteers/>
7. <https://www.ontario.ca/laws/regulation/100299?search=quality+assurance+measure>

ADDITIONAL RESOURCES

Health Equity Impact Assessment Tool <http://www.health.gov.on.ca/en/pro/programs/heia/tool.aspx>

The COVID-19 vaccine, informed consent and the recruitment of volunteers, Jennifer O'Neill, Journal of Medical Ethics Blog, Posted on November 23, 2020

Answering Patient Questions about COVID-19 Vaccines Updated – January 8, 2021, Ontario College of Family Physicians: <https://www.ontariofamilyphysicians.ca/tools-resources/covid-19-resources/covid-vaccines-patient-questions.pdf>

Ontario College of Family Physicians Website, <https://www.ontariofamilyphysicians.ca/tools-resources/covid-19-resources/covid-19-vaccines>

Ministry of Health Website - COVID-19 Vaccine-Relevant Information and Planning Resources
http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/covid19_vaccine.aspx

CPSO Policy on Consent to Treatment

<https://www.cpso.on.ca/Physicians/Policies-Guidance/Policies/Consent-to-Treatment#:~:text=Physicians%20must%20obtain%20valid%20consent,do%20not%20agree%20with%20it.>

CNO Practice Guideline on Consent

https://www.cno.org/globalassets/docs/policy/41020_consent.pdf