

# Requirements for consent for Covid 19 vaccine

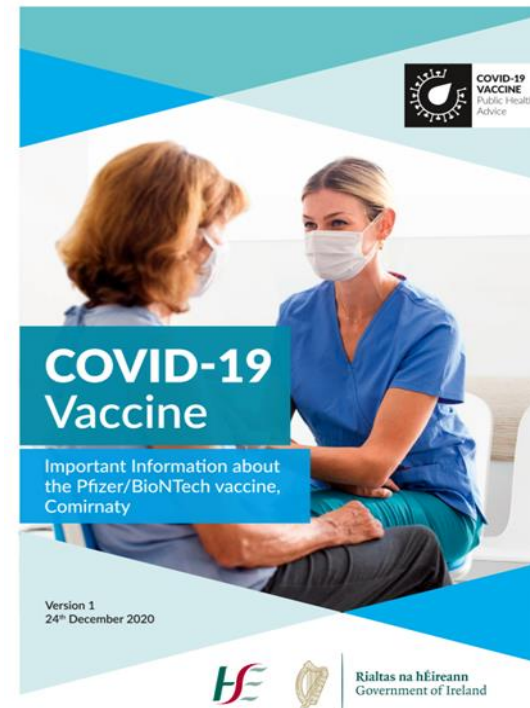
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## COVID-19 Nursing Homes Expert Panel

Examination of Measures  
to 2021

Report to the Minister for Health



- 79% of deaths from COVID-19 occurred in over 75 age group (by 14<sup>th</sup> July 2020)
- 56% of all deaths occurred in nursing homes.
- In NH outbreaks, of residents who caught COVID-19, 17.3% died

# Occupation and risk of severe COVID-19: prospective cohort study of 120 075 UK Biobank participants

- Healthcare workers = 8X risk vs non-essential workers.
- Social care (child/older care) = 2.5X
- Transport workers = 2.2X
- Teachers = 1.4X
- Essential workers generally = 1.6X

*Of NH healthcare workers who caught COVID-19, about 10% were hospitalised* (West of Ireland, 2nd wave data)

# 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”.*

# 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

# What information?

- Tailored to individual needs and wishes, prior level of knowledge, preferred communication styles...
- Provide information that a reasonable person in person's situation would expect to be told:
  - Side effects or complications of an intervention;
  - Likelihood intervention will be successful;
  - Risks of doing nothing or taking an alternative approach.
- A risk is significant if a reasonable person in person's position, if warned, would attach significance to it...
  - Common, even if minor, side effects
  - Rare but serious outcomes - death, permanent disability...
  - **Helpful often to put risks in perspective** (1/100,000 is roughly annual risk of death from homicide in Ireland)

# Comirnaty (Pfizer/BioNTech)

COVID-19 can be a very serious life-threatening illness.

Getting a COVID-19 vaccine should protect you – and those around you - from the serious complications of COVID-19. We don't know yet how long the protection may last

Like all medicines, vaccines can cause side effects in some people.

A lot of people (more than one in 10) are sore where the injection is given or get muscle pain, headache and fever. These are temporary and usually mild symptoms.

A few people (up to one in 100) feel unwell or have some swelling of glands in the armpit

Rarely (up to one in 1,000) people can get a temporary one-sided facial drooping (Bell's palsy)

Very rarely (about 1 in 100,000 - in other words 99,999 of 100,000 don't get it) there is a serious allergic reaction (anaphylaxis) to the vaccine. The vaccinator is trained to treat such reactions.

Those known to be allergic to components of the vaccine – which is very rarely the case - shouldn't receive it

The COVID-19 vaccine has gone through the same safety checks as other licensed vaccines. However, it is new and long-term side effect information is limited.



# Providing information

Provide information in a way that will best support person to make their own decision, e.g. right place and time

Validity of consent isn't dependent on how information is provided

- The HSE information leaflet provides the important information about the vaccine.
- There will also be an easy-read version.
- If appropriate, these should be provided in advance to people (and/or those close to them).
- For some, it will be easier if the information is given verbally by healthcare professionals.

# 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”.*

# Presumption of capacity

Presumption of capacity unless the contrary is shown.

*“Presumption of capacity is to consent and decision making what the presumption of innocence is to criminal law”.*

- 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
- **People don't need to “prove” they have capacity**
- If when you explain about vaccination the person seems to understand and consents to the vaccine you can operate on the basis that they have the capacity to consent.

# Capacity requirements

- Does the individual understand the information relevant to the decision, including the risks of refusing vaccination?
  - General understanding of the most important points - person doesn't have to become an expert
- Is the individual able to retain the information long enough to make a decision?
  - Retain long enough – it's not a memory test
- Can the individual use and weigh the information to make a decision?
  - Most people start now with an understanding of the pandemic and risks and effects on life and most will have had previous experience of vaccinations
- Can the individual communicate the decision?
  - Communication can be verbal, using sign language or any other means of communication.

# 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 11<sup>th</sup>)
- (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
- Staff familiar with a resident or those close to the person may be of considerable assistance in this regard



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?

- 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

# 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**

# Conclusions

- COVID-19 has had a devastating effect on those in residential care, on those who work with them and has also disproportionately impacted on those close to residents due to visiting restrictions.
- The vaccine offers a real hope of reducing future infection and restoring important quality of life choices such as visiting.
- The informed consent process for the COVID-19 vaccine follows well established principles
- The pandemic does create new challenges in communicating effectively, especially with those in residential care but the principle of supporting people to make their own decisions remains.