

Our Ref: 67754

22 June 2021

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Re: Freedom of Information Request

Please find below the response to your recent Freedom of Information request regarding Informed Consent within NHS South Sefton CCG.

Request/Response:

1. Please provide me with all examples any prompt sheets given to medical staff working in the area of delivering Covid-19 vaccines in relation to informed consent for those receiving the vaccines.

Every COVID-19 vaccinator in South Sefton has completed consent training as part of their essential e-learning requirement. Training for the consent process including informed consent is contained in the NHS e-learning for health module entitled "Core Knowledge for COVID-19 Vaccinators".

Consent is mentioned in the role descriptor "action cards" for vaccinators and GP clinical lead and each vaccinator and GP has a copy of the relevant action card.

Staff do not have specific prompts for informed consent. If a vaccinator has any query regarding consent then they would discuss it with the GP prescriber for the vaccination session. Vaccinators and GPs can access the internet in the clinic for the mental capacity act or other consent related documents if necessary.

Documents noted above are included as appendix 1-3.

2. Please also provide me with details of how many staff have received training in the area of informed consent in relation to the delivery of Covid-19 vaccines within the period 1st January 2020 to the present day.

There are 157 vaccinators and GP prescribers on the South Sefton vaccination programme. They have all undertaken consent training within their required e-learning, as outlined above.

Appendix 1

Consent training for South Sefton Vaccinators
Included in NHS e-learning for health module
"Core Knowledge for COVID-19 Vaccinators"

1. Have you obtained consent?

Before giving a COVID-19 vaccine, vaccinators must ensure that they have obtained informed consent from the patient or that a best interest decision has been made if the patient does not have mental capacity at the time of vaccination.

In order to be able to consent to vaccination, the vaccinee should receive an explanation of the treatment and its benefits and risks, either verbally from a clinician, or in the form of a leaflet and letter.

When assessing capacity to consent, the professional should be guided by the principles of the [Mental Capacity Act](#).

Hyperlink to <https://www.nhs.uk/conditions/social-care-and-support-guide/making-decisions-for-someone-else/mental-capacity-act/>

Select the **What does consent consist of?** tab to continue.

2. What does consent consist of?

Consent is a process that must consider three factors:

Consent is a process that must consider three factors:

- **Factor one:** The person giving consent must be appropriately informed; they must have the necessary information in order to make the decision
- **Factor two:** Consent must be given voluntarily by the individual without undue pressure or coercion
- **Factor three:** The person consenting must have the capacity to make the decision

3. What information should be given?

Information to be given includes:

- Vaccine to be given and the disease that will be prevented
- Benefits/risks of vaccination versus risks of the disease
- Any new information that has become available since consent to previous doses of this vaccine were given if applicable

- Any possible vaccine reactions and how to treat these
- Follow-up/information as to any further doses required
- How any personal data will be stored and kept (information governance)

How much information should you give?

This will be personal to the individual at the time, and will depend on their previous knowledge and discussions with others.

Consent is a process, not a one-off discussion:

- Give people as much information as they need and/or want to make an informed decision
- Some people will just 'trust' what you say while others want lots of information; either is fine
- How much each individual needs is up to them, no one is obliged to seek full information

4. What is informed consent?

- The need for 'informed consent' is a legal requirement and the patient's views must be respected and consent sought.
- Sufficient evidence-based information must be provided to the person to enable them to make a balanced and informed decision about their care and treatment. As well as a general explanation of the procedure, there is also a duty to explain the risks inherent in the procedure and the risks inherent in refusing the procedure.
- Consent can be given verbally, in writing (although there is no requirement for written consent or a particular consent form) or it can be implied (non-verbal consent) but however it is given, the person must understand what they are consenting to.
- The consent process should not be an unnecessary barrier to vaccinating. If there are any issues or uncertainties with seeking or gaining consent, ask for advice from an experienced colleague rather than abandon the offer of vaccination.
- If you are responsible for obtaining consent from vaccinees, you should ensure you have received specific, more detailed training in this, for example, through undertaking session Legal Aspects (442-0021) [this is an Immunisation project, but the quick link is the unique identifier of the session in the hub].

5. Capacity

All adults are considered to have capacity to consent to receiving vaccinations unless there is evidence to suggest that capacity is limited.

The law relating to decision-making and consent varies across the UK.

The England and Wales '[Mental Capacity Act' 2005](#) (MCA) and in Scotland, '[The Adults with Incapacity Act' 2000](#), set out the criteria and procedures to be followed in making decisions when patients lack capacity to make these decisions for themselves.

The Acts also grant legal authority to certain people to make decisions on behalf of patients who lack capacity.

- [What should an adult be able to do to be considered to have capacity?](#)

If an adult is able to do the following three things, then they should be considered to have capacity and their decision should be respected:

1. Understand the information that you are giving them about the vaccine and any potential risks from it or from the disease it protects against
2. Consider the information you have given them and retain it for long enough to make a decision on whether to accept or decline the offer of vaccination
3. Communicate their decision to you

- [What actions can be taken to support and optimise a person's ability to make a decision?](#)

As a person's capacity to consent can fluctuate, there are some actions that can be taken to support and optimise a person's ability to make a decision. These include:

- Making [reasonable adjustments](#) to facilitate decision making or accommodate individual needs
- Using communication tools such as 'Easy read' leaflets
- Speaking with them at their best time of day
- Asking someone who the person knows and trusts to speak to them

If an adult does not have capacity and there is no [Lasting Power of Attorney \(LPA\)](#) (read a full definition of this term), [Welfare Attorney](#) (read a full definition of this term) or [appointed deputy](#) (read a full definition of this term), a best interest decision will need to be made.

- [What must be considered in order to make a best interest decision?](#)

To make a best interest decision, the following must be considered:

- The person who lacks capacity should be involved in the decision-making process if possible, particularly if their capacity fluctuates. If capacity does fluctuate, the healthcare professional would accept consent given at the time
- Any previously expressed wishes or behaviours such as previously consenting to vaccination should be acknowledged
- The offer of vaccination should be discussed with those close to the patient such as their carer, relatives or anyone appointed as a Lasting Power of Attorney (LPA) for Health and Welfare, or those named by the person to be consulted on vaccination if practical
- The person's actual interests at the time the vaccine is offered

This process should be documented and the decision recorded.

It is good practice to inform nursing or care home management teams of any plans to vaccinate residents in advance of the scheduled date. This will allow time to address any potential issues.

Select the hyperlink to go to the [Mental Capacity Act 2005](#)

Appendix 2

South Sefton PCN, COVID-19 Vaccination Programme

ACTION CARD v4

GP/ANP Prescriber

Role	The main role of the GP/ANP is to act as clinical supervisor for the site, provide advice for other staff or patients, deal with medical emergencies and sign off the patient specific directive (PSD).
TASKS	
Where and when?	Vaccination sessions run between 08.30 – 13.30 and 14.30 -19.30. The sites are Maghull Town Hall, Hall Ln, Maghull, Liverpool L31 7BB, with good car parking opposite the tennis courts and North Park Health Centre, 290 Knowsley Rd, Bootle L20 5DQ. Park next door at the May Logan Centre to keep the Health Centre car-park free for patients
On-arrival	Report to the shift supervisor on arrival and sign-in. Bring ID.
Introductions	Introduce yourself to the various staff. You will meet everyone at the “huddle” before the session. Ask if any vaccinator is doing their first shift and if so mentor them during the shift. Check that the vaccinators are aware of any updated guidance regarding COVID-19 vaccines.

Anaphylaxis kit	Familiarise yourself with the anaphylaxis kit and defib and run a test. Check the adrenaline and syringes are in the green grab bag in the resus bay at Maghull Town Hall or in room 1 at North Park Health Centre.
Infection control	Maintain oversight of infection control and bring any issues to the attention of the shift supervisor. We aim to avoid the risk of COVID transmission through airborne or direct transmission. Always wear a mask and adhere to social distancing guidelines. A disposable apron should be worn and changed regularly when vaccinating. Gloves are optional but hand gel must be used between patients. Vaccinators will be responsible for keeping their work-station clean and for cleaning the seats with a wipe between patients. Please also acknowledge the essential work undertaken by our volunteers.
The Vaccinators	The vaccinators are from different backgrounds, nursing, retired doctors, medical students, pharmacists, HCAs and paramedics. They have all completed e-learning and an observed assessment of competency.
Vaccine preparation	Pharmacists oversee vaccine preparation. The pharmacy technicians will reconstitute the Pfizer vaccine for collection by the vaccinator, on a blue tray with six syringes and needles. Vaccinators will draw up the 0.3 ml dose. There should be six doses from most vials (but don't draw any one dose from more than one vial). If only five doses are withdrawn then the vaccinator should inform the pharmacist when they return the finished blue tray. The AZ vaccine is also supplied on a blue tray with the required number of syringes (8 or 10)
Clinical screening	<p>The screening questions are generally asked by the vaccinators but the GP prescriber can do this to speed-up patient flow. Note the</p> <p>For patients on anticoagulants, if the INR is fine or if on an NOAC, the advice is to press on the injection site for 2 minutes after injection.</p> <p>Anaphylaxis advice is in the Green Book (hard copy available on request): <i>“There are very few individuals who cannot receive the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.</i></p> <p><i>The vaccine should not be given to those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to:</i></p> <ul style="list-style-type: none"> • a previous dose of the same COVID-19 vaccine • any component (excipient) of the COVID-19 vaccine e.g. polyethylene glycol <p><i>The Pfizer BioNTech and Moderna mRNA vaccines contain polyethylene glycol (PEG). PEGs (also known as macrogols) are a group of known allergens commonly found in medicines, many household products and cosmetics. Medicines containing PEG include some tablets, laxatives, depot steroid injections, and some bowel preparations used for colonoscopy. Known allergy to PEG is rare but would contraindicate receipt of this vaccine. It is unclear whether PEG is the only cause of allergic reactions in patients with systemic allergic symptoms after the first dose of Pfizer-BioNTech vaccine.</i></p> <p><i>The rate of anaphylaxis reported to date to the AstraZeneca vaccine is in line with the expected rate of anaphylaxis to non-COVID vaccines. The AstraZeneca vaccine does</i></p>

	<p>not contain PEG but does contain a related compound called polysorbate 80. Some people with PEG allergy may also be allergic to polysorbate 80. However, polysorbate 80 is widely used in medicines and foods, and is present in many medicines including monoclonal antibody preparations. Some injected influenza vaccines (including the main vaccine used in over 65 year olds) contain polysorbate 80. Individuals who have tolerated injections that contain polysorbate 80 (such as certain influenza vaccines) are likely to tolerate the AstraZeneca vaccine</p> <p>More recent communications about specific vaccine scenarios can be found below:</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  COVID-19 vaccination and bloc19_vaccination_pregi </div> <div style="text-align: center;">  PHE_11920_COVID- </div> </div>
Clinical assessment	If a person falls ill it's the responsibility of the GP/ANP to assess and form an action plan. This consultation will need documenting on the clinical recording form and communicating with the patient's GP surgery.
Vaccine queries	The PHE email address for vaccine queries is england.cm-imms@nhs.net
Referral for hospital vaccination	To access hospital immunisation for patients with a history or allergy or allergic reactions to dose 1 of COVID-19 vaccine, based on the green book algorithm, complete the details on a clinical recording form and give the form to the shift-supervisor or site manager who will store it in the box file on their desk.
Yellow Card reporting	Report any reactions to COVID-19 vaccination via the Yellow card scheme https://coronavirus-yellowcard.mhra.gov.uk/
Consent	By attending it seems likely the patient wishes the vaccine. They should receive written information about the vaccine at reception. Consent is verbal. If the patient does not have capacity then either the LPA gives consent or a "best interest" decision is required. Being vaccinated is almost certainly in their best interests
PSD	If the vaccinator is not a prescriber you will be asked to sign the PSD. If a prescriber is vaccinating they don't need the PSD but the screening questions are still relevant to check there is no contraindication to vaccination. BMA guidance on PSDs is at https://www.bma.org.uk/advice-and-support/gp-practices/prescribing/patient-group-and-patient-specific-directions
Reserve list for vaccination	Decide on priorities for vaccination from the reserve list of patients / staff who can be called at the end of the day so that all vaccine doses are used. . Refer to national guidance and priority groups however to avoid wasting vaccine patients outside those groups can be vaccinated at your discretion.
EMIS access	The Pinnacle system allows you access to Summary Care Record, though does not have much clinical information. For patients from SS PCN practices you can log in to EMIS. Please remember to bring your log-in details.
Pinnacle system & documentation	Each vaccinator will have an admin assistant who will enter information on to Pinnacle (the IT system for the vaccine programme). There are paper copies of the record form to use in case of IT failure so legible handwriting is

	essential. Remember to bring your Pinnacle log-in with you.
Responsible to	Site Manager
Contacts	For questions or suggestions please contact Drs Ken Lamden Kenneth.lamden@pc24.nhs.uk or Pete Chamberlain Peter.Chamberlain@southseftonccg.nhs.uk

V4, 5.5.21

Appendix 3

South Sefton PCN, COVID-19 Vaccination Programme

ACTION CARD v4

Vaccinator

Role	To deliver COVID-19 vaccinations in a Vaccination Centre in South Sefton
Tasks	<ul style="list-style-type: none"> • To report to the Site Manager/Shift Supervisor on arrival and sign-in • Participate in the safety huddle at the start of your shift • Read the bay etiquette document on the wall of your bay/treatment room • To set up your vaccination work-station prior to the session • To check the identity of the patient and assess the patient as eligible for vaccination – complete the clinical questions on the vaccination recording form • Obtain informed consent for vaccination • Whilst using a PSD then request the GP/ANP prescriber to look over the completed form and prescribe vaccine (process varies across sites) • Vaccinate with COVID-19 vaccine as appropriate • Complete the clinical and vaccination details on the vaccination recording form or enter them on the Pinnacle software. You may have an admin assistant to help with this, • To advise the patient of their leave time with a 15 minute wait for those receiving the Pfizer Vaccine or driving home after AZ • To tidy and clean your work-station at the end of the session and restock with non-vaccine consumables as necessary • To highlight low stock levels to shift supervisor
Pinnacle system	You should receive a Pinnacle log-in before your first shift. Remember to bring your log-in details with you.
Rotify – electronic staffing rota	You will receive a Rotify link when you are provided with your contract. Once you have created log in details, please book yourself into shifts and access the site daily for clinic updates and programme communications. When you are unable to fulfil a previously booked shift, please give us as much notice as possible by ringing the site phones: Maghull Town Hall VS – 07979 936519 North Park Health Centre VS – 07979 938229
Infection control	We aim to avoid the risk of COVID transmission through airborne or direct transmission. Always wear a mask. A gown should be worn and changed

	regularly when vaccinating. Gloves are optional but if worn, should be changed with each patient. Hand gel must be used between patients if hands are bare until the hands become sticky then handwashing facilities should be used near the medicines management area. The vaccinator is responsible for keeping their work-station clean. Clean the seats with a wipe between patients. Please adhere to social distancing guidelines.
Patient flow	Patients book in at reception, have their demographic details completed on their vaccination recording form and receive a COVID-19 vaccination information leaflet. They wait in the seated area until a place is available at a vaccination station, when a volunteer will escort them to the vacant station. After Pfizer vaccination they sit in the supervised departure area for 15 minutes before leaving, those receiving AZ that are driving should be advised to sit in their car for 15 minutes before driving home.
Vaccine preparation	If using the Pfizer vaccine, this will be reconstituted by a pharmacist and then you must collect it in a tray with the vial and 6 syringes at the pharmacy station. If you use less than six doses from the vial please inform the pharmacist. AZ will provide 8 or 10 doses and may provide up to 2 more than this – again please inform pharmacy technician.
Drawing up the vaccine	The bung should only be punctured once by each syringe. Any air bubbles or excess vaccine must be expelled whilst the syringe is still in the vial. Do not remove the syringe from the vial to expel any air bubbles or excess vaccine.
PSD signing	If operating under a PSD a GP/ANP will be available to sign on the vaccine recording form
Clinical queries	Computers are available for searching the Green Book or COVID-19 vaccination websites, a hard copy is also available on each site. A GP/ANP will be available for queries.
Medical attention	If the patient becomes unwell alert the supervising GP immediately and assist as needed. Record the clinical details and obs on the clinical recording form
Anaphylaxis kit	At Maghull Town Hall the anaphylaxis kit is in the resus station next to the waiting area, along with other resus equipment and at North Park Health Centre it is in room 1
Responsible to	The Site Manager

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