

Consent for Covid 19 vaccine

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COVID-19 vaccination and consent

- Principles of informed consent process and good practice (HSE National Consent Policy) is the same.
- Some people will need support to make their own decisions, and some will be unable to do so even with support
- COVID-19 vaccine safety profile and effectiveness in line with previous vaccines
- Challenges: logistics, communicating through masks, lack of easy access to supports such as family, misinformation
- The potential seriousness of COVID-19 means the balance of benefit over risk is overwhelming for high risk groups

“While it is up to you to decide to get the vaccine, the HSE strongly recommends that you do so as soon as we offer it to you”.

Who can seek consent?

- A health or social care worker who is familiar with the important information about the purpose, benefits and risks of the vaccine. (No need to be an expert.)
- It doesn't have to be a doctor or nurse
- It doesn't have to be the person administering the vaccine

What is valid and informed consent?

The person must:

1. Have received sufficient information in a **comprehensible** way about the nature, purpose, benefits and risks of intervention
2. Make a voluntary choice.
3. Have capacity to make that particular decision (understand relevant information, retain it long enough to make a choice, use or weigh it in making the decision and communicate decision by any means)

Presumption of capacity unless the contrary is shown

People don't need to "prove" they have capacity

Validity of consent isn't dependent on how information is provided (leaflet, verbally or other) or how consent is documented (electronic, note in chart or form)

Make a voluntary choice

- People must not be put under undue pressure to make a particular choice
- They must understand they have a choice

BUT

- This is not inconsistent with trying to persuade someone to make a particular choice.
- Healthcare professionals should not be 'neutral' about the value of COVID-19 vaccination especially for high risk groups.

If someone lacks capacity to decide re COVID-19 vaccine?



“... if he or she was unable to give such consent, the will and preferences of the person was established and the administration was for the benefit of the person; “

STATUTORY INSTRUMENTS.

S.I. No. 698 of 2020

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 7) REGULATIONS 2020

- HSE National Consent Policy
 - *“No other person such as a family member, “next of kin”, friend or carer and no organisation can give or refuse consent...on behalf of an adult person who lacks capacity to consent unless they have **specific legal authority** to do so”.*
 - Include ‘those who have a close, ongoing, personal relationship’ in discussions, ‘not to make the final decision’ but to provide greater insight into the views and preferences of the person.

Who has "specific legal authority" to consent if the person can't consent?

- In practice, almost nobody!!
- Wards of Court
- (Enduring Power of Attorney made under current law does not include a healthcare decision).

For COVID-19 vaccination there is no signature/ box for 'third party consent'

Procedure for Wards of Court

- Ultimate responsibility for healthcare decisions rests with the President of the High Court. (Wards can also have a Guardian ad Litem (court appointed representative) or Committee (often a family member authorised to make personal care decisions))
- It has been confirmed that there is no requirement to seek a Court Order or Court Consent for administration of the vaccine. The President of the HC wrote to the Minister of Health that “she is concerned that wards will get the vaccine, on the direction of their clinicians, without undue delay”. (Irish Times Dec 11th)
- The President has recently issued specific directions regarding how the consent process and vaccination should operate for Wards
- The Ward, and the Committee or Guardian ad Litem should be given as much advance notice of vaccination as possible. and where possible, more than two days in advance.
- A Committee/GAL may make an application to the Court to seek to prevent vaccination, which application must be made within 7 days of the notification of the decision to vaccinate.

- If, after they have been provided with information on the vaccine, the Ward consents or agrees to vaccination, it should proceed. There is no need to notify the Court or seek their approval.
- If, after efforts to inform and persuade them, a Ward refuses vaccination a capacity assessment should be carried out by the treating clinician to see if they understand the consequences of their decision.
- If the Ward **has capacity to refuse** vaccination, the vaccine should **not** be administered. The office of the Wards of Court need be notified only if refusal could adversely impact on the person's placement.
- If the Ward **does not** have capacity to refuse vaccination,
 - Written notification of the capacity assessment should be sent to the Ward and Committee/GAL and should include a decision whether vaccination will or will not proceed based on the person's best interests.
 - If the best interests decision is to vaccinate the Ward, a Committee/GAL may make an application to the Court to seek to prevent vaccination.
 - If the best interests decision is not to vaccinate - e.g. if vaccination would distress the person to such an extent that it would damage relationships with his or her carers - the Office of the Wards of Court is to be notified of the decision and the rationale for not receiving the vaccine.

Documenting Wards of Court process

The following should be included in the person's healthcare record:

- Record of advance notice of vaccination to the Ward, GAL/Committee
- Detail efforts to help the Ward make an informed decision
- Details of the decision to vaccinate or not and the rationale for the decision, including Ward consent or informed refusal, capacity assessment (if it was required) and consideration of best interests of the person (if it was required)
- All written notifications to Ward, GAL, Committee or Courts

But what about 'Next of Kin'?

- A false belief persists among healthcare staff (and the public) that consent should be sought from the 'next of kin' (if a person can't consent)
- In fact this only means that that person should be contacted in the event of an emergency.
- “No other person such as a family member, “next of kin” ..., can give or refuse consent...on behalf of an adult person who lacks capacity to consent unless they have specific legal authority to do so”.
- For COVID-19 vaccination there is no signature/ box for 'third party consent'

Determining will and preferences?

Ask the person!

- If they agree – vaccinate. (This ‘assent’ is an expression of their preferences rather than consent)
- If they refuse (‘dissent’)
 - Individuals who indicate verbally or otherwise that they do not wish to be vaccinated should not be vaccinated

However

- The reasons for refusal should be explored: sometimes it may be a need for additional time or explanation
- In some cases, the person may, even with support, be entirely unable to understand what is proposed
- Because vaccination is for the benefit of the person, every practicable effort should be made to persuade (not coerce or force) them to accept it

If the person can't answer for themselves, those close to the person – that is, those with a close ongoing relationship with the person and who knows him or her - may have an idea of what the person would have wanted. (Staff who know the person well may also be able to help).

You must make clear to them that they are advising whether the person would have agreed to the vaccine if they were able to do so.

A brief note should be made in the medical records of such discussions and their outcome

This is distinct from those close to person expressing their own views on vaccination

Whether or not somebody had previous vaccinations / had children vaccinated can be a very helpful pointer to their views

What if those close to a person disagree with vaccination?

- Explore why they disagree with a proposed intervention
- Carefully consider their views
 - They are closer to and know person better than a professional and mean the best
 - They may have a better insight in likely will and preferences
 - Nobody wants those close to be the person to be upset
- Seek to allay concerns
- Involvement of the General Practitioner may be very helpful
- **Ultimately**, in these circumstances, unless the objections are clearly based on the likely will and preference of the person and unless the person him or herself objects, and if it is still felt to be the right choice and for the benefit of the person, **vaccination should proceed.**

Why?

- The person lacking capacity has a right to life and to the highest attainable standard of health. Determining the appropriate course of action encompasses a recognition of the rights of the person.
- It is not appropriate not to give a vaccine that is for the benefit of the person given the magnitude of risk from COVID-19 especially for high risk groups.
- Deferring vaccination to allow further discussion is often not a realistic option and may leave the person at high risk for infection and its consequences.
- This advice is in accordance with the Statutory Instrument regarding COVID-19 vaccination

Conclusions

Think supporting decision making more than capacity/incapacity!

Person has capacity and consents – **vaccinate**

Person doesn't have capacity and agrees/doesn't refuse – **vaccinate**

Person has capacity and doesn't consent – **don't vaccinate**

Person doesn't have capacity and refuses – **don't vaccinate**