

# Mass Vaccinations - Consent

## Purpose

The purpose of this paper is to provide an outline of how Consent will be managed across the Essex footprint in relation to Mass Vaccinations.

## Key Message

Obtaining valid consent; addressing mental capacity assessments, best interest decisions, and administration of any vaccination requirement including restraint, are the responsibility of health.

## Context

When the various vaccines to offer protection against Covid-19 are approved, one of the key considerations in how to provide the vaccines to the population will be how to address the consent of the individual.

Vaccination is a medical procedure and requires the consent of the individual before it can be carried out. In order to give consent, an adult must have the capacity to do so. *“Consent must be obtained before starting any treatment or physical investigation or before providing personal care for a patient. This includes the administration of all vaccines.”* Green Book on Immunisation against Infectious Diseases (page 7)

<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

Some of the most vulnerable to the virus are also those who are most likely to lack capacity to consent, especially those suffering from dementia related conditions in residential care. These adults are the most likely to be in the first cohort of those receiving the vaccine so it is vital that there is a clear and simple method of addressing consent.

The Coronavirus Act 2020 does not contain any power that allows vaccination to be provided without consent.

The Secretary of State for Health and Social Care has not ruled out making vaccination compulsory if take up of the Covid vaccines is low but there are no current plans to do so.

This note sets out a path to a simple process that balances the rights of the individual against the importance of mass immunisation and the preservation of life.

## Capacity

The Mental Capacity Act 2005 provides the framework to make decisions for those who lack the capacity to do so themselves.

The Act specifically deals with medical treatment, such as immunisation. Section 5 provides protection from liability to any person who carries out medical treatment, as long as that person reasonably believes that the adult lacks capacity to make that decision and that the treatment is in the adult’s best interest.

This does not apply to liability arising from negligence. An advance decision to refuse the treatment also prevents this defence being used.

If the treatment requires restraint, then there are two additional conditions:

1. The first condition is that the person reasonably believes that it is necessary to do the act in order to prevent harm to the adult.
2. The second is that the act is a proportionate response to—
  - a. the likelihood of the adult suffering harm, and
  - b. the seriousness of that harm.

As consent for the Covid vaccine is the responsibility of health, as is any subsequent best interest assessment, Social Care would not be involved in the vaccination process nor any restraint that may be required.

Paragraph 5.38 of the Mental Capacity Code of Practice provides an example of best interests and vaccinations:

***“Scenario: Considering wishes and feelings as part of best interests***

*Andre, a young man with severe learning disabilities who does not use any formal system of communication, cuts his leg while outdoors. There is some earth in the wound. A doctor wants to give him a tetanus jab, but Andre appears scared of the needle and pushes it away. Assessments have shown that he is unable to understand the risk of infection following his injury, or the consequences of rejecting the injection.*

*The doctor decides that it is in the Andre’s best interests to give the vaccination. She asks a nurse to comfort Andre, and if necessary, restrain him while she gives the injection. She has objective reasons for believing she is acting in Andre’s best interests, and for believing that Andre lacks capacity to make the decision for himself. So she should be protected from liability under section 5 of the Act (see chapter 6).”*

## Court of Protection

Because the law provides a clear decision-making route, there is no need for an application to the Court of Protection, unless there are exceptional circumstances, these may include:

- Dispute over capacity
- Strong current views of the adult
- Strong views of family/ friends, especially if they hold deputyship or LPA
- Past views of adult, for example, advance decision against this type of treatment or religious belief (such as Jehovah’s Witness)

## Who is the decision maker?

- The person who would make the best interest decision on behalf of an adult who cannot make that decision themselves is the clinician providing the treatment.
- Therefore, the responsibility for ensuring the capacity assessment and best interest process rests with the NHS – or Health practitioner providing the vaccination.
- ECC does have overarching public health responsibilities and will be an integral part of the vaccine roll out but does not operate as a decision maker in this case.
- ECC could identify people we know do not have capacity and share this with partners – If we are notified of who the proposed vaccine patients are in advance we could share our data on what we know regarding capacity (previous relevant decisions, knowledge that there are written advance wishes on healthcare etc.) to help identify individuals where capacity decisions need to be made in advance.

## Simplified procedure

Once the identity of those in the first cohort is known, the capacity and best interest process can be carried out immediately – this can frontload the process and hopefully make it as efficient and quick as possible.

The Act requires that the assessment considers whether the adult will have capacity when they receive the vaccination, but this can be identified for nearly all adults (especially those with progressive conditions such as dementia) well before it is provided as long as the assessment covers this.

There are national consent forms developed for all health staff to use as part of the vaccine programme, which will help to embed a robust approach to consent. [Social Care Staff Consent](#) / [Resident Consent](#)

They have also offered to provide legal support to the local NHS to navigate any issues and take any legal action as needed