

Consent for Covid 19 vaccine

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What's not new?

- Vaccines and vaccination, including effective roll-out in residential care and the role of staff in, for example, annual flu vaccination
- 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

What's new?

- COVID-19 and associated effects
- Misinformation: virus deniers, anti-maskers, bleach!
- Challenges: logistics, communicating through masks, lack of easy access to supports such as family and friends
- The potential seriousness of COVID-19 for NH residents (and workers) means the balance of benefit over risk is overwhelming and

“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?

All hands on deck!

- Consent is best sought by a health **or social care worker**
 - Who knows the person, their background and how best to communicate with them –
 - Who has familiarised themselves 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, and often won't be, the same person as the vaccinator

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
- The potential seriousness of COVID-19 for residential care residents means the balance of benefit over risk is overwhelming

“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”.

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



STATUTORY INSTRUMENTS.

S.I. No. 698 of 2020

“... 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; “

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"?

- In practice, almost nobody!!
- Wards of Court
 - 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.
 - In the case of a dispute with the committee of the ward that cannot be resolved locally, the matter should be referred to the Registrar of the Wards of Court.
 - The President of the High Court has written to the Minister of Health stating that "she is concerned that wards will get the vaccine, on the direction of their clinicians, without undue delay". (Irish Times Dec 11th)
- (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'

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)
- Sage advocacy (2018): An online Red C poll – 52% believed, wrongly, that anyone named as “Next of Kin” can make healthcare or other major decisions on another person’s behalf.
- In fact this only means that that person should be contacted in the event of an emergency.

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

Supporting before and during vaccination

- Preparation (days/weeks) before vaccination):
 - Talking about the vaccine in a natural way.
 - Social Stories (outlining what the vaccine involves)
 - Desensitisation - help relax & build up confidence in vaccination process
 - Light hearted role-play one or two scheduled times every day.
- Environment: Quiet space with as little stimulation as possible – when vaccine allows preferably own home - and plenty of time so doesn't feel pressured or rushed
- Familiar, trusted person to reassure and support
- Numbing Cream or pain relief for the area of injection
- Short-acting anxiolytic, e.g. very anxious or needle phobia

- Therapeutic Touch:
 - To reassure the person – they may wish their support person to hold their hand, or touch them in some other way
 - To stabilise a persons' arm who may have tremors, or unexpected movements from anxiety or other issues
 - Some people may reach out to touch/hold the syringe and may need to be supported so that they do not pose a risk to themselves or the vaccinator
- Distraction: Identify things that help distract e.g. movie on iPad, music on headphones, favourite object, squeeze a stress ball, chat about favourite things; simple visualization.
- Motivation: Something the person really likes: favourite drink, dessert, magazine

Be imaginative and creative!

What if those close to a person disagree with vaccination?

- A woman in our nursing home is 83 yrs, moderately frail and has an MMSE of 22/30. She wishes to receive the vaccine. Her daughter and next of kin has given us strict instructions by phone, email and by registered letter that “I DO NOT CONSENT TO XXXXX RECEIVING THE COVID VACINATION”
- A man in our unit is 87 yrs, unable to communicate because of dementia but physically well and enjoys life. His son has been on the phone to insist that his father is not to get the ‘experimental Covid vaccine”

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 for those in residential care**

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 vulnerable people and the effectiveness and risk profile of the vaccine
- Deferring vaccination to allow further discussion is not a realistic option
- The practicalities of vaccination in residential care during the pandemic means that someone who doesn't get vaccinated when scheduled to do so may not have an early opportunity to avail of it later and may remain 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**