

CONSENT FOR VACCINATION FOR COVID-19: GUIDING PRINCIPLES

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This document has been updated as of 5 March 2021 and replaces all prior versions

PURPOSE

The purpose of this document is to lay out the principles and processes of consent for vaccination against Sars-CoV-2 generally and to describe the consent process to be adopted in relation to the delivery of the vaccination for Sars-CoV-2.

PRINCIPLES OF CONSENT

Consent is the giving of permission or agreement for an intervention such as a vaccination following a process of communication about the proposed intervention. This requirement is consistent with fundamental ethical principles, with good practice in communication and decision-making and with national health and social care policy. The need for consent is also recognised in Irish and International law.

Informed consent involves a process of communication between a healthcare worker and a person that enables that person to have a clear understanding of the nature of the intervention, and likely risks and benefits of receiving it, thus enabling the person to make an informed choice about whether or not to proceed. A person may withdraw their consent from a procedure at any time prior to the start of that procedure/intervention.

For informed consent to be valid, the person must:

- Have received sufficient information in a comprehensible manner about the nature, potential risks and benefits of the proposed intervention, of any alternative intervention and of not receiving the intervention,
- Not be acting under duress; and,
- Have the decision-making capacity to make the decision (even if requiring support to do so).

There is no maximum duration for consent. Consent remains valid for an indefinite period unless:

- It is withdrawn
- There has been a change in the individual's capacity to give consent
- There has been a change to the proposed intervention to which the individual has previously given consent.

CONSENT AND VACCINATION FOR SARS-COV-2

In order to give valid, informed consent, a person should be provided with written information in advance. Information should be provided in a format accessible for that person and translation/interpretation support should be made available as required. In the context of vaccination for Sars-CoV-2, the HSE Vaccination Leaflet should specify the vaccine being given. As a general principle, all material risks and benefits of the vaccine must be disclosed. Additionally, in relation to Covid-19 vaccination such information should include individual as well societal benefits that may be conferred by 'herd immunity'.

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For the purposes of vaccination for Covid-19, Statutory Instruments 698 of 2020 and 81 of 2021 outline those healthcare professionals (in addition to medical doctors) who can administer the vaccine and, if required, adrenaline. They are:

1. A registered nurse (including a registered midwife),
2. A registered pharmacist,
3. An advanced paramedic,
4. A paramedic,
5. An emergency medical technician,
6. A person registered in the register of the Physiotherapists Registration Board established under section 36(1)(a) of the Health and Social Care Professionals Act 2005 (No. 27 of 2005)
7. A person registered in the register of optometrists of the Optical Registration Board established under section 36(1)(a) of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), or
8. A registered dentist.

They also have to have received training in the administration of the product, as approved by the regulatory body for the profession concerned or, in the case of a regulatory body that does not have legal authority to approve such training, as approved by the Health Service Executive following consultation with the regulatory body.

These healthcare professionals may seek consent to vaccination. In addition, healthcare workers who do not fit within these categories may, provided they have an adequate understanding themselves of the relevant information about the vaccine, seek consent from and support the person to make their decision.

Very specifically, it is important to note consent requirements in the following situations and that the general principles of consent apply:

Wards of Court: The Wards of Court Office has confirmed that there is no requirement to seek a Court Order or Court Consent for the administration of the vaccine unless a person who is a ward of court refuses to be vaccinated and is assessed by their medical doctor to lack the capacity to make that specific decision and the medical doctor considers that the administration would be in the best interests of the ward. In the case of a dispute between the individual and their committee that cannot be resolved locally, the matter should be referred to the Registrar of the Wards of Court. Further information is available here:

<https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/>

For individuals detained under the MHA 2001, the same principles of seeking consent also apply and detention does not preclude the need to obtain consent or imply that a person lacks capacity to make an informed decision about vaccination.

SITUATION/CONDITION-SPECIFIC CONSENT

While there is a general presumption that people have capacity to consent, there are situations when people may need additional supports to make decisions. Consent is always specific to the proposed intervention.

Impaired Capacity

If there are concerns about an individual's capacity to consent to vaccination, the following considerations apply:

- Is the decision urgent or could it be deferred until the person regains capacity to make their own decision?
- Where the person has communication difficulties, every practicable effort should be made to support them through the use of communication aides or to support them with the assistance of others who may have an insight into how the person communicates.
- If the person is unable with support to express fully their own will and preferences, any view that they can express will be central to the decision. This can be supported by discussions between the Health Care Worker and trusted people close to the person about the person's will and preferences.
- The person should be given information in a manner and language that they understand in relation to the vaccination.
- The person should have access to an independent advocate and/or a someone nominated by the individual to support them in their decision-making e.g. a friend or family member.

All people are presumed to have capacity to give consent and assessment of capacity should take place when there are concerns about an individual's capacity. There **are four key considerations in determining if a person has capacity to consent:**

1. Does the person understand the information relevant to the decision, including the risks of refusing vaccination?
2. Is the person able to retain the information long enough to make a decision?
3. Can the person use and weigh the information to make a decision? This may involve enabling another person to help the individual.
4. Can the person communicate their decision? Communication can be verbal, using sign language or any other means of communication.

A person must fulfil all of these criteria in order to be determined to have capacity to make a decision. People should be provided access to a private space to maintain confidentiality during the consent process, as far as is practicable. A person's decision to refuse should be respected.

It is important to note that no other person such as a family member, 'next of kin', friend or carer and no organisation can give or refuse consent to vaccination on behalf of an adult person who lacks capacity to consent. An attorney under the Powers of Attorney Act 1996 does not have authority to make a healthcare decision such as consent to/refusal of vaccination. The views of anyone the person has nominated to be consulted and of people who have a close, ongoing, personal relationship with the individual should be considered in ascertaining the individual's will and preferences, beliefs and values. However, such persons do not have authority to give or refuse consent on behalf of the individual.

In the case of a person who has been assessed as lacking capacity to make a specific decision about vaccination for Sars-CoV-2, HSE National Consent Policy currently notes (5.6): "*Irish case law,*

national and international guidelines suggest that in making decisions for those who lack capacity, the health and social care professional should determine what is in their best interests, which is decided by reference to their values and preferences if known”.

The Policy (5.6.3) notes that even if the individual lacks decision-making capacity in relation to this decision, the expressed views of the individual nonetheless carries great weight. In the presence of incapacity, the expressed views of the person carries great weight. If someone cannot express an opinion: *“Decisions should be made in the best interests of the [person] bearing in mind the principles outlined above. It is good practice to inform those close to the [person] of the planned interventions and to seek their agreement if possible. However, it is important to remember that the primary duty of the health and social care professional is to the [person themselves]”.* If an individual who lacks capacity can express a preference to receive or forgo an intervention, *“[s]uch preferences should in general be respected.”*

This procedure should be followed when considering vaccination for a person who has been assessed as lacking decision-making capacity, noting that that the benefit of most people will be best served by vaccination. This is particularly the case for people in a higher-risk group. If the individual cannot express a preference, those with a close ongoing relationship to them should be informed about vaccination and asked to indicate what they think the person’s wishes would be. The outcome of this discussion should be documented in the healthcare record. **People who do not wish to have the vaccine should not be given against their will.**

People who are extremely frail or approaching the end of life

Norwegian authorities have reported a number of deaths among nursing home residents shortly after vaccination against Covid-19, although there is no certain connection at present between these deaths and the vaccine.

Given that the benefit from vaccination begins only about 10–14 days following the first dose and full protection is not achieved until 7-14 days following the second dose of the vaccines currently in use, it is not appropriate to vaccinate people if their expected duration of life is less than that for the vaccine to take effect and if, in that context, their overall care is focused on comfort and dignity.

Decisions on the potential benefit or otherwise of the vaccine for those who are extremely frail and/or approaching end of life should form part of the considerations during the consent process with the patient, and in consultation with their families as appropriate, and may need input of more than one healthcare professional.

Pregnant Women

In Ireland, to date, the incidence of Covid-19 amongst pregnant women has remained very low and there have been no Covid-related deaths in this group, unlike many other European countries.

The available data do not indicate any safety concern or harm to pregnancy, and pregnant women can be vaccinated at certain stages of pregnancy, following agreement with their obstetric care giver. . Pregnant women who meet the priority criteria for vaccination and their obstetric caregivers should engage in shared decision-making in advance of vaccination. Counselling should balance available data on vaccine safety, risks to pregnant women from SARS-CoV-2 infection, and a woman’s individual risk for infection and severe disease. Where the risk/benefit is favourable, the two doses should be given at least 21 days apart. The two-dose schedule should not commence before 14 weeks gestation and should be completed by 33 weeks gestation.

DIGITAL REGISTRATION AND CONSENT

A national registration system is now being constructed under the auspices of information technology within the HSE. Individuals will be able to register and consent on-line. Others will also be able to register people who are either unable to register themselves or lack the capacity to consent to vaccination. Such a person could be a trusted friend or family member, the Person in Charge (PIC) of a Registered Care Facility or the proprietor of a registered Mental Health Facility.

There will be three options for those using the registration system in relation to consent:

1. I consent **OR**
2. I confirm this person has given their consent for this (if an administrator/trusted other is entering the data on behalf of another person prior to or at the time of vaccination) **OR**
3. This person cannot give consent and is being vaccinated in accordance with an assessment of their will and preferences and for their benefit

Vaccinators will have access to this information at the time of vaccination. In the case of those for whom others register who have been deemed to lack capacity to consent, this is a registration, not a consent process, and the process of consent/determination of benefit/will and preferences should be recorded in the individual's healthcare record, with option 3 selected.

Pregnant Women

For these women, the following questions will pertain on the digital registration process:

- 1) Are you pregnant? (if YES, then...)
- 2) I am between 14 weeks and 33 weeks pregnant **AND**
- 3) I confirm I have discussed the risks and benefits of receiving the COVID-19 vaccine with my obstetric care provider, they have confirmed I am at the correct stage of pregnancy to receive the vaccine and complete the course of two doses before 33 weeks of pregnancy and I consent to receive the vaccine. Written confirmation from the obstetric care provider is **not** required.

SUMMARY

It is generally presumed that individuals have capacity to consent and informed consent involves providing sufficient and appropriate material to enable informed decision-making. A three-tiered approach to the provision of this information is recommended:

1. The essential information required for informed consent-the HSE Vaccine Information Leaflet.
2. Provide the product information leaflet which will be available on-line and in hard copy.
3. More detailed information for those who would like it. There are links on HSE website with accessible information and available in other formats.

Information must be made available in other formats to those who lack digital access or may have issues with digital literacy.

The absence of complete access to a digital system should not prevent proceeding with vaccination, provided that the information required, e.g. for those with impaired capacity or pregnant women, is outlined in the patient record.

For those with impaired capacity, every reasonable effort should be made to enable a person to make an informed decision about receiving the vaccination. In situations where this is not possible, the final decision on whether or not to vaccinate an individual lies with the healthcare professional, having assessed decision-making capacity specifically with reference to the four key

questions set out above. The basis on which the individual has been assessed as lacking decision-making capacity to make this decision and the basis on which the benefit of the vaccine to the individual has been determined should be documented in the healthcare record.

Pregnant women should only be vaccinated, pending a shared decision-making process between themselves and their healthcare provider, between weeks 14 and 33 of gestation.

DOCUMENTS REFERENCED/CONSIDERED

1. Assisted Decision Making Act 2015.
2. HSE Policy on Consent <http://bit.ly/ConsentQID>
3. Mental Health Act 2001
4. Advices of the Attorney General to the HSE regarding the Covid Vaccine 2020.
5. STATUTORY INSTRUMENTS. **S.I. No. 698 of 2020** MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 7) REGULATIONS 2020
6. STATUTORY INSTRUMENTS. **S.I. No. 81 of 2021** MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 4) REGULATIONS 2021