

## Information Regarding Assessment and Consent for Immunisation under a Patient Specific Direction (PSD)

### Purpose

This document outlines the requirements for assessment and obtaining valid consent for immunisation delivered under a Patient Specific Direction (PSD). It clarifies the roles and responsibilities of prescribers, registered healthcare professionals, and unregistered staff involved in vaccination delivery, in line with [UK Health Security Agency \(UKHSA\) guidance](#), Nursing and Midwifery Council (NMC) standards, and Specialist Pharmacy Service (SPS) advice.

Following clarification from the NMC and SPS, this document confirms that prescribers cannot delegate responsibility for clinical assessment or the consent process for vaccination. While supporting tasks such as information gathering and pre-screening may be undertaken by others, accountability for assessment and consent remains solely with the prescriber.

Further information on legal mechanisms for vaccination is available from [NHS England](#). This document should be read alongside all referenced guidance and supporting materials.

### Scope

This guidance applies to all healthcare professionals involved in the immunisation programme, including prescribers, registered healthcare professionals, and healthcare support workers (HCSWs).

### Principles of Consent

- Consent must be freely given, voluntary, and without coercion.
- The individual giving consent must have the mental capacity to do so.
- Consent may be given by:
  - The individual themselves, where they have capacity.
  - A person with parental responsibility (for children who lack capacity).
  - An authorised representative holding a Lasting Power of Attorney (LPA) for health and welfare.
  - A court-appointed deputy.
- Consent is a process rather than a one-off event and may be withdrawn at any time.
- Consent for one vaccine or dose does not automatically apply to future doses or other vaccines unless this has been explicitly agreed.

### Responsibilities

### **Prescribers (e.g. operating under Patient Specific Directions)**

Prescribers hold full professional and legal responsibility for the vaccination decision. This includes:

- Undertaking the clinical assessment to determine suitability for vaccination.
- Obtaining valid, informed consent for the specific vaccine being administered.
- Ensuring the patient understands the purpose of the vaccine, its risks and benefits, and any potential side effects.
- Not delegating assessment or consent to registered or unregistered staff.
- Reviewing and verifying any information gathered through pre-screening or administrative processes undertaken by others.
- Documenting the assessment and consent clearly in the patient's clinical record.

Consent may be obtained verbally face to face or over the telephone, electronically (e.g. via Accurx), or in writing, but must always be carried out and confirmed by the prescriber.

### **Registered and Unregistered Staff Administering Vaccinations**

Registered and unregistered staff may support the vaccination programme by:

- Undertaking administrative tasks or information gathering (e.g. pre-screening questionnaires).
- Providing standard, NHS-approved vaccine information.
- Administering vaccines in accordance with the PSD and within their scope of competence, once a valid prescription, assessment, and consent have been completed by the prescriber.

These activities do not replace or remove the prescriber's responsibility for assessment and consent.

### **Patient Is not Receiving the Vaccination for the First Time**

Registered or unregistered staff may administer subsequent doses (e.g. seasonal influenza vaccination), provided that:

- The prescriber is personally satisfied that prior informed consent remains valid.
- The prescriber is satisfied that there have been no relevant changes to the patient's medical history or circumstances that would affect suitability for vaccination.
- Basic safety checks are completed at the time of vaccination (e.g. confirming the patient is not acutely unwell and that no new contraindications have arisen).

Escalation to the prescriber or another registered healthcare professional must occur if:

- The patient expresses concerns or wishes to discuss risks or benefits further.
- There is any change in the patient's health status.
- Additional or more detailed assessment is required (e.g. due to immunosuppressive therapy).
- Any other concerns arise.

### **Patient Is Receiving the Vaccination for the First Time**

Where an individual has not previously received the vaccine:

- The prescriber must carry out the clinical assessment, provide vaccine-specific information, and obtain and record informed consent.
- Communication may occur through direct discussion or other methods such as Accurx, letter, or email, but responsibility for confirming understanding and consent remains with the prescriber. Details of the Accurx consent processes are available on our website. We are grateful to Dr Dhanji (Deputy CEO, LMC and Vaccination Lead) of LLR LMC for agreeing to this information being shared with Avon LMC members.
- Other staff may assist with pre-screening or administrative processes; however, the prescriber must review, confirm, and act on this information before signing the PSD.

### **Good Practice Principles**

- Always confirm that the patient is content to proceed at the time of vaccination, including for subsequent doses.
- Re-seek consent where:
  - The patient withdraws consent or requests further discussion.
  - New safety information becomes available.
  - The vaccine formulation, indication, or schedule changes.
- Provide information in accessible formats, including translated materials and interpreter support where required.
- Ensure consent is documented, even when obtained verbally.

### **References and further reading**

[UKHSA Green Book, Chapter 5](#)

[NHS Specialist Pharmacy Service guidance on PGDs.](#)

General Medical Council (2021) [Good practice in proposing, prescribing, providing and managing medicines and devices - GMC](#)

NMC (2025) [Useful information for prescribers - The Nursing and Midwifery Council](#)

[Annual flu programme - GOV.UK](#)

Version	Date	Summary of Changes	Author
1.0	Dec 2025	Initial version issued. Provided guidance on consent to immunisation and the role of Healthcare Support Workers (HCSWs), including administration of vaccines following prior consent and assessment by registered healthcare professionals under relevant legal mechanisms.	Kim Ball
1.2	May 2026	Document revised following clarification from the Nursing and Midwifery Council (NMC) and Specialist Pharmacy Service (SPS). Clarifies that prescribers operating under a Patient Specific Direction (PSD) cannot delegate clinical assessment or the consent process. Explicitly defines prescriber accountability for assessment, consent, and documentation. Clarifies limits of registered and unregistered staff roles to supporting and administrative tasks only. New vaccine-specific legal mechanism table	Kim Ball

## Summary of Legal Mechanisms

Legal Mechanism	Who can use it	Can tasks be split?	Who can carry out clinical assessment & consent process?	Who can administer?	Supervision requirements
<a href="#">Patient Group Direction (PGD)</a>	Registered health care professionals as defined in law, note this excludes registered Nursing Associates	No, supply and/or administration of medicine must not be assigned or delegated to any other person under a PGD.	Registered health care professionals as defined in law, note this excludes registered Nursing Associates. All parts of the process must be undertaken by the same person.		Registered HCPs do not have any specific supervision requirements under a PGD however access to supervision where required is considered best practice.
<a href="#">Patient Specific Direction (PSD)</a>	Patients must be individually reviewed by a prescriber as being suitable for receiving the treatment.	Yes, non-registered and registered staff can work under a patient specific direction if the prescriber is assured that staff are trained, competent and they take full accountability for all tasks.	A registered healthcare professional must complete the clinical assessment. For a PSD, this is normally done by the prescriber. Other staff may carry out pre-screening, but the prescriber must ensure consent is valid before signing the PSD.	Administration can be carried out by trained and competent non-registered or registered healthcare workers.	Unregistered HCPs should have access to supervision at all times
<a href="#">Vaccine Group Direction (VGD)</a>	Registered health care professionals as defined in law, note this excludes registered Nursing Associates	VGDs allow some tasks within the vaccination process, such as vaccine preparation, administration and record keeping to be delegated to suitably trained registered and non-registered healthcare practitioners. Each VGD will specifically state which tasks can be delegated and to whom and this may vary between VGDs, so it is important to check each VGD carefully.	VGDs do not permit delegation of clinical assessment to receive the vaccine nor gaining informed consent, these activities must be undertaken only by registered healthcare practitioners listed in the legislation.	VGDs permit delegation of certain tasks to other registered and non-registered healthcare practitioners, which tasks can be delegated, and to whom, will be determined by the national health protection agency writing the VGD (e.g. UKHSA) and will be clearly stated within each VGD. Note: preparation of a vaccination for administration under a VGD must be undertaken by the same individual who is administering the vaccine.	Where a registered healthcare practitioner delegates any part of the VGD process to another practitioner they must provide supervision throughout that part of the process. This supervision must occur whether the practitioner a task is delegated to is registered or not. In practice this means they must physically remain within the same premises or clinical area throughout the episode of care and be available to intervene if required.

