

# Requirements for consent for Covid 19 vaccine - Principles for practice

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# Background

- COVID-19 is a new and frightening disease
- Effective vaccines and vaccination is not new
- COVID-19 vaccine safety profile and effectiveness in line with previous vaccines
- COVID-19 vaccination has been dramatically effective in preventing serious disease in residential care

# Basis of vaccination

- Person consents to vaccination, even if needs support to do so
- The person can't consent even with support but
  - Vaccination is not contrary to his/her will and preferences AND
  - Vaccination is for his/her benefit

Vaccinate

Vaccinate

# Consent and Will and Preferences

- Consent is the giving of permission or agreement for an intervention following a process of communication about the proposed intervention.
- Will and preference
  - Based on the law regarding vaccination (not ADM Act)
  - The person's own voice- however expressed counts even if they lack capacity to consent



- People with disability are all individuals with distinct needs
- Some can give/refuse consent with no/some/ a lot of support
- Some communicate verbally/non-verbally

# Support people during vaccination process

- Supporting people to understand the information about the vaccine and to make their own informed choice whenever possible
- Supporting those who are unable to consent to express their will and preference regarding vaccination
- Supporting people through the vaccination itself



**Family and carers are the experts  
in how to do this**

# For the benefit of the person...

- A person who lacks capacity has the same right to life and to the greatest possible standard of health as everyone else.
- COVID-19 vaccines are safe and effective
- For those in high risk groups, the potential benefits greatly outweigh the risks
- Vaccination is strongly recommended by the HSE, by professional groups like the Irish Royal College of Physicians and the World Health Organisation

# TILDA report on “persons ageing with an intellectual disability”

High rate of pre-existing conditions associated with poorer outcomes for COVID-19.

- 66% overweight/obesity.
- 52% cardiovascular disease
- 30% epilepsy
- 10% diabetes

The pandemic has been particularly difficult for people with disability - 50% indicated stress or anxiety as a result

Updated estimates of coronavirus (COVID-19)  
related deaths by disability status, England: 24  
January to 20 November 2020

- Risk of death involving COVID-19 was 3 times greater for those with physical disability and almost 4 times greater for those with a learning disability
- Highest death rate among people with disabilities was aged 55-64y – that is, 20 years younger than peak in general population.

# What is informed consent?

The person must:

1. Have received sufficient information in a way they can understand
2. Make a voluntary choice.
3. Have capacity to make that particular decision

# Consent - information

The person must receive sufficient information in a way they can understand about the nature, purpose, benefits and risks of vaccination and of not being vaccinated

Provide information in a way that will best support person to make their own decision, e.g. right place and time, tailored to individual needs, prior level of knowledge, preferred communication styles...

Family and carers are essential to this process for many people with disabilities

- Risks include
- Common, even if minor, side effects
- Rare but serious outcomes: (important to keep in perspective - 1/100,000 is roughly annual risk of death from homicide in Ireland)

- The HSE vaccine information leaflet has the important information
- There are also easy-read versions.
- For some, easier if information given verbally by healthcare professionals.

Coronavirus  
**COVID-19**



## Vaccine information

26th January 2021

### What is COVID-19 coronavirus?

COVID-19 is a very infectious illness which can cause serious illness, hospitalisation and even death. COVID-19 is caused by a new type of Coronavirus that was discovered in December 2019.

### Why is it important to get a COVID-19 vaccine?

Some people who get COVID-19 can get serious complications which make them very sick. People with Covid-19 may need treatment in hospital or in intensive care. COVID-19 can even cause people to die. There is no way to know how COVID-19 will affect you if you get it. And if you get sick, the virus could spread to other people like your family and friends.

The COVID-19 vaccines will offer you protection from COVID-19.

Vaccines teach your immune system how to protect you from disease. COVID-19 vaccines are effective at stopping people from getting sick with COVID-19. If you have been vaccinated, when you come into contact with COVID-19 infection, your immune system should stop the infection from making you sick. Some people might still get COVID-19 even after having the vaccine.

# Consent - 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.
- We should not be 'neutral' about the value of COVID-19 vaccination

# Consent - Capacity to decide

- Understand the information about the vaccine
- Retain it long enough to make a choice
- Use or weigh the information in making the decision
- Communicate decision by any means

Presumption of capacity unless the contrary is shown.

- Diagnosis of, say, dementia, intellectual disability or the need for some support do not change starting presumption
- Making an “unwise” decision is not of itself indicative of lacking capacity to make a decision

# 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

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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**”.*

There is a false belief among healthcare staff and the public that consent should be sought from the ‘next of kin’ (if a person can’t consent)

# Who has "specific legal authority"?

- In practice, almost nobody!!
- Wards of Court
  - Responsibility for healthcare decisions rests with the President of the High Court who has recently issued specific directions regarding how the consent process and vaccination should operate for Wards
  - President 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)

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

# Determining will and preferences?

Ask the person!

- If they agree – vaccinate.
- If they refuse
  - 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
- 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 who know him or her best may have an idea of what the person would have wanted.

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

# Conclusions

Think supporting decision making more than capacity/incapacity!

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

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

Person has capacity and consents – **vaccinate**

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