

Consent for Vaccination for Sars-CoV-2.

PURPOSE

The purpose of this document is to elucidate the issues relating to consent for vaccination against Sars-CoV-2. Vaccination against this novel coronavirus has been developed in a rapid time-frame due to international co-operation and investment in its' development. A number of vaccinations are either in development or now have approval for administration, following successful Phase 3 trials.

This document will lay out the principles and processes of consent generally and will then describe consent in specific situations. The process of consent will include processes specific to the operationalisation of 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 provider and an individual that enables that individual to have a clear understanding of the nature of the intervention, and likely risks and benefits of receiving it, thus enabling them to make an informed choice about whether or not to proceed. Individuals 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- It is withdrawn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 client's capacity to give consent
- There has been a change to the proposed intervention to which the individual has not given consent.

CONSENT AND VACCINATION FOR SARS-COV-2

In order to give valid, informed consent, an individual must be provided with written information, the HSE Vaccine Information Leaflet, about the vaccination in advance of vaccination, otherwise consent will not be valid. Information should be provided in an accessible format and translation/interpretation support should be made available as required. In the context of vaccination for Sars-CoV-2, the HSE vaccination leaflet will need to reflect the specific vaccine being given. As a general principle, all material risks and benefits of the vaccine must be disclosed. Additionally, in relation to Covid vaccination, it is important to emphasise individual as well societal benefits that may be conferred by 'herd immunity'.

Those being vaccinated should be able to understand, retain, or communicate:

- The anticipated benefits of vaccination in the simplest of terms
- The likely side effects from vaccination and any individual risks they may run should be addressed, and
- The disbenefits/risks of not consenting to the vaccination.

People should be provided access to a private space to maintain confidentiality during the consent process.

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

1. Wards of Court: the Registrar of the Wards of Court has confirmed that there is no requirement to seek a Court Order or Court Consent for the administration of the vaccine. Those who indicate verbally or otherwise that they do not wish to be vaccinated should not be vaccinated. In the case of a dispute between the person and their committee that cannot be resolved locally, the matter should be referred to the Registrar of the Wards of Court.
2. For those detained under the MHA 2001, the same principles of seeking consent also apply and detention does not preclude the need to obtain consent.

SITUATION/CONDITION-SPECIFIC CONSENT

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

The following conditions need to be considered when consent is being obtained if there are concerns about capacity to consent:

- Consideration should be given at all times to the urgency of the decision in question- does the decision need to be made immediately and, if there is a likely to be a change in the persons condition, could their decision-making capacity improve.
- 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 through those who have an insight into how the person communicates.
- If the person is unable with support to express fully their own goals and preferences, any view that they can express will be central to the decision. This can be supported by discussions between HCW's and trusted people close to the person about the person's goals 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 self-nominated support person e.g. trusted friend or relative.

There are four key considerations in determining if a person has capacity to consent:

1. The ability to understand the information relevant to the decision, including the risks of refusing vaccination.
2. The ability to retain the information long enough to make a decision-the information only needs to be retained for long enough to make a decision.

3. The ability to use the information to make a decision-this may involve enabling another person to help the individual.
4. The ability to communicate the decision; this can be verbal, using sign language or any other means of communication.

A person must fulfil each of these criteria in order to be determined to have capacity to make a decision.

Although not widely known, 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 unless they have specific legal authority to do so. An attorney under the current Enduring Power of Attorney Act currently does not have authority to make a healthcare decision such as vaccination. The views of anyone the person asks to be consulted and of people who have a close, ongoing, personal relationship with the person such as family or friends should be considered and may be invaluable in eliciting the person's values, beliefs and goals.

In the case of a person for whom it is judged that they lack capacity to make a decision about vaccination for Sars-CoV-2, using the above principles, the HSE National Consent Policy 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 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 someone 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 in someone judged to lack capacity, noting that the best interests of most people will be best served by vaccination. This is particularly the case for anyone in a higher risk group. If the person cannot express a preference, those with a close ongoing relationship to them should be informed about vaccination and what they think the person would have wanted. The outcome of this discussion should be documented in the healthcare record.

In summary, every 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 to vaccinate someone lies with the healthcare professional using the 'best interests' principle and having assessed decision-making capacity specifically with reference to the four necessary considerations outlined above. The reasons for lack of capacity and 'best interests' should be documented in the healthcare record.

DIGITAL CONSENT

A national registration system is now being constructed under the auspices of information technology within the HSE. Thus, individuals will be able to register and consent on-line or others will be able to register for them e.g. the Person in Charge (PIC) of an RCF or the proprietor of a registered Mental Health Facility. Vaccinators will have access to this information at the time of

vaccination. In the case of those for whom others notify their consent on-line, this is a notification of consent and the process of consent should be recorded in the individual's healthcare record. For those who cannot consent, consider a 'best interests' tick box on the digital consent form.

RECOMMENDATIONS

1. Provision of Patient Information

We recommend a three-tiered approach to the provision of patient information:

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

2. Digitalisation of Consent

- Information must be made available in other formats to those who lack digital access or may have issues with digital literacy.
- A link the product information leaflet will be available.
- A checklist of consent should include the following and be available to the vaccinator:
 - Location of consent-a copy should be stored in the healthcare record.
 - In the case of those who lack capacity to consent, it should be indicated on the form that they are receiving the vaccination under 'best interests' principle.
 - Confirmation that the person has had access to the essential information needed for informed consent.
 - Confirmation that the person is happy to proceed at the time of vaccination, thus consent is re-confirmed.

3. Other Recommendations:

- Advance notification the Person-in-Charge of an RCF/Proprietor of a longer-term Mental Health Facility in order to enable consent in a timely manner.

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